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ASIA EDITION

Volume 19 | Issue 2 | February 2024

Next-Gen ADCs

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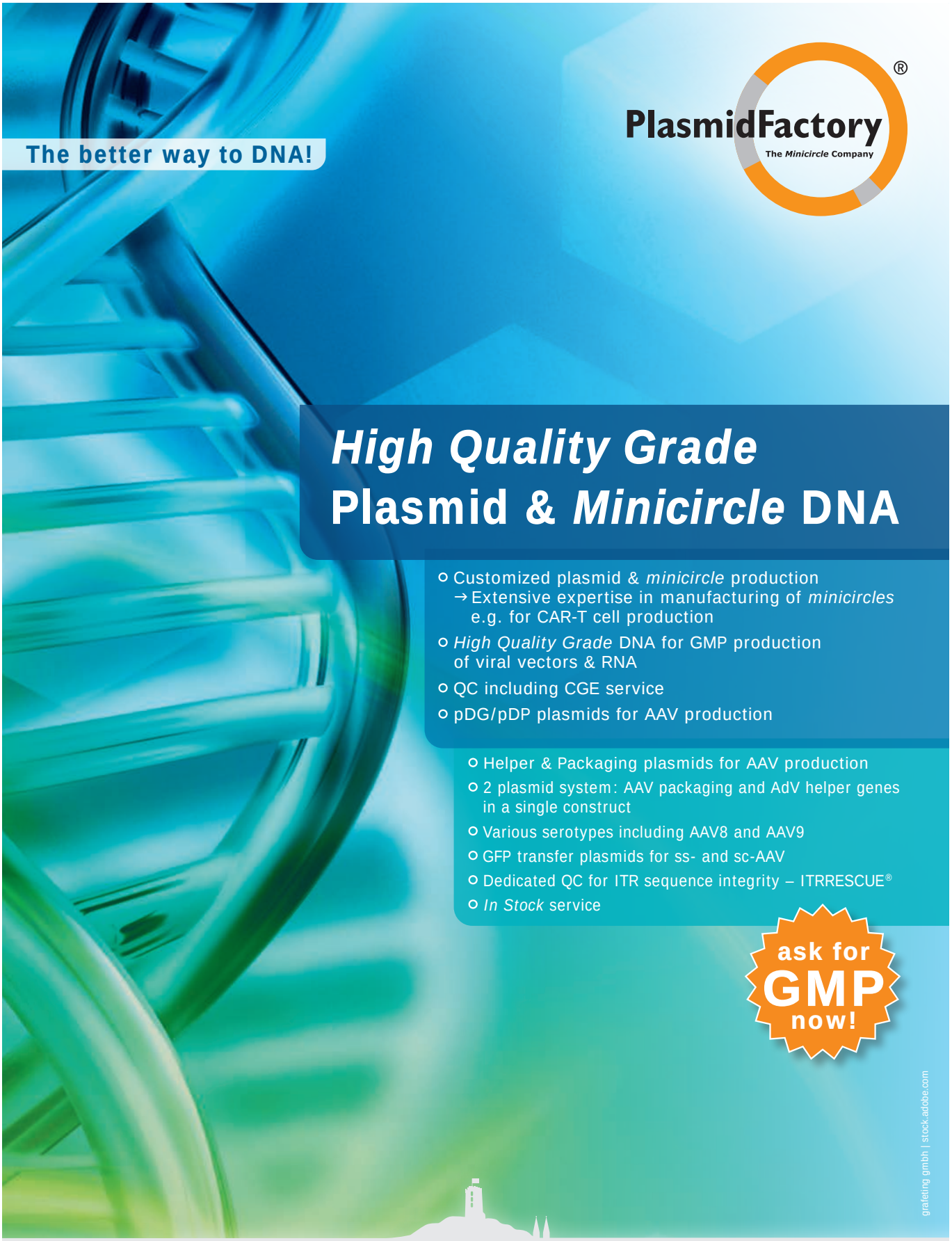

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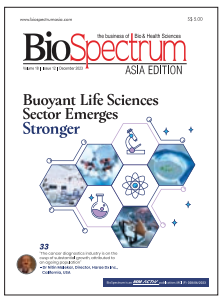

Acknowledgement/ Feedback

I wanted to express my sincere appreciation for the interest you've shown in Lunit throughout 2023. Your articles have been a vital part of our journey, sharing our stories and innovations with the world. I am truly grateful for the time and effort you've invested in showcasing our work.

- Jaewhan, Korea

Thank you for publishing Vetter's article published in BioSpectrum Asia's new year edition. Thank you again for this great opportunity.

- Sarah, US

Thank you for the interview feature on the Korean arm of West Pharmaceutical, a leading manufacturer of packaging components and delivery systems for injectable drugs and healthcare products.

- Hui Hui Lin, Singapore

Great to kick off 2024 with a phage feature in BioSpectrum's January edition, titled 'Combating AMR with Bacteriophages', with insights from key phage researchers and proponents of phage therapy in India.

- Pranav Johri, India

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Letter from Publisher

Ravindra Boratkar
Publisher &
Managing Editor,
MD, MM Activ Sci-Tech
Communications Pvt. Ltd.

Dear Readers,

Antibody-Drug Conjugates (ADCs) have been described as a biological missile for targeted cancer therapy. The therapy combines advantages of highly specific targeting ability and highly potent killing effect to achieve accurate and efficient elimination of cancer cells. It is a major research and development now in anti-cancer drugs.

The first ADC was approved in 2000 and the space has experienced a renaissance in recent times. Major pharmaceutical players as well as startups are announcing deals in this space practically every day. Within the Asia-Pacific (APAC) region, China stands at the forefront of ADC drug development. GlobalData reports that numerous domestic companies in China are actively shifting their focus towards the creation of pioneering ADC-based treatment options, particularly for solid tumors like breast, gastric, and bladder cancer. On this Cancer Day, our content team has delved deeper into the exciting realm of ADCs, exploring advancements and unravelling the advantages they offer compared to other therapies like cell and gene therapies.

As our content team continuously explores and writes about new technologies that are becoming available, medtech is naturally an area of focus. If we take New Zealand's example, in 2010, it had only 40 to 50 companies in the medtech arena. Today there are more than 200. A Deloitte strategic and economic report estimates that by 2050, the sector's growth will have produced a cumulative additional $4.2 billion in GDP and nearly 8,000 full-time jobs. The New Zealand Government supports and invests in a range of projects, partnerships and programmes to boost the country's medtech sector.

There are areas where New Zealand already leads the way, both on the research side, where for example, Auckland Bioengineering Institute (ABI)'s at Waipapa Taumata Rau, University of Auckland work in computational physiology and digital twins is well-respected around the world, and on the commercial side, where startups such as Alimetry have won international prizes. In another article our team explores New Zealand's efforts in becoming a medtech powerhouse.

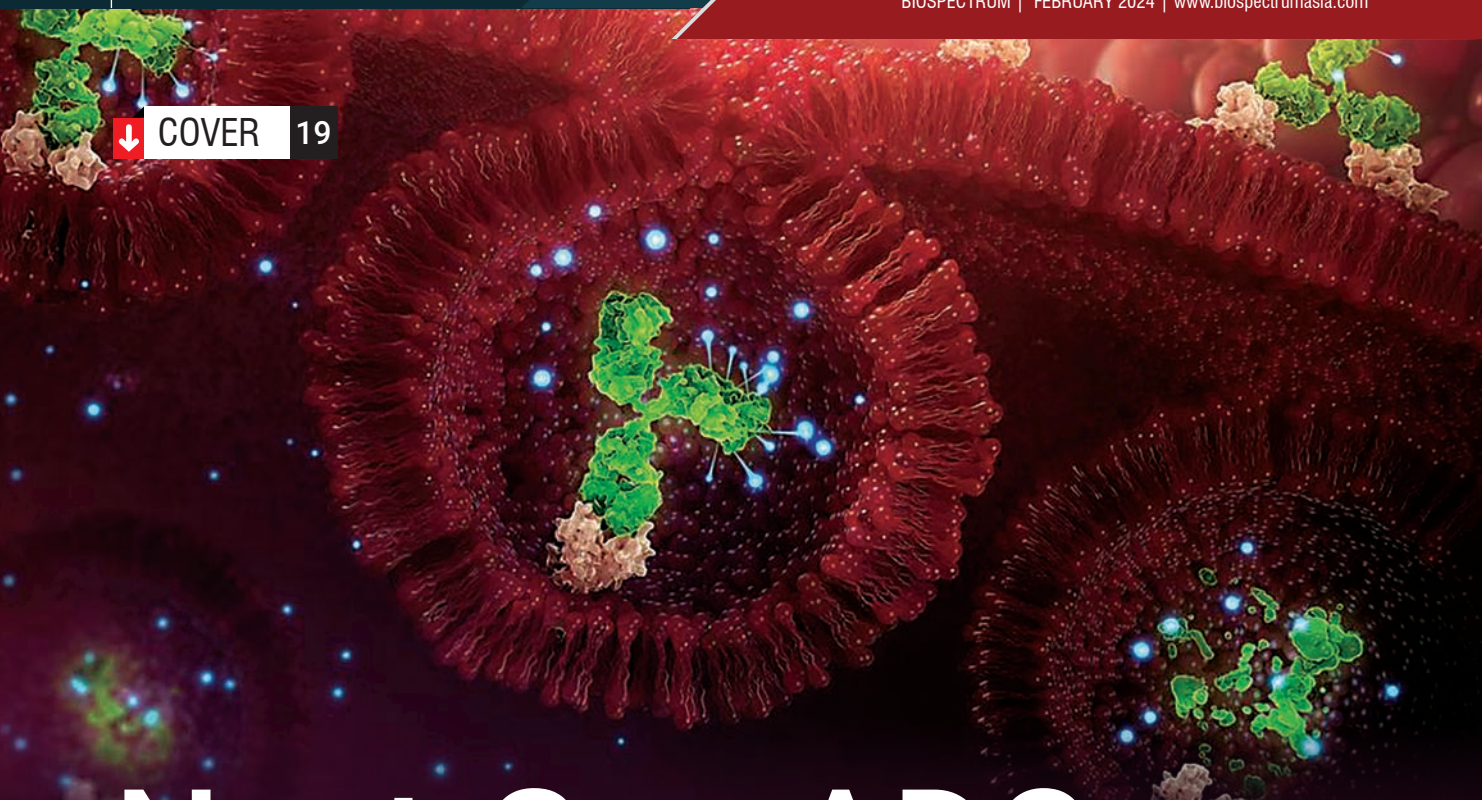
In yet another article, the content team has tried to throw some light on the progress taking place in APAC's rare disease drug discovery and its market. However, the landscape of rare disease medicine in the Asia Pacific is much more dynamic and is constantly evolving. Promising efforts are underway in the regions, offering hope for a brighter future for patients and their families.

The thought leadership piece is about revolutionising life sciences research and delivery with a new approach to modelling complexity.

All this and much more in this month's edition, makes it an interesting reading.

Thanks & Regards,

Ravindra Boratkar
Publisher & Managing Editor



COVER 19

Next-Gen ADCs as Precision Weapon Against Cancer

Antibody-Drug Conjugates (ADCs) are emerging as a crucial frontier in targeted cancer care. Although the first ADC was approved in 2000, the space has experienced a renaissance in recent times. Major pharmaceutical players like Novartis and Pfizer, including startups, are announcing deals in this space almost every day. Within the Asia-Pacific (APAC) region, China stands at the forefront of ADC drug development. GlobalData reports that numerous domestic companies in China are actively shifting their focus towards the creation of pioneering ADC-based treatment options, particularly for solid tumours like breast, gastric, and bladder cancer. When we observe World Cancer Day on February 4, we explore the promising world of next-gen ADCs, exploring advancements and unravelling the advantages they offer compared to other therapies like cell and gene therapies.

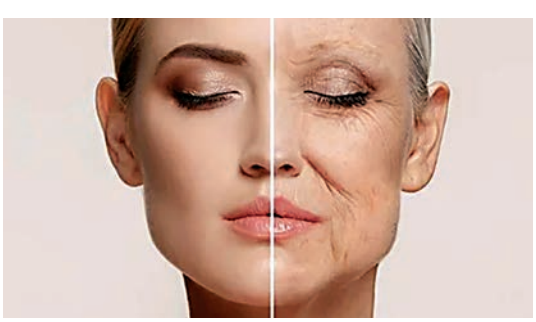
22
Trailblazing Impact of Antibody-Drug Conjugates

Joe Daccache,
Project Leader, DeciBio

Cervical Cancer

Medtech

SPEAKING WITH



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REGULARS

EMBRACING MED MARIJUANA USE

Dr Milind Kokje
Chief Editor
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Japan has allowed cannabis-based medicines, while Thailand is reversing its open policy limiting the use of cannabis for medical purposes only. The Japanese parliament recently decided to legalise medicines derived from cannabis, thus allowing use of cannabis-based medical products. In legal terms, cannabis and THC (a psychoactive chemical in cannabis) have been categorised as regulated narcotics. The new law, to be effective within a year, permits medical use, and on the other hand also strengthens Japan's strict position on recreational use of cannabis by incorporating more harsh punishments than the earlier.

For instance, people caught using or possessing marijuana may have to face seven years imprisonment. Earlier, consuming marijuana was legal, but its possession led to up to five years in prison. As a result, in 2020, out of nearly 750 people arrested for marijuana possession 30 per cent claimed lack of penalty for consumption. Hence, such loopholes have been removed from the new law to maintain the country's stand against cannabis since 1948. The harsher legal steps are a result of the rise in the consumption of marijuana, particularly among youngsters in Japan.

In Thailand, the government has come back a step from its earlier decision over cannabis. Medical marijuana has been legal since 2018 in Thailand. It also became the first Asian country to decriminalise cannabis by delisting marijuana as a narcotic in June 2022 making it no longer a crime to grow and trade marijuana and hemp products, or to use any parts of the plant to treat illnesses. This change allowed cafes and restaurants to serve cannabis infused food and drinks. However, the condition was that the products should contain less than 0.2 per cent THC. By decriminalising anyone above 20 and not pregnant or breastfeeding was allowed to use cannabis in the residence and food containing its extracts were allowed to be consumed in licensed restaurants.

The policy change resulted in seeing a lucrative cannabis industry catering to Thai citizens and foreign nationals. A large number of cannabis cafes and weed dispensaries were opened at popular tourist destinations in the country. Some cities even organised weed festivals. At the same time, much of the weed on sale was stronger than 0.2 per cent in THC. Thus, 6 months back, the new Prime Minister Srettha Thavisin announced the limiting of its use for medical purposes. Accordingly, the health ministry released a Draft Bill limiting cannabis and cannabis-related products limited to medical and health purposes only. The Bill also outlines hefty fines or prison sentences for up to one year for offenders.

Rectifying the policy by going a step back is expected to affect several commercial establishments like cannabis-based food and café businesses. The entire industry of cannabis-based dispensaries, spas, restaurants, cafes and festivals is estimated to be worth over one billion dollars in the next few years. Hence there is some opposition to the government's decision. Hence, the government sought public opinion on the draft. However, by the time this article is being written the government appears to be determined to go ahead with its decision.

Cannabis contains over 100 cannabinoids and of them two are clinically most relevant. They are considered as beneficial treatment options in epilepsy, chronic pain and for sleep in cancer. But as per the Global Burden of Diseases 2019 study, cannabis consumption ranks third worldwide among consumed substances of misuse.

However, countries are coming forward to allow the use of cannabis for medical products. Thailand has done it, followed by South Korea and now Japan. In India, a company has introduced a first line of clinically trialled medical cannabis products. In Malaysia, 81 per cent of the population and 74 per cent of doctors support medical cannabis, as per a survey. Thus, cannabis medicines is an emerging market and Prohibition Partners estimate that it could be worth $5.98 billion this year in Asia. However, as experts suggest, this needs to be supported by clinical trials. BS

Singapore lays focus on manpower planning for future national crises

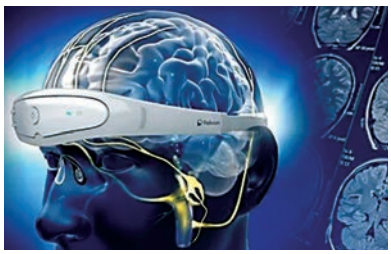
The Ministry of Health (MoH), Public Service Division (PSD), and the Singapore Airlines (SIA) Group have signed a Memorandum of Understanding (MoU) to formalise the commitment to collaborate on manpower planning and deployment for future national crises in Singapore, building on the collaboration started in 2020 during the COVID-19 pandemic. This includes training SIA and Scoot cabin crew volunteers in peacetime, so that they are ready to step up and take on various healthcare support roles as part of the national response for future crisis situations. The SG Healthcare Corps will facilitate the training and deployment of around 50 SIA and Scoot cabin crew, who will volunteer their time as SIA Group Ambassadors at Khoo Teck Puat Hospital and Changi General Hospital from April 2024. These SIA Group Ambassadors will be part of a pool of around 200 trained SG Healthcare Corps care volunteers who will serve alongside the healthcare workforce to meet the needs of patients. Formalising this MoU to build the reserve healthcare workforce is part of the government's efforts to prepare for another pandemic.

Korea gives license to Euvichol-S, simplified formulation of oral cholera vaccine

The International Vaccine Institute (IVI) and EuBiologics Co have announced the licensure for export by the Korean Ministry of Food and Drug Safety (KMFDS) of Euvichol-S, a simplified formulation of the oral cholera vaccine (OCV) Euvichol-Plus that is prequalified by the World Health Organization. The licensure of Euvichol-S is the culmination of a comprehensive phase 3 clinical trial conducted by IVI and paves the way for a potential solution to the critical shortage of OCV worldwide. The ongoing global shortage of OCV has hindered the deployment of effective cholera control efforts, exacerbating the impact of unprecedented cholera outbreaks in 2022 and 2023. In 2019, IVI received support from the Bill & Melinda Gates Foundation to reformulate Euvichol-Plus, with the potential to reduce production costs by 20 per cent and increase production capacity by 38 per cent. IVI reformulated Euvichol-Plus by reducing components from five to two and the inactivation process from two to one.

Japan approves first at-home migraine treatment in the form of Neurolief's neuromodulation device

US-based Neurolief has announced the approval of its neuromodulation device, Relivion, by the Japanese Ministry of Health, Labor and Welfare (MHLW). This approval marks a historic moment for Neurolief and its partner Sawai Pharmaceutical Co., as Relivion becomes the first neuromodulation device approved in Japan for at-home use in the acute treatment of migraine. Relivion is a novel, non-invasive multi-channel brain neuromodulation technology.



It stands out by concurrently stimulating the occipital and trigeminal nerve branches in the head, effectively modulating brain networks associated with debilitating migraine headaches.

Marketing efforts for Relivion will be led by Sawai Pharmaceutical Co., which have entered into an exclusive partnership agreement with Neurolief for development and commercialisation of Relivion for migraine and depression indications in Japan. With the introduction of the Relivion neuromodulation system in Japan, Sawai aims to elevate the landscape of acute migraine treatment options which is currently limited primarily to drug therapy.

New Zealand to make amendments to International Health Regulations

The Ministry of Health is inviting the views of New Zealanders on proposals to update a significant global health agreement. The International Health Regulations (2005) (IHR) aim to prevent and control the spread of disease and other public health hazards between countries to protect the health of their citizens. They define countries' rights and obligations in handling public health events and emergencies that have the potential to cross borders. While the IHR serves countries well, IHR can be improved to ensure that the

regulations continue to be fit for purpose. International negotiations are currently being held on amendments to the IHR. The Ministry is interested in New Zealanders' views on the proposed amendments to help inform New Zealand's position as it contributes to the ongoing negotiations. The consultation is only one of the steps involved in considering whether the IHRs are in New Zealand's national interest and will inform ongoing negotiations. Other steps that are still required before New Zealand agrees to be bound by changes to the IHRs include seeking agreement from Cabinet, conducting a National Interest Analysis, and presenting that Analysis and the text of the IHR changes to Parliament for Treaty Examination.

Saudi Arabia approves first CRISPR/Cas9 gene-edited therapy for treatment of sickle cell disease

US-based Vertex Pharmaceuticals has announced that the Saudi Food and Drug Authority (SFDA) has granted Marketing Authorisation for CASGEVY (exagamglogene autotemcel [exa-cel]), a CRISPR/Cas9 gene-edited therapy, for the treatment of sickle cell disease (SCD) and transfusion-dependent beta thalassemia (TDT). CASGEVY is approved for the treatment of people 12 years of age and older with SCD or TDT. The Kingdom of Saudi Arabia has among the highest prevalence rates of SCD and TDT in the world, with thousands of patients living with these genetic blood disorders. The Ministry of National Guard Health Affairs (MNGHA) is the first Authorised Treatment Centre (ATC) in Saudi Arabia. Vertex is working to qualify additional hospitals as ATCs to bring CASGEVY to patients, including the King Faisal Specialist Hospital (KFSH). In order to enable rapid access to CASGEVY, Vertex is working to secure listing on hospital formularies to support reimbursement as soon as possible.

India to open new state branches of National Centre for Disease Control and BSL-3 labs

India's Union Minister of Health and Family Welfare Dr Mansukh Mandaviya recently laid the foundation stone for National Centre for Disease Control (NCDC) Regional Branch in Assam, State branches in 6 States (Haryana, Tamil Nadu, Karnataka, Odisha, West Bengal and Mizoram) and biosafety level or BSL-3 labs in 2 States (Himachal Pradesh and Jharkhand) virtually. He also inaugurated a temporary NCDC Regional branch in Bhopal, Madhya Pradesh.

These new NCDC branches and BSL-3 labs will strengthen the country's capacity for pandemic preparedness and disease surveillance with 'One Health' approach. Dr Mandaviya informed that a forward-looking strategy has been envisaged for the NCDC's evolution through which it is planned to establish 30 NCDC state branches, 5 NCDC regional branches and 10 BSL-3 laboratories in phase-wise manner for decentralising the presence of NCDC.

AstraZeneca buys Gracell for $1B to further cell therapy ambition

British biopharmaceutical firm AstraZeneca has entered into a definitive agreement to acquire Gracell Biotechnologies Inc., with operations in the US and China, furthering AstraZeneca's cell therapy ambition. The proposed acquisition will enrich AstraZeneca's growing pipeline of cell therapies with GC012F, a novel, clinical-stage FasTCAR-enabled BCMA and CD19 dual-targeting autologous chimeric antigen receptor T-cell (CAR-T) therapy, a potential new treatment for multiple myeloma, as well as other haematologic malignancies and autoimmune diseases including systemic lupus erythematosus (SLE). The upfront cash portion of the consideration represents a transaction value of approximately $1 billion.

China's WuXi Biologics announces research service agreement worth $20M with BioNTech

China's WuXi Biologics has signed a research service agreement with Germany-based BioNTech SE, a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. Under the terms of the agreement, WuXi Biologics leverages its proprietary antibody discovery technology platforms to discover two undisclosed targets of preclinical investigational monoclonal antibodies for BioNTech to develop next-generation therapeutic product candidates. WuXi Biologics will receive a $20 million upfront payment for granting exclusive rights to these investigational monoclonal antibodies to BioNTech and is eligible to receive additional payments, including payments for research, development, regulatory, and commercial milestones, as well as tiered royalties. WuXi Biologics offers a full spectrum of both end-to-end and modular discovery services – from idea to preclinical candidate identification – using industry-leading technology platforms and comprehensive discovery capabilities.

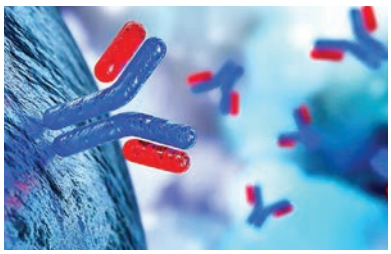
Menarini Group, Insilico Medicine ink oncology deal worth $500M

The Menarini Group, a leading international pharmaceutical and diagnostics company headquartered in Italy, and Stemline Therapeutics, Inc., a wholly-owned subsidiary of the Menarini Group focused on bringing transformational oncology treatments to cancer patients, along with clinical stage generative artificial intelligence (AI)-driven biotechnology company Insilico Medicine (based in the US and Hong Kong), have entered into an exclusive licensing agreement granting

Stemline the global rights to develop and commercialise a novel, small molecule KAT6A inhibitor designed using Insilico's AI platform, as a potential treatment for hormone sensitive cancers and other oncology indications. KAT6A is known to play an important role in several cancers. Overexpression of KAT6A correlates with poor clinical outcomes in patients with ER+/HER2- breast cancer, the most common subtype of breast cancer. Under the terms of the agreement, Stemline will provide a $12 million upfront payment to Insilico. The combined value of the deal, including all development, regulatory, and commercial milestones, is over $500 million, followed by royalties up to double digits.

Korea's LegoChem Biosciences inks $1.7B pact with J&J for ADC development

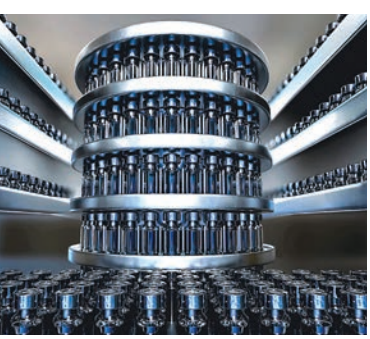
South Korea's LegoChem Biosciences (LCB) has entered into a license agreement with Janssen Biotech, Inc. (Janssen), a Johnson & Johnson (J&J) company, to develop and commercialise LCB84, a Trop2 directed antibody drug conjugate (ADC). Under the terms of the agreement, LCB will grant Janssen an exclusive, worldwide license for the development and commercialisation of LCB84. LCB is eligible for up to potentially $1.7 billion in



total consideration including an upfront payment of $100 million, an option exercise payment of $200 million as well as potential development, regulatory, and commercial milestone payments, plus tiered royalties on net sales. The companies will collaborate during the ongoing Phase 1/2 clinical trial, with Janssen solely responsible for clinical development and commercialisation after option exercise. LCB84, a Trop2 directed ADC applying LCB's next-generation ADC platform technology and Trop2 antibody licensed from Mediterranea Theranostic, S.r.l, is being studied in a recently initiated Phase 1/2 clinical trial in the US.

Indian Immunologicals invests Rs 700 Cr in new vaccine manufacturing plant in India

Indian Immunologicals Limited (IIL) has started construction of its new greenfield veterinary vaccine facility to manufacture the Foot and Mouth Disease Vaccine (FMD-Vac) as well as Foot and Mouth Disease + Haemorrhagic Septicaemia Vaccine (FMD+HS-Vac) in Hyderabad's Genome valley, India. This brand-new unit will have a



BSL3 facility for the manufacture of drug substances and a fill-finish capability for the production of both drug products, FMD vaccine and the FMD+HS vaccine. Telangana State Industrial Infrastructure Corporation Ltd (TSIIC), a Government of Telangana undertaking, had allotted the land to IIL at Biotech Park, Phase III, Karkapatla, Siddipet district in Telangana. The proposed facility has a capacity of 150 million doses/annum of FMD vaccine or FMD+HS vaccine each. With an investment of approximately Rs 700 crore, the proposed facility is expected to create more than 750 direct and indirect jobs.

AGC invests ¥ 50B to expand biopharmaceutical CDMO capability in Japan

AGC Inc, Japan-headquartered manufacturer of glass, chemicals, and high-tech materials, has decided to expand its biopharmaceutical contract development and manufacturing organisation (CDMO) capability at the AGC Yokohama Technical Center. The total investment for the expansion is expected to be approximately 50 billion Japanese yen. Development services for gene and cell therapies are planned to begin first in 2025, followed by development and manufacturing services for mRNA pharmaceuticals, biopharmaceuticals made using mammalian cell cultures and gene and cell therapies in 2026. This expansion has been selected by the Japanese Ministry of Economy, Trade and Industry (METI) as part of its 'Developing biopharmaceutical manufacturing sites to strengthen vaccine production project'. AGC will introduce dual-use facilities that can be applied to manufacturing of vaccines in the event of a pandemic. In addition to mammalian cell culture bioreactors which have one of the largest capacities as a CDMO in Japan, the expansion will also include facilities for the leading-edge field of mRNA pharmaceuticals and gene and cell therapies. Furthermore, fully operational, it is expected to employ approximately 400 employees and contribute to the advancement of the society and biotech industry.

Specialised Therapeutics, Ascendis Pharma to commercialise endocrinology therapies in Australia and SE Asia

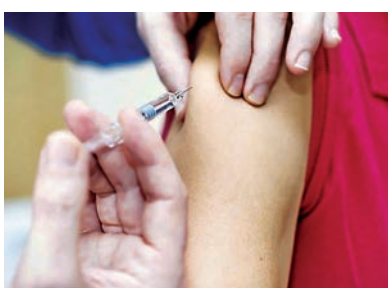
Singapore-based biopharmaceutical company Specialised Therapeutics Asia (ST) has added three new endocrinology therapies to its specialist portfolio, following an exclusive distribution agreement with Danish company Ascendis Pharma A/S. Under the terms of the agreement, ST will commercialise Ascendis Pharma's weekly injectable paediatric human growth hormone treatment SKYTROFA (lonapegsomatropin), hypoparathyroidism treatment YORVIPATH (palopegteriparatide) and investigational achondroplasia therapy TransCon CNP (navepegritide). The agreement spans ST's key regions of Australia, New Zealand, Singapore, Malaysia, Brunei, Thailand, and Vietnam. Two of the products included in this agreement are already internationally approved. Once-weekly SKYTROFA is a human growth hormone (hGH) approved in the United States for the treatment of paediatric patients aged >1 years weighing >11.5 kg with growth failure due to inadequate secretion of endogenous growth hormone (GH) and in the European Union for growth failure in children and adolescents aged from 3 to 18 years due to insufficient endogenous growth hormone secretion (growth hormone deficiency [GHD]).

Canon and Olympus enter into commercial alliance for endoscopic ultrasound systems

Canon Medical Systems Corporation and Olympus Corporation, both in Japan, have reached an agreement to collaborate on Endoscopic Ultrasound Systems. Canon Medical will develop and manufacture diagnostic ultrasound systems used in Endoscopic Ultrasonography (EUS), and Olympus will perform the sales and marketing efforts. The aim of this collaboration between Canon's Aplio i800 diagnostic ultrasound system for EUS and Olympus' Ultrasound Endoscope is to provide the market with advanced EUS equipment capable of delivering high-quality image diagnoses. Canon Medical and Olympus are focusing on technological advancements and enhancing diagnostic performance in the EUS field, with plans for global expansion, starting in Japan and Europe. In the field of EUS, Olympus has worked closely with physicians to develop new equipment to enhance imaging and diagnostic methods and expand procedures, helping gain and maintain a high share of the global market.

Zuellig Pharma & Substipharm Biologics expand access to Japanese Encephalitis vaccine across Asia

Singapore-based Zuellig Pharma has announced its commercialisation partnership with French pharmaceutical company Substipharm Biologics, to expand access of the IMOJEV Japanese encephalitis vaccine across nine markets in Asia, including Brunei, Cambodia, Hong Kong, Malaysia, Myanmar, Philippines, Singapore, Taiwan and Vietnam. Japanese Encephalitis (JE) is transmitted with mosquitoes and causes inflammation in the brain and



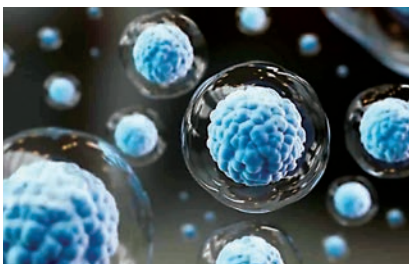
is the leading cause of vaccine-preventable encephalitis in Asia. The disease currently has no treatment except for the preventative protection provided by the JE vaccine such as IMOJEV. In addition to the current warehousing and distribution (W&D) agreement with Substipharm Biologics for Brunei and Thailand, Zuellig Pharma will now also provide W&D and sales & marketing support to Substipharm Biologics in Taiwan. This is bolstered by the capabilities of ZP Therapeutics, a division of Zuellig Pharma, which has extensive & proven in-market expertise in furthering access to healthcare products in Asia.

Orbis International & NIDEK scale up AI-based eye screenings in Vietnam

Orbis International has announced an important in-kind and financial donation from NIDEK to support Orbis's artificial intelligence (AI)-based screening services in Vietnam. The donation of six specialised fundus cameras, which take images of the retina (back of the eye), will support the scale up of Orbis' AI-based diabetic retinopathy screening programme in Vietnam. These cameras are expected to support the screening of 72,000 patients with diabetes over the next three years. The addition of the NIDEK cameras to Orbis's programme will expand its presence to six high-volume screening health facilities in three provinces across Vietnam – including Giao Thuy District Health Center and Nam Dinh General Hospital in Nam Dinh province, Nghe An Endocrinology Hospital and Tay Bac Regional Hospital in Nghe An province and Can Tho General Hospital and Can Tho Heart Hospital in Can Tho city – improving capacity to detect and promptly treat diabetic retinopathy, a potentially blinding disease that every person with diabetes is at risk of developing.

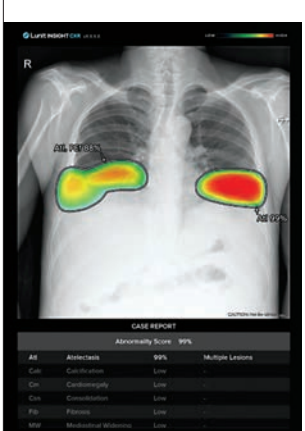
Cipla announces joint venture in US with Kemwell Biopharma and Manipal Education & Medical Group

Cipla (EU) Limited, UK, a wholly owned subsidiary of India-based pharma firm Cipla, has announced a strategic collaboration with Kemwell Biopharma (through its subsidiary Kemwell Biopharma UK Limited) and Manipal Education & Medical Group (through its subsidiary MNI Ventures, Mauritius) to incorporate a joint venture in the United States (US). The primary goal of this joint venture is to develop and commercialise novel cell therapy products for major unmet medical needs in the United States, Japan, and EU regions. Cipla (EU) will secure a 35.2 per cent stake in the joint venture company. By capitalising on Cipla's leadership in product development and commercialisation and aligning with Kemwell's expertise in biologics and Manipal's expertise in healthcare delivery, this strategic collaboration is aimed at expediting development, manufacturing, licensing, import and export of cutting-edge cell therapy products to cater to patients globally.



Lunit AI solutions to power Samsung's X-ray devices for advanced chest screening

South Korea-based company Lunit, a leading provider of artificial intelligence (AI)-powered solutions for cancer diagnostics and therapeutics, has announced a three-year supply contract with Samsung Electronics (Samsung Healthcare). The collaboration centres around the integration of Lunit's AI technology into Samsung's premium X-ray devices, elevating the accuracy and speed of chest screening. Under the terms of the contract, Lunit will supply Samsung Electronics with two AI-powered chest screening solutions: Lunit INSIGHT CXR and Lunit INSIGHT CXR Triage. The initial phase of this collaboration will see the X-ray devices, enhanced with Lunit's AI solutions, targeting the markets in the US, Canada, and Europe. Future phases aim to expand this to the Middle East, South America, and Southeast Asia, thereby broadening the global reach. In line with the urgency of cases typically encountered in Intensive Care Units (ICUs) and Emergency Rooms (ERs), X-ray devices with the Lunit INSIGHT CXR Triage are expected to be primarily deployed in these high-stakes medical settings.



TVM Capital Healthcare invests in Vietnamese startup Alina Vision

The Fred Hollows Foundation, Australia, Rohto Pharmaceutical, Japan, and TVM Capital Healthcare, Singapore and Dubai, have announced the closing of a significant equity investment in Alina Vision, a leading eye care business which currently operates two hospitals in Vietnam. Alina Vision was founded by international development organisation The Fred Hollows Foundation in 2018. Over the past five years The Fred Hollows Foundation and Rohto Pharmaceutical, a leading eyecare company in Japan, have provided financial backing, eye surgery training and clinical support to Alina Vision to grow the organisation from inception to more than 80 employees across two eye hospitals. Alina Vision completed over 2,800 cataract surgeries in 2023 and has a vision to grow its network to a chain of hospitals across Vietnam with significantly increased capacity. Cataracts represent the most common cause of blindness in individuals aged 50 years and over in Vietnam, affecting mainly women. The demand for cataract surgeries is expected to rise significantly, surpassing the available service supply.

CEPI partners with Korean startup Lemonex to advance mRNA vaccine delivery

Norway-based Coalition for Epidemic Preparedness Innovations (CEPI) has partnered with Lemonex Inc., a biotechnology startup in the Republic of Korea, to advance their mRNA drug delivery technology, DegradaBALL, which has the potential to both minimise post-mRNA vaccination side effects and improve access to future mRNA vaccines. CEPI is providing Lemonex up to $4.6 million in funding to evaluate the safety of the DegradaBALL mRNA vaccine platform in a Phase I clinical study taking place at Seoul National University Hospital. The funding will also support the development of a freeze-dried formulation which could reduce complex-cold chain vaccine storage requirements and increase the use of mRNA vaccines in the Global South. The new partnership forms part of CEPI's plan to expand the use of and access to novel RNA innovations for potential use against a future epidemic or pandemic threat, including unknown or as-of-yet unidentified pathogens (Disease X), in alignment with the 100 Days Mission.

Novartis acquires Chinese startup SanReno Therapeutics to enhance kidney diseases treatment

China-based startup SanReno Therapeutics, a clinical-stage company specialising in the discovery, development, and commercialisation of innovative therapies for kidney diseases, has announced its acquisition by Novartis, a global medicines company. Following the acquisition's closure, SanReno became an indirect, wholly-owned subsidiary of Novartis. The founding investors of SanReno, including Pivotal bioVenture Partners China, Frazier Life Sciences, Samsara BioCapital,

and Versant Ventures, have sold their equity securities in SanReno. Established in late 2021 as a joint venture between the investor consortium and Chinook Therapeutics (now part of Novartis), SanReno holds exclusive rights in Greater China and Singapore for two late-stage assets targeting Immunoglobulin A Nephropathy (IgAN): atrasentan and zigakibart. Completed within the first two years of SanReno's formation, this acquisition is one of the few transactions where a Chinese biotech company has been acquired by a multinational pharmaceutical company.

ImmunoScape & Experimental Drug Development Centre ink cell therapy partnership in Singapore

Singapore-based biotech startup ImmunoScape has announced a partnership with the Experimental Drug Development Centre (EDDC), Singapore's national platform for drug discovery and development hosted by the Agency for Science, Technology and Research (A*STAR). ImmunoScape's core antigen-specific T cell immune profiling technology was developed at A*STAR's Singapore Immunology Network and is exclusively licensed from A*STAR. Since its spinout from A*STAR in 2016, ImmunoScape has developed a cutting-edge, high-throughput, T cell receptors (TCR) discovery platform that produces a broad and emerging portfolio of novel, safe, and efficacious TCRs against solid tumours. In this new partnership, ImmunoScape will leverage its catalog of highly potent tumour-specific TCR candidates for the joint development of innovative off-the-shelf TCR-based bispecific molecules with EDDC. These molecules contain two distinct binding sites and are engineered to bind and activate T cells, redirecting them towards tumour sites for interaction with cells expressing the unique tumour-specific antigen through the TCR.

FUST Lab takes surfactant-free dispersion equipment to Japanese market

Spin-off company from the Korea Research Institute of Standards and Science, FUST Lab's DEBREX Nano-Emulsion/Dispersion equipment enters the Japan market to explore collaboration and distribution. FUST Lab is a technology-based Korean startup developing highly uniform nanoscale dispersion/emulsification technologies without surfactants, utilising its original innovative ultrasonic technology. Dispersion/emulsification technology for mixing two or more immiscible substances, is a key technology used in various productions such as cosmetics, pharmaceuticals, specialty and functional coatings, secondary batteries, and chemicals. FUST Lab will participate in the Manufacturing Equipment sector at Tokyo Interphex Week 2024 (June 26-28, Big Sight, Tokyo), the largest exhibition for the pharma-bio sector, as the first step to prepare to enter the Japanese market.

SOPHiA GENETICS and Karkinos Healthcare partner to advance cancer research in India

US-based cloud-native software company SOPHiA GENETICS has announced that it will partner with Indian startup Karkinos Healthcare, as the later will adopt the SOPHiA DDM Platform to advance cancer testing and research for blood cancers and solid tumours to underserved areas in low and middle-income countries. The SOPHiA DDM Platform is designed to compute a wide array of genomic variants and continually hone machine learning algorithms to detect rare and challenging cases.

Karkinos Healthcare will use SOPHiA GENETICS' technology to expand its offerings, advance research and streamline workflow for a variety of blood cancers, including Myeloid cancer and Lymphoma. In addition, the company will analyse solid tumours for a variety of cancer types including ovarian, prostate, breast, pancreas, lung, colorectal, skin, and brain cancers. The SOPHiA DDM Platform offers tailored NGS-based workflows to streamline processes, from sample to report, to accelerate analysis. By using the SOPHiA DDM Platform, researchers from Karkinos Healthcare will quickly obtain high-quality and reproducible data that will ultimately accelerate clinical research studies and advance the use of precision medicine.

WHO urges countries to accelerate efforts for tobacco control

Globally there are 1.25 billion adult tobacco users, according to the latest estimates in the World Health Organization (WHO) tobacco trends report. Trends in 2022 show a continued decline in tobacco use rates globally, with about 1 in 5 adults worldwide consuming tobacco compared to 1 in 3 in 2000. The report shows that 150 countries are successfully reducing tobacco use. Brazil and the Netherlands are seeing success after they implemented MPOWER tobacco control measures, with Brazil making a relative reduction of 35 per cent since 2010 and the Netherlands on the verge of reaching the 30 per cent target. WHO urges countries to accelerate efforts for tobacco control as there is still much work to be done.

"The Global Tobacco Industry Interference Index 2023", published by STOP and the Global Center for Good Governance in Tobacco Control, shows that efforts to protect health policy from increased tobacco industry interference have deteriorated around the world.

WHO launches appeal for $1.5B for key emergencies in 2024

The World Health Organization (WHO) has launched an appeal for $1.5 billion to protect the health of the most vulnerable populations in 41 emergencies around the globe in 2024. The appeal covers the emergencies that demand the highest level of response from WHO, with the aim to reach over 87 million people. It is being issued in a context of complex emergencies cutting across crises of conflict, climate change and economic instability, which continue to fuel displacement, hunger, and inequality. The funding would go to the African Region, with $334 million; the Eastern Mediterranean Region, with $705 million; the European region, with $183 million; the Western Pacific Region, with $15.2 million; the South-East Asia Region, with $49 million; and the Americas Region, with $131 million.

WHO grants Emergency Use Listing to Biological E's COVID-19 vaccine Corbevax

Biological E (BE), an India-based vaccines and pharmaceutical company, has announced that the World Health Organization (WHO) has granted an Emergency Use Listing (EUL) to their Corbevax vaccine, which is India's first indigenously developed COVID-19 vaccine that is based on protein sub-unit platform. The Drugs Controller General of India (DCGI) already approved the vaccine for restricted use in emergency among adults, adolescents and young children in a sequential manner from December'21 to April'22; as well as India's first heterologous COVID-19 booster shot for adults age 18 and above in June'22.

BE has been working on a next-generation COVID-19 vaccine that is based on the XBB1.5 variant of the SARS-CoV-2 virus, which would conform to WHO TAG-CO-VAC recommendations. BE's candidate vaccine has completed all required pre-clinical animal studies, which suggest that it will provide adequate protection against the currently circulating variants.

Chrysalis-based 'living bioreactors' may accelerate new vaccine production

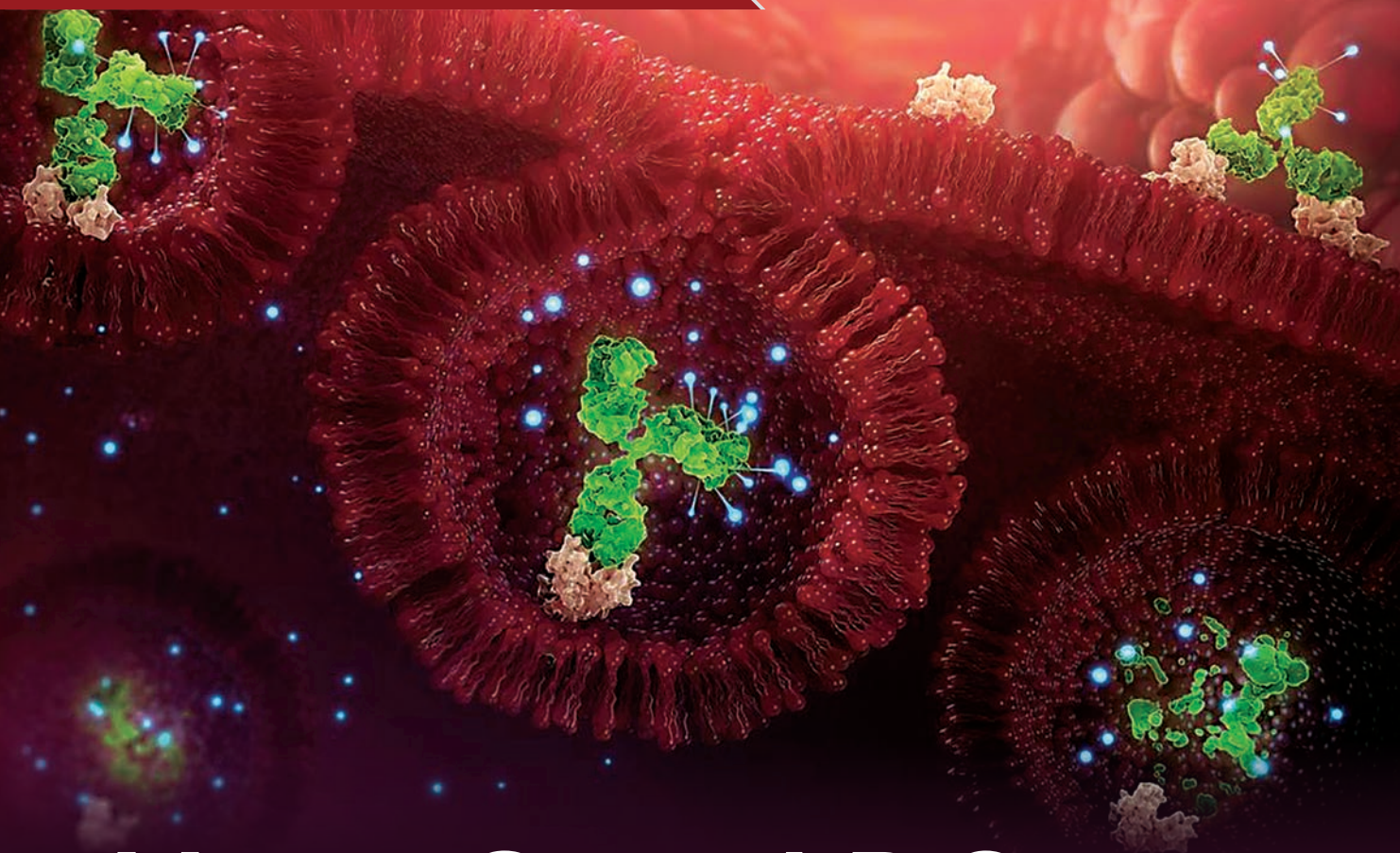
Scientists in Spain are to investigate whether moth chrysalises infected with an insect virus known as a baculovirus could act as 'living bioreactors' in a new rapid vaccine production technique to help protect people faster from pandemic threats. In a project funded with a Coalition for Epidemic Preparedness Innovations (CEPI) award of up to $3.14 million, researchers at Algenex, a Spanish biotech company, will further develop their chrysalis-based baculovirus vaccine platform technology, known as CrisBio. The aim of the project is to conduct a pre-clinical proof of concept study for a vaccine against influenza, and to demonstrate CrisBio's potential application for rapid and large-scale human vaccine production. By enabling swift scalability and early large-scale production of viral antigens needed for vaccines, Algenex's CrisBio technology could bypass the need for smaller, iterative bioreaction processes and regulations, potentially expediting vaccine production timelines.

US-based Gates Foundation announces largest healthcare budget ever of $8.6B in 2024

US-based Bill & Melinda Gates Foundation has announced its largest annual budget to date as it works toward the goal of a healthier, more prosperous world for all. With global health budgets in decline overall, a portion of the additional funding will go toward advancing global health innovations that will save and improve the lives of some of the world's most vulnerable people, including newborn babies and pregnant mothers living in low-income communities. The foundation's $8.6 billion 2024 budget was formally approved by its board of trustees on January 13. The budget, which represents an increase of 4 per cent over last year and is a $2 billion increase over the 2021 budget, comes as global contributions to health in the lowest-income countries are stalling. The foundation has committed to increasing its annual spending to $9 billion by 2026. The incremental resources for 2024, both financial and human capital, seek to accelerate efforts for greatest impact across the foundation's diverse priorities, ranging from polio eradication to scaling child azithromycin delivery in the world's highest mortality settings to improving digital courseware in postsecondary education to accelerating the world's tuberculosis (TB) drug portfolio.

Novo Nordisk Foundation signs $25M partnership with CARB-X to fight drug-resistant infections

Denmark headquartered Novo Nordisk Foundation is committing up to $25 million to support the early-stage development of innovative tools to prevent, diagnose and treat the most dangerous drug-resistant bacterial infections. The three-year grant will go to US-based Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), the leading global non-profit public-private partnership in this space. Antimicrobial resistance (AMR) threatens to unravel societies and the global economic system by increasing the risks of performing routine medical procedures such as caesarean sections, hip replacements and chemotherapy, impairing our food chain, and diminishing productivity. According to the World Bank, in a high AMR-impact scenario, the world would lose 3.8 per cent of its annual GDP by 2050, with an annual shortfall of $3.4 trillion by 2030. A key part of the solution is the development of new vaccines, diagnostic tools, antibiotics, and other innovative interventions that can help prevent these infections, diagnose them quickly and accurately, and treat them effectively.



Next-Gen ADCs as Precision Weapon Against Cancer

Antibody-Drug Conjugates (ADCs) are emerging as a crucial frontier in targeted cancer care. Although the first ADC was approved in 2000, the space has experienced a renaissance in recent times. Major pharmaceutical players like Novartis and Pfizer, including startups, are announcing deals in this space almost every day. Within the Asia-Pacific (APAC) region, China stands at the forefront of ADC drug development. GlobalData reports that numerous domestic companies in China are actively shifting their focus towards the creation of pioneering ADC-based treatment options, particularly for solid tumours like breast, gastric, and bladder cancer. When we observe World Cancer Day on February 4, we explore the promising world of next-gen ADCs, exploring advancements and unravelling the advantages they offer compared to other therapies like cell and gene therapies.

Cancer poses a significant challenge for the pharmaceutical industry, driving a constant search for improved oncology drugs. The industry has now put the spotlight on antibody-drug conjugates (ADCs), representing a promising frontier in targeted cancer treatment. 2023 was a big year for ADCs, marked by a total of 76 deals (by December 26, 2023) encompassing licensing agreements, collaborations, and acquisitions. Majority of the big pharma companies have either announced acquisitions or partnership with smaller biotech companies in this space, the latest entrant is Johnson & Johnson (J&J) which on January 8, 2024, made a significant move with a $2 billion acquisition of ADC developer Ambrx Biopharma, bolstering its ADC pipeline. Just a few weeks back, on December 26, 2023, J&J sealed a substantial $1.7 billion deal with South Korea's LegoChem Biosciences for the development and commercialisation of LCB84, a promising Trop2-directed ADC. The preclinical data for LCB84 highlighted a distinct safety and efficacy profile across various cancers, underlining the significance of these strategic advancements in the ADC landscape.

China is making significant strides in the ADC sector, riding the partnership wave with major pharmaceutical companies. Bristol Myers Squibb, in collaboration with SystImmune, entered an exclusive agreement to jointly develop and commercialise BL-B01D1, an innovative EGFRxHER3 bispecific ADC. SystImmune is spearheading efforts in mainland China, while Bristol Myers Squibb oversees developments elsewhere. GlaxoSmithKline (GSK) strategically fortified its oncology portfolio by acquiring Hansoh Pharma's gynaecologic cancer candidate (HS-20089), showcasing a commitment to addressing specific cancer types. In a clinical trial collaboration agreement, Eisai and China-based Bliss Biopharmaceutical partnered for BlissBio's ADC candidate targeting Human Epidermal Growth Factor Receptor 2 (HER2) in cancer treatment. AstraZeneca joined the ADC surge with the acquisition of China-based LaNova Medicines, gaining access to LaNova Medicines' preclinical candidate LM-305, focused on relapsed and refractory multiple myeloma.

Shanghai-based DualityBio, a clinical-stage company, stands out for its cutting-edge ADC technology platform. The firm is emerging as a fan favourite with both big pharma and local firms. In April, last year DualityBio made headlines by selling two ADC assets to the German mRNA giant BioNTech for an upfront payment of $170 million. Building on this achievement, the collaboration between DualityBio and BioNTech expanded in August to globally advance, manufacture, and commercialise a third ADC candidate, DB-1305. Strengthening its position, DualityBio entered into an agreement with BeiGene in July 2023, granting BeiGene an exclusive option for a global clinical and commercial licence for an investigational preclinical ADC therapy targeting specific solid tumours. In October, DualityBio further solidified its standing by securing global out-licensed rights from local firm MediLink Therapeutics for their ADC targeting HER3.

One of the major highlights in this space was Pfizer's $43 billion acquisition of Seagen. Seagen is a pioneer in ADC technology, with four of the 12 total FDA-approved and marketed ADCs using its technology industry-wide. Another noteworthy deal in this space is AbbVie's proposed $10 billion deal to acquire ImmunoGen, and its flagship cancer therapy ELAHERE (mirvetuximab soravtansine-gynx), a first-in-class ADC approved for platinum-resistant ovarian cancer (PROC). The acquisition accelerates AbbVie's commercial and clinical presence in the solid tumour space.

American pharma major Eli Lilly made two acquisitions in this space last year. In October 2023, the firm acquired French biotech Mablink Bioscience, a pre-clinical biotechnology company pioneering the development of next-generation ADCs via its PSARLink proprietary platform for an undisclosed amount. In June 2023, the firm had acquired ADC developer Emergence Therapeutics for $7 million.

Another noteworthy collaboration was between Daiichi Sankyo and Merck. The two pharma majors formed a global collaboration for three DXd ADC candidates: HER3-DXd, I-DXd, and R-DXd. This partnership entails joint development and potential worldwide commercialisation, excluding Japan where Daiichi Sankyo retains exclusive rights.

This is proving to be a lucrative period for ADC developers, benefiting from a surge in deal-making. ADC companies are becoming prime targets for private equity and venture capital investment. EY Life Sciences reports that a substantial 52 per cent of private equity and VC investment in the first quarter of 2023 was directed towards emerging treatment modalities, encompassing ADCs, gene therapies, and peptides.

Asian scenario

The region has also witnessed a flurry of activities. 2024 started with Roche's billion dollar licensing agreement with Chinese startup MediLink Therapeutics regarding its lead candidate YL211, targeting c-Mesenchymal epithelial transition factor (c-Met) against solid tumours. South Korea's

LegoChem Biosciences, which has previously inked a pact with J&J secured KRW 550 billion from Orion to become a global ADC powerhouse. Singapore based Hummingbird Bioscience licensed its HER3-ADC, HMBD-501, to Endeavor BioMedicines for up to $430 million in milestone payments. Takeda, the Japanese pharma majors secured exclusive global rights from Innate Pharma for ADCs targeting celiac disease.

Major contract research development and manufacturing organisations (CDMO) in the region are taking initiatives to ramp the production and manufacturing of ADCs. Samsung Biologics is intensifying its ADC production efforts with strategic investments. The firm has invested in Araris Biotech AG, a leader in proprietary ADC-linker technology. The firm has also partnered with AimedBio after an investment by Samsung Biologics joined an equity investment in AimedBio, a Korean biotech company. WuXi Biologics from China has also announced plans to spin off its ADC operation.

LOTTE BIOLOGICS, based in South Korea, is actively pursuing partnerships and initiatives to establish itself as a prominent player in the ADC sector. With an ongoing ADC facility expansion in Syracuse, USA, the company aims to offer services spanning the entire ADC value chain, from product development to commercial production, leveraging its platform technology.

Why are ADCs becoming popular?

The first ADC drug, Pfizer's Mylotarg, received United States Food and Drug Administration (US FDA) approval in 2000. However, it was withdrawn from the market in 2010 due to toxicity concerns raised in a post-marketing trial. In 2017, Mylotarg was reintroduced at a lower dose for a specific subset of leukaemia patients, following FDA clearance. The next ADC, Seagen's Adcetris, reached the market after an 11-year gap.

The list of FDA-approved ADCs has rapidly expanded in recent years, with eight products gaining approval between 2019 and 2022. Currently, a total of 13 drugs have received approval so far. It is worth noting that some of these treatments, like Roche's Kadcyla (trastuzumab emtansine) and Daiichi Sankyo/AstraZeneca's Enhertu (trastuzumab deruxtecan), have swiftly evolved into blockbuster successes for their respective owners.

The overall pipeline of clinical prospects is growing, there are approximately 100 ADC candidates now in clinical development and well-over 150 candidates in preclinical development. (Source: Wuxi Biologics). Analysing data from 2022, Beacon Intelligence's analysis found that the number of new ADCs entering

"Today's approved ADC therapies are showing game changing clinical activity particularly in the solid cancer indications. ADCs are "off-the-shelf" therapies readily available to a large patient population. In the cellular therapy space, logistical and production challenges and certainly also cost and time-to-treatment constraints still need to be tackled or improved."

- Dr Martin Steegmaier,
Chief Scientific Officer,
SOTIO Biotech, Czech Republic

"Over the last couple of years ADCs have demonstrated very compelling clinical benefits. This benefit has been enabled by technological advancements that have established the right balance between safety and efficacy for the drug that is conjugated to the tumour targeting antibody, as well as by improvements to the stability of the linker that joins the drug to the antibody."

- Dr Jerome Boyd-Kirkup,
Chief Scientific Officer,
Hummingbird Bioscience, Singapore

"ADCs developed to deliver extremely potent toxins against tumours have now proven to be valuable therapies. We are seeing an expansion of their role as they have a cost advantage over very complex, more expensive therapies. There is a lot of hope that next generation ADCs will one day deliver treatment that will change the lives of people facing cancer."

- Dr Léo Marx,
Medicinal Chemist, Bioconjugates Manager,
Debiopharm, Switzerland

the clinic had doubled compared to 2021. A large amount of this research was emerging from the US, but when Asian countries were grouped together, the amount of clinical assets being developed there outnumbered those in the US. IQVIA's 2023 report on global oncology trends also outlined that R&D growth into solid tumour research is a major focus across the industry, and ADCs are becoming a larger part of this research. This is due to ADC clinical prospects being concentrated on solid tumour targets, with 65 per cent growth over the last five years in assets in the area.

While most approved ADC therapies have targeted liquid cancers, the focus is now shifting towards solid tumours. Here is an insight into why there's a sudden interest and outpouring of billions of dollars into this space.

"While ADCs have been in use since their first approval in 2000, the recent surge in interest can be attributed to the substantial increase in approvals, with more than half of the 13 total approvals occurring in the last three years. This trend is expected to continue, as Daiichi's Anti-Trop2 ADC is anticipated to join the market in 2024. The growing number of approvals has prompted many pharmaceutical companies to want to further explore the potential applications of ADCs in various oncology indications and enhance their efficacy. This heightened interest aligns with the maturity of current ADC technology platforms, reflecting decades of research and technological advancements in every component of ADCs. Clinical trials demonstrating the safety and efficacy of ADCs across a range of cancer indications have further strengthened their appeal, particularly in addressing previously hard-to-treat solid tumours," said Dr Christian Rohlff, CEO of Oxford BioTherapeutics, UK.

Oxford BioTherapeutics (OBT) is a clinical stage oncology company with a pipeline of first-in-class ADCs, with its lead asset, OBT076 currently in Phase 1b clinical trials. A further nine programmes are in preclinical development in partnership with ImmunoGen.

When a cytotoxic drug is delivered to a tumour cell as an antibody-drug conjugate, its effectiveness increases by several logs than if it were to act alone on cancer cells. Over the last decade or so, ADC technologies have evolved substantially from initially first-generation molecules where the cytotoxic payload is randomly attached to the targeting antibody and the resulting drug product is rather heterogeneous and unstable to second or even third generation ADCs where cytotoxic payload conjugation is site-specific and much more stable.

"As a consequence, today's ADC molecules are

Trailblazing Impact of Antibody-Drug Conjugates

« **Joe Daccache,** Project Leader, DeciBio

The field of Antibody-Drug Conjugates (ADCs) has experienced a remarkable transformation, shifting from dormancy to a surge in technological advancements. The sudden interest in ADCs is driven by their promising combination with Immunotherapy (I/O), yielding astonishing datasets.

Despite a perceived stagnation post-Kadcyla, recent breakthroughs, particularly in linker technology, have injected new vitality into the field. The landscape has evolved with heightened innovation, integrating platforms, and artificial intelligence (AI) into drug discovery processes. Initially associated mainly with oncology, ADCs are even sparking excitement in non-oncological applications.

The evolution of ADC technology has led to substantial improvements in therapeutic indices, enhancing their effectiveness. The four generations of ADCs, with the latest defying established norms, showcase the industry's commitment to advancing the technology. This commitment has resulted in a notable turnaround from a historically sluggish funding climate, as evidenced by the surge in ADC deals in 2023.

Since 2019, 10 out of 15 ADCs have gained approval, reflecting the growing stability and specificity of the technology. ADCs are poised to have the most valuable pipeline among

next-generation modalities, emphasizing their strategic importance in pharmaceutical development.

The financial landscape of the ADC field in 2023 saw substantial investments, with an average fundraising amount of $84.4 million and a total of $760 million raised. The majority of deals focused on technology platforms, particularly linkers and conjugation technologies which constituted approximately 28 per cent. Acquisitions dominated the scene, accounting for around $54 billion, highlighting the robust financial activity in the space.

Pfizer's $43 billion acquisition of Seagen, the largest deal of the year, underlines the industry's confidence in the potential of ADCs. The appetite for ADCs is evident, with high demand extending even to preclinical and discovery-stage programmes. Advances in linker technologies and favorable clinical data have accentuated pharma's hunger.

Comparing ADCs to other emerging therapeutic modalities, such as cell and gene therapies, underscores the unique advantages that they bring to the forefront. ADCs are highly specific and have become very stable, thereby reducing off-target effects and potential side effects on healthy tissues. This targeted precision is a significant advantage, contributing to a more favourable safety profile, even with the bystander effect of newly developed ADCs.

Additionally, manufacturing and scalability are areas where ADCs shine. They are relatively less complex to manufacture and are easy to administer, making them readily available and easier to implement in healthcare settings. This simplicity in production makes ADCs more scalable and cost-effective; they offer a more streamlined and accessible therapeutic option.

More importantly, ADCs follow the established regulatory pathway for traditional biologics, which is generally faster and less complex compared to the regulatory framework for cell and gene therapies. The latter, being a relatively new field, faces evolving and challenging regulatory paths.

Stepping into 2024, an expectation of more deals, especially M&As, positions ADCs at the forefront of pharmaceutical development. The emphasis on technology advancement and the precision offered by ADCs over alternative modalities further solidify their role as a transformative force in the evolving landscape of targeted therapies. BS

> "While recent advances in ADCs have been revolutionary, further innovation is necessary. To date, around 90 per cent of cancer patients are either not eligible, or do not respond to existing ADC treatments, which all target the same pool of about 20 tumour antigens."

- Dr Christian Rohlff,
CEO of Oxford BioTherapeutics, UK

showing a much improved pharmacokinetic and stability profile, resulting in a substantially widened therapeutic window. To date, approximately one third of all antibody-based therapeutics in clinical development are ADCs (roughly 350), and there are 13 ADCs approved by the US FDA for treating various haematological and solid cancers. At this point in time the field is rapidly progressing, exploring immune-stimulating ADCs, protein-degrader ADCs, conditionally active ADCs, or even bispecific ADCs and dual-payload ADCs, to tackle challenges such as tumour heterogeneity or evolving resistance to ADCs. Beyond its use in oncological indications, ADCs are starting to show great potential in non-oncological indications including, but not limited to metabolic and immunological diseases," said Dr Martin Steegmaier, Chief Scientific Officer, SOTIO Biotech, Czech Republic.

SOTIO is developing the next generation of potent immunotherapies for patients with cancer.

Echoing the similar sentiments, Dr Jerome Boyd-Kirkup, Chief Scientific Officer, Hummingbird Bioscience said "ADCs are a treatment modality that aims to deliver a cytotoxic drug payload specifically to tumour cells. Over the last couple of years ADCs have demonstrated very compelling clinical benefits. This benefit has been enabled by technological advancements that have established the right balance between safety and efficacy for the drug that is conjugated to the tumour targeting antibody, as well as by improvements to the stability of the linker that joins the drug to the antibody. For the realisation of the broad promise of ADCs, it is critical that the ADC targets a highly tumour-specific antigen, such as HER2 or HER3, and does not inadvertently attack non-cancer cells. Given the early successes in a few types of cancer there is great interest in finding target antigens for more cancers as well as in engineering better ADC molecules that can benefit more patients."

Singapore based Hummingbird Bioscience is at the forefront of engineering new ADCs for a variety

US FDA approved Antibody-Drug Conjugates				
S No	Drug	Company	Condition	Approval Year
1	Mylotarg	Pfizer/Wyeth	Relapsed acute myelogenous leukemia (AML)	2017; 2000
2	Adcetris	Seagen Genetics, Millennium/Takeda	Relapsed HL and relapsed sALCL	2011
3	Kadcyla	Genentech, Roche	HER2-positive metastatic breast cancer (mBC) following treatment with trastuzumab and a maytansinoid	2013
4	Besponsa	Pfizer/Wyeth	Relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia	2017
5	Lumoxiti	Astrazeneca	Adults with relapsed or refractory hairy cell leukemia (HCL)	2018
6	Polivy	Genentech, Roche	Relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL)	2019
7	Padcev	Astellas/Seagen Genetics	Adult patients with locally advanced or metastatic urothelial cancer who have received a PD-1 or PD-L1 inhibitor, and a Pt-containing therapy	2019
8	Enhertu	AstraZeneca/ Daiichi Sankyo	Adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens	2019
9	Trodelvy	Immunomedics	Adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for patients with relapsed or refractory metastatic disease	2020
10	Blenrep	GlaxoSmithKline (GSK)	Adult patients with relapsed or refractory multiple myeloma	2020 (Withdrawn in 2022)
11	Zynlonta	ADC Therapeutics	Large B-cell lymphoma	2021
12	Tivdak	Seagen Inc	Recurrent or metastatic cervical cancer	2021
13	ELAHERE	ImmunoGen	Platinum-Resistant Ovarian Cancer	2022

of cancers, leveraging our capabilities in rational discovery of optimal tumour targeting antibodies, coupled with our innovations in new payloads and linkers.

Magic bullets for targeted cancer therapies?

Paul Ehrlich envisioned ADCs with the concept of a 'magic bullet' developed in 1907 and yet the first ADC was only approved in 2000. Since then, a steady increase in clinical studies for new ADCs has been observed leading to the emergence of new compounds capable of improving treatment outcomes for patients with various cancer types.

"When Paul Ehrlich, the famous German Nobel Prize laureate, postulated the concept of the 'Magic Bullet' more than 100 years ago, conceptually he likely envisioned some wonder drug pretty close to what is administered today as an ADC to patients in need. In comparison, cellular therapies or other gene therapies have an equally high potential to revolutionise today's treatment paradigms or already have shown amazing responses particularly in patients treated for haematological malignancies. In contrast, the field of cellular therapies still awaits a breakthrough when it comes to treating solid cancers. Remarkably, today's approved ADC therapies are showing game changing clinical activity particularly in the solid cancer indications. Both modalities have equally high potential to contribute to significant patient benefit but cellular or CART cell therapies have yet to establish themselves as approved drug regimens in the solid cancer indications where we still face a particularly high medical need. In addition, ADCs are "off-the-shelf" therapies readily available to a large patient population. In the cellular therapy space, logistical and production challenges and certainly also cost and time-to-treatment constraints still need to be tackled or improved," said Dr Steegmaier.

Cancer includes a very complex set of different diseases and fortunately many technologies are competing to develop new approaches to treat each of these diseases.

"ADCs developed to deliver extremely potent toxins against tumours have now proven to be valuable therapies. We also are seeing an expansion of their role as they have a cost advantage over very complex, more expensive therapies. We are also observing a very wide diversity of antibody conjugates capable of recognising more than one target or being able to deliver molecules with more specific mode of action in the tumour. There is a lot of hope that next generation ADCs will one day deliver treatment that will change the lives of people facing cancer," said Dr Léo Marx, Medicinal Chemist, Bioconjugates Manager, Debiopharm, Switzerland.

Debiopharm is an independent biopharmaceutical company with an ongoing commitment to develop tomorrow's standard of care to cure cancer and infectious diseases and improve patient quality of life.

Furthermore, ADCs are antibody targeted chemotherapeutic molecular entities meaning they are generally well tolerated by patients. Notably, ADCs don't encounter some of the efficacy challenges faced by cell therapies in treating solid tumours.

"ADCs are a modality that are much more

Big Pharma ADC Deals/Acquisitions			
Company	**Date**	**Deal/ Acquisition Details**	**Amount (Upfront/Total)**
Roche	January 02, 2024	With Medilink Therapeutics regarding its lead candidate YL211, targeting c-Mesenchymal epithelial transition factor (c-Met) against solid tumours	Nearly $1 billion
Johnson & Johnson	January 8, 2024	Acquisition of ADC developer Ambrx Biopharma, bolstering its ADC pipeline.	$2 billion
Johnson & Johnson	December 26, 2023	Pact with LegoChem Biosciences for ADC development	$1.7 billion
Bristol Myers Squibb	December 11, 2023	Pact with SystImmune to jointly develop and commercialize BL-B01D1, a potential first-in-class EGFRxHER3 bispecific ADC	$800 milion/ Up to $8.4 billion
GlaxoSmithKline	December 20, 2023	Acquired Hansoh Pharma's gynaecologic cancer candidate (HS-20089)	-
AbbVie	November 30, 2023	Acquired ImmunoGen, and its flagship cancer therapy ELAHERE for ovarion cancer	$10 billion
Eli Lilly	October 18, 2023	Acquired french firm Mablink Bioscience	-
Eli Lilly	June 29, 2023	Acqired ADC developer Emergence Therapeutics	$7 million
AstraZeneca	May 15, 2023	Acquired LaNova Medicines' preclinical candidate against relapsed and refractory multiple myeloma	$55 million
Eisai	May 7, 2023	Agreement with China-based Bliss Biopharmaceutical for its ADC candidate directed against Human Epidermal Growth Factor Receptor 2 (HER2)	-
BioNTech	April 3, 2023	Collaboration with DualityBio for ADCs	Nearly $1.5 billion with $170 million upfront
Takeda	April 3, 2023	Agreement with Innate Pharma for ADC development for celiac disease	$410 million
Pfizer	March 13, 2023	Acquisition of ADC pioneer Seagen	$43 billion

accessible to develop and manufacture versus cell and gene therapies. At their heart they leverage the advantages of two very well known drug classes – the safety and exquisite targeting ability of antibodies as well as the tumour killing properties of chemotherapy drugs. Cell and gene therapies are more time- and cost-intensive, and require specialised facilities for patients. With these considerations, ADCs may benefit more patients than cell and gene therapies," said Dr Jerome Boyd-Kirkup.

Are ADCs truly the golden ticket to targeted cancer therapies. In 2022, cell and gene therapies dominated the scene and continue to be integral to pharma. Now, the industry is shifting focus to develop more cutting-edge and inventive therapies. Do ADCs offer a better alternative to treatments like cell and gene therapies?

"Unlike CAR-T therapy, which remains an expensive and personalised treatment option, ADCs are an 'off-the-shelf'; treatment, making them more widely available and cost effective. Engineered as targeted therapies, ADCs selectively kill tumour cells whilst sparing healthy tissues- a significant advancement compared to non-targeted approaches in many standard of care chemotherapy treatments. Multiple clinical trials have recently demonstrated efficacy and safety of a variety of linker payload combinations against a handful of tumour antigens. The next generation of ADCs, by applying validated ADC platforms against novel cancer specific antigens, have the potential to reach patients who currently have few treatment options. ADCs being a targeted therapy with an antibody linked to a cytotoxic payload, circumvent some of the efficacy challenges faced by cell and gene therapies. Notably, ADCs like Padcev for bladder cancer, Elahere for ovarian cancer, and Kadcyla, Trodelvy, and Enhertu for breast cancers have demonstrated significant efficacy in solid tumours." said Dr Rohlff.

Recent safety concerns, including evidence suggesting that the long- term consequences of random viral gene integration could cause secondary cancers, have dampened the popularity of cell and gene therapies, shifting the interest to ADCs which have the potential to overcome many of these challenges. However, it's not the be-all and end-all for cancer; there are hurdles to overcome.

"While recent advances in ADCs have been revolutionary, further innovation is necessary. To date, around 90 per cent of cancer patients are either not eligible, or do not respond to existing ADC treatments, which all target the same pool of about 20 tumour antigens," said Dr Rohlff.

But nonetheless, ADCs have offered a stronger hope that the elusive cure for cancer will finally be on the horizon. The ADC market, valued at $9.7 billion in 2023, is expected to more than double, reaching $19.8 billion by 2028. The race is on to secure a significant share of this expanding market, making it an intriguing space to observe. BS

Ayesha Siddiqui

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Breakthroughs in Rare Diseases Therapeutics

2024 rings positive for those suffering from some kind of rare disease. On January 16, 2024, Vertex Pharmaceuticals and CRISPR Therapeutics announced that the US Food and Drug Administration has approved the use of Casgevy, a therapy that uses CRISPR gene-editing to treat the serious blood disorder, transfusion-dependent beta-thalassemia, marking the second major US regulatory approval for the emerging gene-editing technology. This approval is a testament to the breakthroughs in therapeutics for rare medical conditions.

The previous year witnessed many promising developments in the fight against rare diseases. The recent Casgevy's FDA approval for beta-thalassemia comes just one month after the US drug regulator approved the use of Casgevy in treating sickle cell disease — which is notably the first time the CRISPR-based treatment received a regulatory green light in the United States.

Casgevy uses the novel CRISPR gene-editing technology to modify patients' blood cells and transplant the modified cells back into the bone marrow, triggering an increase in the production of haemoglobin, according to the FDA.

Rare diseases are considered as a significant health challenge. Between 5,000 and 8,000 rare diseases have been identified and these diseases, though not prevalent like other diseases, as a group, affect 6 to 8 per cent of the global population. Rare diseases present unique problems for not only the individuals living with the rare medical condition but for caregivers, researchers, policymakers, and industries as well.

More than 80 per cent of rare diseases are caused by genetic or congenital aberrations, and 75 per cent present with a wide range of neurological symptoms and physical and intellectual disabilities. Sadly, rare diseases mostly affect children or young adults, and even worse, several siblings can be affected in the same family. As such, these diseases come with substantial hardship for both parents and patients. Hence, advancing therapies to cater to their well-being is of utmost critical.

Urgency for R&D

The APAC region is teeming with exciting new frontiers in rare disease treatment, offering hope for patients previously facing limited options. Ever since the 'Action Plan for Rare Diseases' was launched in 2018 by the APEC Life Sciences Innovation Forum (LSIF) – to improve access to diagnosis, treatment, and care for people with rare diseases – several countries in the Asia Pacific region have become members. As of October 2023, 21 APEC member economies are participating in the plan that is dominated by APAC-based countries.

Several drugs have either been approved by the respective country's regulatory authorities or have been approved for clinical trial initiation. In 2023, for Acute Graft-versus-Host Disease (GVHD), a cell therapy developed by the Australian company Genetic Technologies received approval in Japan for treating steroid-refractory acute GVHD. This offers a new option for patients facing this life-threatening complication of bone marrow transplants.

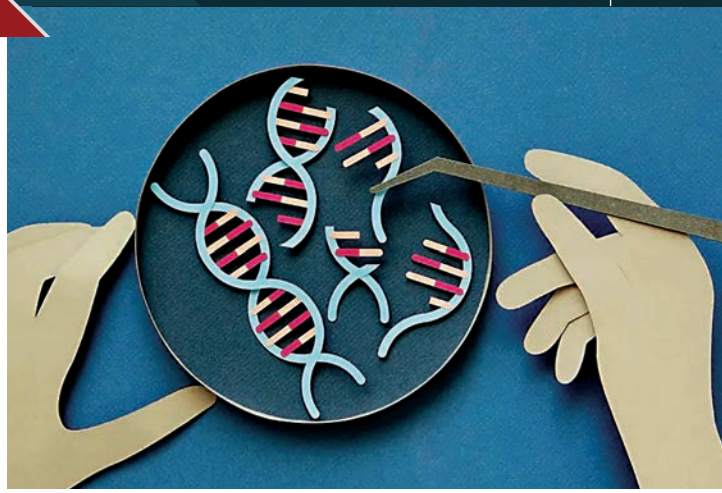
Zolgensma, a gene therapy for Spinal Muscular Atrophy (SMA) types 1 and 2, was approved in China in 2023. This groundbreaking therapy offers a single-dose solution for infants and young children with SMA, addressing a critical need in the region.

Funding for this unmet area has also been recorded. The Australian government has announced 27 grant recipients under the 2021 Rare Cancers, Rare Diseases and Unmet Need (RCRDUN) grant opportunity. The grants have been awarded to 27 projects, which aim to increase clinical trial activity in Australia for rare cancers and rare diseases by supporting new, high-quality research.

Significant strides in the rare diseases in the APAC region include:

1. Precision Medicine: Traditional one-size-fits-all approaches are giving way to targeted therapies based on individual genetic profiles. This personalised approach holds immense potential for rare diseases with diverse genetic causes, allowing for more effective and specific treatments.

Early last year, the National Health Research



Institutes (NHRI) inked an MoU for precision medicine collaboration with Singapore's KK Women's and Children's Hospital. The two parties will collaborate in three areas: whole-genome sequencing (WGS) clinical services and translational research for rare diseases, with a particular focus on Chinese genetic characteristics.

2. Gene Editing Tech: Techniques like CRISPR-Cas9 and TALENs offer the potential to permanently correct genetic defects at the source, leading to potential cures for various rare diseases. While still in the early stages, preclinical and clinical trials are ongoing for conditions like Leber's congenital amaurosis, Duchenne muscular dystrophy, and beta-thalassemia.

South Korea's Celltrion is developing a gene therapy for Duchenne Muscular Dystrophy (DMD) using CRISPR-Cas9 technology, with plans for clinical trials in 2024. This potentially curative approach targets specific genetic mutations causing DMD.

3. Gene and Cell Therapy: Stem cell transplants and gene therapy vectors are being explored to introduce healthy genes or repair defective ones. This approach holds promise for diseases like haemophilia, sickle cell disease, and lysosomal storage disorders. For instance, China's GenScript Biotech is developing gene therapies for Hunter syndrome and Leber's congenital amaurosis. GenScript is also developing gene therapies for both types of haemophilia, aiming to provide a permanent cure by introducing functional copies of the missing clotting factor genes. In late 2023, Japan approved Cerezyme, a recombinant enzyme replacement therapy, for Gaucher disease type 1. This approval expands treatment options and access for patients in the region.

4. AI and Big Data: Advanced computational tools are aiding in drug discovery, patient diagnosis, and clinical trial design. By analysing vast amounts of genetic and clinical data, AI can help identify disease patterns, predict treatment responses, and accelerate the development of new therapies.

Researchers at China's Peking University are developing AI models to analyse medical images like CT scans and MRI scans for early detection of rare lung diseases like idiopathic pulmonary fibrosis. Australian researchers, on the other hand, are working on AI-assisted diagnosis of genetic diseases. Researchers at the Garvan Institute of Medical Research are developing AI models to analyse facial features and genomic data for rapid diagnosis of rare genetic syndromes, particularly in newborns.

Building virtual patient cohorts has also been trending for the past few years and is showing a higher trend for future research and deployment. AI is being used to create virtual patient cohorts based on clinical data and electronic health records. This allows researchers to study rare diseases more effectively even with limited patient numbers.

Several startups have also forayed into this space. For example, Ubie Inc., a Japan-based startup, has signed a comprehensive collaboration agreement with Takeda Pharmaceutical Co. to promote digital transformation, which aims to guide people to appropriate medical care for rare diseases.

Regional Collaboration

This story throws some light on the progress taking place in APAC's rare disease drug discovery and its market. However, the landscape of rare disease medicine in the Asia Pacific is much more dynamic and is constantly evolving. Examples cited here are just a glimpse into the promising efforts underway in the regions, offering hope for a brighter future for patients and their families.

But, it's important to note that access to these innovative therapies remains a big challenge in many parts of APAC. Affordability, healthcare infrastructure, and awareness of early detection all play a role in ensuring equitable access for patients across the region.

Though the Orphan Drug Act of many APAC countries incentivises drugmakers to prioritise rare diseases in their pipelines and gives companies marketing exclusivity for additional years before generics enter the market, there is a long road ahead. The APAC region needs to solidify more collaboration between governments, academic institutions, and biopharma companies. Efforts like the APEC Rare Disease Action Plan and the Asia Pacific Rare Disease Network (APRDN) need to increase their knowledge sharing, resource allocation, and clinical trial opportunities. BS

Anusha Ashwin

New Zealand MedTech Guns for Global Reach

New Zealand's medical technology industry is experiencing rapid growth. In 2022, the Technology Investment Network (TIN) reported that 17 MedTech companies ranked among the country's top 200 technology firms. A mix of established and emerging innovators is addressing challenging issues, from innovative surgical techniques to AI-driven micro-implantable devices. This transformation is fuelled by substantial support from both the government and private sector. Let's delve into the details of New Zealand's thriving MedTech ecosystem.

From a burgeoning industry with a handful of homegrown companies to a powerhouse boasting over 200 players, the New Zealand MedTech sector is booming and the sector is worth around $2.1 billion, according to Uniservices.

New Zealand aims to be the leader in the MedTech space and has announced various initiatives and programmes to that extent.

"The New Zealand Government supports and invests in a range of projects, partnerships and programmes across the science, innovation and technology system," said ***Danette Olsen, General Manager Science System Investment and Performance, Ministry of Business, Innovation and Employment (MBIE), New Zealand.***

MedTech-iQ Aotearoa, a national innovation collaboration, aims to accelerate the success of the New Zealand MedTech sector. It's a 'world-first' initiative targetting the $815 billion global medical device and digital health market. This virtual hub, linked to physical hubs in Auckland, Wellington, Christchurch, and Dunedin, employs a strategic, country-wide approach to enhance New Zealand's economic and physical health outcomes through MedTech collaboration and innovation. Deloitte Access Economics estimates a $1.5 billion increase in NZ's GDP by 2050 through MedTech-iQ.

In October 2021, the government announced an investment of $8.1 million over three years in Te Tītoki Mataora, the MedTech Research Translator. The 18-month-old (as of April 2023) programme has already awarded $2.27 million in early seed funding to 40 projects nationwide.

"Government-funded MedTech initiatives include the Te Tītoki Mataora (TTM) MedTech Research Translator, which is hosted by the Auckland Bioengineering Institute (ABI) on behalf of the Consortium for Medical Device Technologies – a collaborative partnership between the University of Auckland, University of Otago, University of Canterbury and Callaghan Innovation. This deep tech research translator focuses on the translation of research that addresses healthcare needs and improves the equity of access to care and outcomes," said Danette Olsen.

In December 2023, Callaghan Innovation introduced the inaugural Ārohia Innovation Trailblazer Grant. Among the eight recipients, three are from the MedTech sector – Wellumio, Alimetry, and Kitea Health. These grants support non R&D activities to advance the commercialisation of world-leading technologies, aiming to transform New Zealand's innovation ecosystem.

"Government agency Callaghan Innovation runs an ecosystem-wide commercialisation hub, which delivers a range of products and programmes to accelerate the commercialisation of HealthTech and emerging HealthTech companies in New Zealand. The HealthTech Activator provides access to support, capability building resources and experienced advisors to help de-risk the early stage commercialisation journey of HealthTech businesses irrespective of their origin (i.e. entrepreneur established, formed via a research or university pathway or from a clinical setting). Callaghan Innovation also operates the Deep Tech Incubator programme, under which three out of four partners invest into med or biotech startups," said Danette Olsen.

"In addition to these specific healthtech investments, Danette Olsen further said that the government also invests in health research and development through the Research and Development

Tax Incentive, and contestable funds such as Endeavour, which encourage researchers to consider a diverse range of ideas and conduct excellent research, with transformational potential across a range of sectors. The Endeavour Fund supported the MARS Programme, which developed a spectral molecular scanner capable of producing 3D colour images of objects inside the body, including bone, soft tissue, and artificial joints. Additionally, another project under the Endeavour Fund explored the feasibility of utilising portable nuclear magnetic resonance (NMR) sensor technology to detect strokes and diagnose brain injuries. ABI has also been allocated $15 million in government funding over five years to support a world-leading project to develop a clinically-oriented framework for mathematically modelling the physiological systems of the human body, known as 12 Labours.

"I think the really big opportunity for NZ lies with virtual human twins, where we use integrative physics-based models of the entire body to interpret data from a wide variety of monitoring devices. We are working with the US and Europe, but I think we can say that NZ is leading the world in the development of personalised, clinically applicable, whole-body models based on modelling the detailed biophysics of physiological mechanisms," said ***Professor Peter Hunter, ABI, University of Auckland, New Zealand.***

ABI, a world-renowned research institution, holds a pivotal role in New Zealand's MedTech sector. The institute has successfully spun out several companies, including The Insides Company, Formus Labs, and Heart Labs.

Creating a global impact

As per the 2022 NZ-US Trade Relationship Report by the New Zealand-US Council, medical instruments claimed the fifth position among New Zealand's leading 30 exports to the US in 2020. With a value of NZ$260 million, sleep apnea machines, making up 76 per cent of total medical instruments exports, now constitute a more substantial share in New Zealand's exports to the States compared to timber or casein. Fisher and Paykel Healthcare primarily manufactures these machines, recognised as Continuous Positive Airway Pressure (CPAP) units, playing a significant role in enhancing sleep quality for consumers in the US. New Zealand companies are also actively pursuing global expansion.

In 2022, Alimetry's new test of gastric function, Gastric Alimetry, received FDA clearance, allowing millions of US patients suffering from gastric disorders to access it within three years of the company's founding. Also in 2022, Toku Eyes entered the US market with the launch of ORAiCLE, an AI platform that assesses heart risk through a retinal scan. In the same year, The Insides Company (TIC) entered the UK and Ireland markets. A partnership with the GBUK Group to distribute the TIC chyme reinfusion device now enables patients with type-2 intestinal failure in these countries to access this innovative technology, facilitating faster re-establishment of oral feeding and providing better outcomes after surgery.

Prominent NZ MedTech Firms

- Alimetry develops breakthrough diagnostic solutions for disorders of gastrointestinal function and motility.
- Kitea Health is building the next generation of micro-implantable devices.
- Toku Eyes is developing tools using AI and retinal photography to enable accessible healthcare for early and accurate diagnosis of health conditions.
- Avasa is a pioneer in advancing surgical techniques for improved patient outcomes.
- Tiro Medical focuses on equitable healthcare and collaborates with UC bioengineering on personalised hospital care and non-invasive breast screening tech
- Wellumio is on a mission to revolutionise healthcare with portable MRI technology, bringing rapid diagnosis and treatment directly to patients.
- Orbis Diagnostics has developed an automated lab-in-a-box, providing rapid and reliable results to inform time-critical health management at the point of need.

Innovative medical devices

In addition to prominent businesses like Fisher & Paykel Healthcare, MedTech Global, and Aroa Biosurgery, a cohort of startups is emerging, addressing diverse areas—from innovative surgical techniques for enhanced patient outcomes to the development of AI-driven micro-implantable devices and wearable medical solutions for gastrointestinal care etc. New Zealand's MedTech industry is at a tipping point, leading the way in global advancements that promise benefits for both its citizens and the global MedTech sector. BS

Ayesha Siddiqui

“AI's superior speed & learning capability make it a natural fit for healthcare tasks demanding precision & early detection”

« **Steven Quoc Hung Truong,** Founder and CEO, VinBrain, Vietnam

Vietnam’s VinBrain is developing AI solutions for healthcare and has developed more than 300 AI models specifically designed for processing medical images. DrAid, its groundbreaking intelligent AI platform, is positioned as the 'right-hand' assistant for healthcare professionals to enhance productivity and reduce patient care costs. Steven Quoc Hung Truong, Founder and CEO of VinBrain shares key insights into the company, its challenges, and ethical and regulatory considerations. ***Edited excerpts:***

How did VinBrain come into existence?

After 26 years abroad, spending 13 years as the Director of Engineering and AI Innovation at Microsoft in the United States, I returned to Vietnam. my homeland, in 2019. The founding of VinBrain can be traced back to a series of coincidental events that occurred at that time, nearly five years ago.

Witnessing my mother's stroke firsthand on one back-home occasion made me acutely aware of healthcare challenges in Vietnam. Leaving my 13-year leadership at Microsoft, I answered Vietnam's billionaire, Chair of Vingroup, Pham Nhat Vuong's call to build a global tech alliance with Vietnamese talents, fueled by ‘forever the entrepreneurship spirit’. Consequently, the firm determination of 18 like-minded talents beside me, who bred the seed of VinBrain in 2019, led us on a mission to alleviate patient suffering and relieve the overburdened healthcare workforce through advanced AI technologies. We aspired to build a health tech company where the core technology was developed by Vietnamese talents, breaking away from the conventional practice of importing solutions from overseas. ‘Infuse AI and IoT to improve people's lives and productivity’ is the company's mission to streamline all its efforts and activities and enable diagnostic radiology and digital healthcare transformation to accelerate to the next level of excellence.

What are the key technological advancements that have propelled VinBrain's position as a leader in AI solutions for healthcare?

DrAid, an intelligent AI platform, is considered our breakthrough in the realm of health tech particularly and AI generally. VinBrain's flagship DrAid, powered by secure AI platform Azure and Azure OpenAI, leverages Microsoft's cutting-edge AI, including Generative AI and ChatGPT-4, to become the ‘right-hand’ assistant for healthcare professionals to improve their productivity and patient care cost. Another notable offering by VinBrain is our pride and pioneer in HealthTech is the ‘ChatGPT for Healthcare’ virtual assistant, DrAid Copilot. This AI companion, at the heart of the DrAid platform, aids physicians in diagnosis, treatment, and managing their growing workload.

Talking about our key technological advancement, it is impossible not to mention our synchronised and comprehensive AI infrastructure, which was built from the very beginning of our establishment.

We have trained our AI models which include medical images, intelligent video analytics, automatic speech recognition, natural language processing and text-to-speech — using NVIDIA DGX SuperPOD.

Our team is also using software from NVIDIA AI Enterprise, an end-to-end solution for AI production, which includes the NVIDIA Clara platform, the MONAI open-source framework for medical imaging development and the NVIDIA NeMo conversational AI toolkit for its transcription model.

How has VinBrain's technology impacted the overall healthcare ecosystem, both in terms of patient care and operational efficiency?

VinBrain's AI technology fuels both radiology and hospital management. In the realm of AI for radiology, VinBrain offers a wide range of product lines such as DrAid Comprehensive Screening,

DrAid Oncology Diagnosis and Treatment, and DrAid Social Impacts Diseases Screening. These AI-powered diagnostic radiology solutions assist doctors to increase substantially the accuracy of anomaly detection while avoiding misdiagnosis and overdiagnosis by chance. As the cream of the crop, this CAD (computer-aid diagnosis) software outweighs in helping oncologists with liver cancer, and rectal cancer diagnosis and treatment, 2 of the top dangerous and intricate cancers. Another exceptional product line plays a vital role in scaling community screening programmes for infectious diseases like tuberculosis in the lung in 2X strategy (Chest X-rays, GeneXpert MTB/RIF tests).

In summary, VinBrain technology focuses on AI-centric solutions to significantly enhance patient care to save more lives and forward doctors toward precision care.

On the healthcare operation side, VinBrain provides intelligent, data-driven, and comprehensive solutions for hospital managers called DrAid Enterprise Data Solution. This indispensable tool benefits not only operators but doctors, medical experts, and patients.

Impact on the Environment (E): It brings comprehensive digitisation of the Diagnostic Imaging industry in Vietnam with more than 150,000 images digitised each month at 100+ Vietnamese hospitals. Thereby, minimising medical waste in the environment.

Impact on Society (S): It reduces the overload of doctors, eliminates repetitive tasks that require less empathy, improves accuracy, supports doctors for better decision-making in examining the toughest cancer - 24/7, bringing sustainable benefits to society, creating smart hospitals, putting patient interests as the best practices.

Impact on Governance (G): It interoperates data among different divisions for Fast retrieval, and lifetime storage on a secured cloud. It converts huge volumes of data produced within the hospitals into knowledge systems for accurate decisions, well data-based for smarter governance.

Can you discuss any significant challenges VinBrain has encountered in developing and deploying AI solutions in healthcare, and how these challenges were overcome?

VinBrain was established just six months before the COVID-19 outbreak, but we quickly adapted to the pandemic by developing DrAid, a tool that screens and detects the virus. It won the Asian Digital Awards and received merit from the Ministry of Health, Vietnam for innovative software that secured society amid the toughest time.

Despite the challenges of developing AI for healthcare, including the need for top talents in computer science and substantial operational costs, VinBrain has successfully navigated these obstacles in quite a speedy way. It's a fact that building and deploying core tech like AI for healthcare demands top talent across computer vision, NLP, engineering, and operations. They must have unwavering passion for this complex field, as we're pioneering uncharted territory. We are lucky to have the talented people who formerly worked abroad for top giant corporations like Microsoft, Amazon, and Samsung gather and become our core team.

In terms of developing and deploying core tech, especially AI for healthcare, it requires us to own only the top computer science talents throughout explainable AI, computer vision, natural language process, engineers, and operators, with consistent passion for a very complex domain like healthcare, because we are the trailblazers to explore very unprecedented field. It accounts for up to 70 per cent of operational fees. The required investment for an AI infrastructure platform is another concern with top trusted security standards and capabilities, and the seamless operation from time to time.

Additionally, we have partnerships with leading research institutes and universities like Stanford, Harvard, UCSD (University of SanDiego California), and Toronto, sharing the same vision 'knowledge for lives' and the motto 'give first' that bonds us to create impactful AI for social good together. These collaborations, along with the use of trusted platforms like NVIDIA and Microsoft, have enabled them to overcome the technical hurdles. Data is a pivotal matter when it comes to training artificial intelligence models. But we have solved that by a big and high-quality representative dataset originating from local (Vietnam – 3.5 million data points), and other nationalities: US, India, China, and Europe.

In the medical field, especially in diagnostic radiology and oncology, it is crucial to quickly acquire extensive medical knowledge, comprehend doctors' daily pain points, and understand radiologists' workflows. To achieve this, we collaborate closely with doctors and medical experts from Vietnam and the US during the annotation stage. We were fortunate to have the support of radiologists, physicians, and professionals from specialised hospitals like the National Cancer Hospital in Vietnam and top general hospitals such as UMC, Vinmec, 108 Military Central Hospital, and Hue Central Hospital. They assisted in validation and research consultations, ensuring a comprehensive

platform for our users. Additionally, we have collaborated with physicians from Stanford University and the University of San Diego California to develop our products further.

In the realm of HealthTech, we also encounter common concerns like any other AI company worldwide. These include the fear of AI replacing doctors, issues with ethics, security, legal regulations, and implementing interoperability within hospitals. Essentially, AI is an innovative technology, and we continue to persuade the market by offering high-quality products. Over 2000 doctors who work with us are satisfied and feel optimistic about their new "right-hand" assistant.

With deployments in various countries, what strategies has VinBrain employed to tailor its products to different healthcare systems and regulatory environments?

VinBrain has strategically focused on several key principles to ensure our AI products seamlessly integrate into diverse healthcare ecosystems worldwide.

First, adaptability and customisation are embedded in our product design. We've created highly adaptable AI solutions, emphasising customisation for seamless integration with diverse healthcare technologies. For example, our modular systems address specific needs like abnormal/normal screening, Tuberculosis screening, Emergency Disease screening, and Comprehensive screening for 52 abnormalities.

Second, we prioritise a standardised deployment process, utilising healthcare standards for smooth integration with systems like PACS/RIS/HIS. DrAid, our flagship product, ensures effortless integration across various systems, offering both cloud and on-premises availability. Our collaboration with NVIDIA, leveraging advanced GPU technology and tools like MONAI and Tensor RT, ensures cutting-edge capabilities.

Thirdly, we can operate on a Software-as-a-Service (SaaS) model that maximises availability and grants clients enhanced customisation control. This approach ensures seamless access to our AI solutions, empowering users to tailor services to their specific requirements. Our dedication to the SaaS model reflects our commitment to a dynamic and responsive healthcare technology platform.

Regulatory compliance is a top priority, guiding our operations in every country. We invest significantly in understanding and adhering to local regulatory frameworks, encompassing data privacy laws and medical device regulations. Our plans include compliance with region-specific bodies such as FDA and CE, ensuring our products meet the highest standards of safety, efficacy, and legal requirements. DrAid is the first and only AI software for X-ray Diagnostics in Southeast Asia to be cleared by The United States Food and Drug Administration (FDA), putting Vietnam on the map of 6 countries owning an FDA-cleared AI product for Chest X-ray Pneumothorax finding.

Given the sensitive nature of healthcare data, how does VinBrain address ethical considerations in the development and deployment of AI models, especially across diverse cultural contexts?

Ethical AI is non-negotiable at VinBrain, especially when handling sensitive healthcare data across diverse cultures. Strict guidelines and global privacy standards form the foundation for responsible AI use. Transparency fosters trust with patients, healthcare professionals, and regulators.

VinBrain builds AI models with explain ability, & interpretability baked in, fostering trust & understanding of decision-making. Transparency extends to users, with clear communication about purpose, scope, and potential impact, ensuring informed consent. Our flagship product, DrAid, exemplifies the commitment to privacy. Built with HIPAA & NIST compliance and secured by Microsoft Azure, it guarantees robust data protection, giving users confidence in their health information's security.

At RSNA 2023, VinBrain showcased its dedication to accessible healthcare in underserved regions with DrAid for Tuberculosis Screening. This cost-effective solution allows large-scale screenings, potentially benefiting an estimated 10.6 million TB-suspected individuals. The positive reception at the exhibition reflects VinBrain's commitment to leveraging technology for impactful and inclusive healthcare solutions. This initiative aligns with VinBrain's overarching commitment to ethical practices, showcasing the company's dedication to innovation and social responsibility in the healthcare landscape.

In your perspective, what are the emerging trends in the intersection of AI and healthcare?

AI's superior speed and learning capability make it a natural fit for healthcare tasks demanding precision and early detection. We see key trends shaping the industry: predictive analytics for early disease, personalised medicine, AI-powered data management, and AI-driven clinical decision support. BS

Ayesha Siddiqui

"Indian pharma is globally competitive and forward-looking in technology, policy and industrial strategy"

From policy frameworks to addressing industry challenges and positioning, the Department of Pharmaceuticals (DoP), Government of India forthcoming initiatives to overhaul the pharma industry, are paving the way towards global pharmaceutical dominance. Dr Arunish Chawla, Secretary, Department of Pharmaceuticals (DoP), Government of India in an exclusive interview with BioSpectrum, shares insights into the comprehensive strategy aimed at reshaping India's pharmaceutical landscape, propelling the nation to the forefront in the global arena. ***Edited excerpts:***

« **Dr Arunish Chawla,** Secretary, Department of Pharmaceuticals (DoP), Government of India

Please provide an overview of the strategic move to reform and redesign the Scheme for Strengthening the Pharmaceutical Industry.

We are charting out a comprehensive strategy to reform and redesign the existing Scheme for Strengthening the Pharmaceutical Industry. This initiative is about enhancing our infrastructure facilities and positioning India as a leader in the pharmaceutical domain.

What's the framework of the revamped scheme and its key sub-schemes?

The revamped scheme is an umbrella initiative with three distinct components. The first is the Assistance to Pharmaceutical Industry for Common Facilities (API-CF), focusing on cluster development. The second is the Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), designed to assist Micro, Small, and Medium Pharma Enterprises (MSMEs) in meeting regulatory standards. The third is the Pharmaceutical and Medical Devices Promotion and Development Scheme (PMPDS), aiming to foster growth in Pharma and Medical Devices Sectors through various initiatives.

How will the newly introduced incentive schemes address the challenges faced by the Indian medical device industry?

While challenges are multifaceted, ranging from high manufacturing costs to import dependency for high-end medical devices, to tackle these issues, we have introduced incentive schemes, including the Medical Device Park scheme. These initiatives aim to level the playing field and support the industry through schematic interventions, such as the Production-Linked Incentive (PLI) scheme for API and medical devices.

How does the policy framework map value chains in the drug and pharma industry and the MedTech industry?

The policy framework is crucial in mapping value chains in both the drug and pharma industry and the MedTech sector. Our goal is to identify key components of finished products and starting materials, ensuring that there is an incentive for value addition within India. The emphasis is on avoiding inversion of duty or tax structure along the value chain to promote industry growth.

Could you elaborate on the country's role and future outlook in the global pharmaceutical landscape?

I firmly believe that "Beyond China plus one, it will be India plus in the future." We are focusing on supplying quality medicines and generics that meet international standards. With nearly half of the $50 billion in exports directed towards supplying quality medicines globally, India is emerging as a global pharmaceutical hub.

What would you like to say about the capabilities of the Indian pharma industry and its global competitiveness?

I want to emphasise that the Indian pharma industry is globally competitive and forward-looking in technology, policy, and industrial strategy. Rooted in science and knowledge, we are evolving to meet the challenges of the future. I encourage belief in the capabilities of the Indian pharma industry as we stride towards becoming a $120 billion-dollar industry. BS

Bhagwati Prasad

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“We no longer need to endure the ravages of ageing”

« **Maxim Kholin,** Founder, Gero, Singapore

Ageing is a natural part and the "last mile" of a human development programme, and Gero pioneered ways to understand, measure, and, ultimately, control its progression. Gero, a longevity biotech physics-enabled biotechnology company from Singapore is creating therapeutics against chronic diseases with a mission to slow down human ageing itself. Gero's machine-learning platform possesses the unique capability to identify potential therapeutic targets for fibrotic diseases by analysing extensive human-based datasets. These discoveries could potentially reshape the landscape of anti-ageing research. In January 2023, the American pharmaceutical giant entered the longevity field by collaborating with Gero. Maxim Kholin, Founder of Gero, takes us through the exciting science of anti-ageing/longevity and why it is no longer confined to the realm of science fiction. ***Edited excerpts:***

What technologies is Gero using to solve ageing?

To my knowledge, we are the only company that is using physics to model biology this way. For example, consider how we approach this. People can predict the trajectory of planetary movement, much like how we analyse vast medical datasets, such as electronic medical records. We discern patterns in the data, akin to predicting future states using equations of motion, and anticipate how a patient's condition may change after therapy, similar to how Gmail suggests sentence completions as you type. Our internal projects are focused on addressing the challenge of ageing, including partial rejuvenation and halting the ageing process. Furthermore, we're actively seeking new rounds of investment to advance anti-ageing therapies and undertake additional projects related to age-related diseases.

We've demonstrated that a significant portion of human ageing is irreversible, a point on which pharmaceutical companies concur. We assist them in identifying new targets for therapies. Our technology platform allows us to differentiate between the irreversible effects of ageing and reversible disease phenotypes, potentially pinpointing the most promising therapeutic targets, as exemplified in our collaboration with the pharmaceutical company, Pfizer.

Ageing seems to be the pet peeve of tech billionaires. Why are the super-rich investing in this area?

In brief, we no longer need to endure the ravages of ageing. Some wealthy individuals possess the intelligence to grasp this fact and the resources to tackle this problem. They are driven by a desire to safeguard their health and longevity and, hopefully, change the world for the better. Ageing inflicts numerous detrimental effects, too numerous to enumerate comprehensively here.

Allow me to highlight a few: Ageing serves as the primary catalyst for age-related diseases such as strokes, adult cancers, and Alzheimer's. As we age, our risk of developing chronic illnesses and succumbing to them doubles approximately every eight years throughout most of our lives. Most age-related diseases remain incurable and lead to death. Preventing these conditions is a prudent strategy. When people receive a cancer diagnosis, for instance, they often fight desperately to prolong their lives, even though the bulk of healthcare expenditures occur in the final years of life, culminating in inevitable mortality. The notion of halting ageing is akin to preemptively addressing the spectre of future cancer, dramatically reducing the likelihood of developing cancer and other chronic ailments by preserving one's health in a youthful state for as long as possible.

Ageing compromises our physical and mental health, including cognitive functioning. It hampers personal and societal progress, particularly in our increasingly complex world, where substantial time is required for learning before one can contribute significantly beyond existing knowledge.

Nobel laureates, for example, tend to make their groundbreaking discoveries around the age of 44, after dedicating decades to learning and research. However, by the time they reach the pinnacle of their scientific achievements, many of their physical and mental faculties are already in decline. Imagine the contributions of individuals like Einstein, Korolev, or Steve Jobs if they had enjoyed an additional 20 healthy and productive years. Our civilisation might have advanced even further in exploring multiple planets.

Menopause constraints women in designing their lives as they wish, subject to the relentless ticking of biological clocks. Ageing, in short, is unpleasant and painful. It is only natural to seek liberation from it. Hence, investing in anti-ageing research and therapies is one of wealth's wisest, most responsible, and beneficial uses. However, it remains a tragedy and a shame that these investments pale in comparison to spending on luxuries and entertainment, among other less vital pursuits. This critique extends not only to the super-rich but to anyone with the means to invest or spend on endeavours less valuable than their health and that of their loved ones.

Furthermore, we should demand increased government funding for research aimed at combating ageing and age-related diseases, as ageing affects us all. Let us not solely burden the super-rich with this responsibility; everyone can contribute through financial means, political action, activism, and various other avenues. Each day, approximately 150,000 people succumb to ageing and age-related diseases, making ageing a leading cause of death. Now that you understand the cost of delaying progress in halting ageing by just one day, what justification can there be?

In light of the irreversible nature of a significant portion of human ageing, how does your company navigate the challenges and opportunities associated with developing anti-ageing therapies? Are there specific areas within the ageing process where your technology platform has shown particularly promising results?

The existence of a model that accounts for the irreversible nature of a significant portion of human ageing is Gero's unique competitive advantage. Therefore, we use the model both for the development of anti-ageing drugs and for age-related diseases. Our model has helped to understand that under the brand of 'ageing,' there are at least two completely different processes: AGEING № 1, Frailty

- it occurs in late-life ageing. It can be reversed. Therapeutic intervention can provide up to 10 years of health span. The longevity industry and Gero's first drug fall into this category. We have demonstrated very good results in rejuvenating mice in two independent laboratories, including the laboratory at the National University of Singapore. We have a therapeutic agent and interest from a leading global pharmaceutical company in this project.

AGEING № 2- 'Thermodynamic'/ true ageing - This is a whole-life process. It's irreversible in a practical sense, but it can be stopped, and this would give a multifold extension of health span and life span. Gero's ambition is to stop ageing.

For these two different types of ageing, different biomarkers have already been developed that allow us to quickly determine whether a drug is working. There is a list of diseases that can be associated with each type of ageing.

What are your thoughts on the APAC longevity industry?

APAC includes many countries with the highest life expectancy in the world. Therefore, I believe that the realisation of the necessity and commercial attractiveness of developing radical therapies against ageing will quickly come to both businesses and governments, especially in these countries, where the proportion of the ageing population is high and will suffer first if there is no significant intervention in the ageing process. We are open to collaboration with governments, investors, and the industry from APAC. BS

Ayesha Siddiqui

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How Biotech Sector Can Capitalise on AI

« **Dr Rajneesh K Gaur,** Scientist F, Department of Biotechnology, Ministry of Science and Technology, Government of India

Artificial Intelligence (AI) is now ramified in every sector including biotechnology. The impact of AI is already visible in the biotech sector and there is a boom of startups using AI for various applications. However, there is a need to develop a holistic regulatory system to make the technology more responsible. Let's explore further.

India has over 1900 AI startups including biotechnology (Zinnov-NASSCOM India Tech Start-up Landscape Report 2022). The pharma industry will be a major beneficiary of AI's applications and might spend around $3 billion on AI in drug discovery by 2025.

In the biotech sector, AI has a big role to play in the analysis, learning, prediction and better decision-making of innovative solutions in areas of agriculture. It includes crop harvesting, monitoring crop and soil, gene editing, forecasting plausible yield), health (such as medical data analysis for finding novel drug targets, forecasting drug efficacy and toxicity, speed up the drug development process, creating personalised medicine, medication management, detecting abnormalities like cancerous tumours, to build new wearable devices that can detect and monitor certain disorders), to modify the genes and traits of animals and create mixed or cross-breed versions, to provide efficient production and better product quality, to identify the locations of genes, classification of protein along with protein's catalytic role & biological function, analysis of gene expression and predictive modelling.

In the last few years, several AI-enabled biotech startups have come up. The application of AI has resulted in the development of a few notable algorithms such as new AI models e.g. 'ProtGPT2' and 'ProGen'. ProtGPT2 and ProGen have been trained on 45 million and 280 million protein sequences respectively. These model software have been used to design new proteins. Application of machine learning resulted in enhancing the accuracy of structure prediction from 70 to >80 per cent. By forecasting the 3D protein structure, AI helps in determining the effect of a substance on the target as well as safety considerations before its synthesis or production e.g. AlphaFold (2023), a Google subsidiary DeepMind algorithm, significantly improved the modelling of 3D protein systems from amino acid sequences. The other biotech startups in the last few years added to the growth of generative AI, including 'Jasper' and 'Stability AI', which has its text-to-image generation tool called 'Stable Diffusion (2022)'. Open-source AI programmes such as 'CRISPR libraries' and 'H2O.ai' are convenient for executing repetitive tasks like data entries and analysis.

AI applications are now slowly culminating in product development and their commercialisation. In the USA, the FDA recently approved a few Software as a Medical Device (SaMD) e.g. IDx-DR (2018) for screening of diabetic retinopathy and 'DiA Imaging Analysis's AI program' (2023) to assist clinicians in performing cardiac ultrasound exams. In 2021, Abbott launched its new artificial intelligence-powered coronary imaging system in Europe. AI is also changing the field of Radiology and Radiotherapy processes and helps in making 'Nanorobots' as novel drug delivery systems to enhance drug efficacy and reduce adverse effects. In India, the development of AI-based products, especially, Medical aids is supported by the Biotechnology Industry Research Assistance Council (BIRAC).

Regulatory Framework

AI provides easier, cheaper, and faster production capabilities with the danger of misusing the technology. In the biotech sector, it may lead to solutions which might compromise social security and the life of human beings such as the design and development of new bioweapons or toxins which are hard to detect. Under these circumstances, AI needs tougher measures to control its misadventure. All the major governments in the world are formulating a

regulatory framework to control the AI field. The USA has multiple Acts for regulating the AI's activities. The various Acts are 'National Artificial Intelligence (AI) Initiative Act (2020)', Algorithmic Justice and Online Transparency Act, Artificial Intelligence (AI) Training Act, AI in Government Act and recently Artificial Intelligence Research, Innovation and Accountability Act (AIRIA), 2023. In line with these acts, the US Food and Drug Administration (FDA) issued the "Artificial Intelligence/Machine Learning (AI/ML)-based Software as a Medical Device (SaMD) Action Plan".

The EU proposed the Artificial Intelligence Act (AIA), which contemplates regulation of AI based on its potential risks, and the General Data Protection Regulation (GDPR), Digital Services Act, Digital Markets Act to protect users privacy and to curb the anticompetitive practices of the tech giants. Australia's 'Artificial Intelligence (AI) Ethics Framework' examines the probability of risk, together with the consequence via suggestive frameworks. Countries like Singapore, China, UAE and Brazil have issued 'National AI Strategies'. In China, no company can produce AI services without proper approvals. India does not have specific laws for data protection but personal information is safeguarded under section 43A and Section 72A of the 'Information Technology Act', 2000. The provisions of the IT Act, combined with the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 (SPDI Rules) establish a technology-agnostic regime for protecting sensitive personal information for all corporate bodies. Recently, the Ministry of Electronics and Information Technology (MeitY), India proposed the 'Digital India Act (DIA)' and stated that the proposed law would regulate "high-risk AI systems" through legal, quality testing framework to examine regulatory models, algorithmic accountability, zero-day threat and vulnerability assessment, examining AI based ad-targeting, content moderation, etc. The Act will be implemented alongside the 'Digital Personal Data Protection Act (2023)'.

Indian Initiatives

The Government of India is also well aware of the potential implications of AI in the country's industrial landscape and has taken several initiatives to enable the AI ecosystem. In 2018, NITI Aayog published its discussion paper titled 'National Strategy for Artificial Intelligence' for identifying some of the sectors like Healthcare, Education, Agriculture, Smart Cities and Mobility for deployment of AI. The Indian Government launched the National Artificial Intelligence Portal called https://indiaai.gov.in/ in May 2020. The portal is a one-stop digital platform for AI-related developments in India, sharing resources such as articles, startups, investment funds in AI, resources, companies and educational institutions related to AI in India. The Data Empowerment and Protection Architecture (DEPA) by NITI Aayog presents a technical framework for people to retain control of their personal data and the means to leverage it to avail services and benefits.

In 2021, the Department of Science & Technology (DST), New Delhi through the Indo-US Science & Technology Forum (IUSSTF) launched a joint collaborative US-India Artificial Intelligence (USIAI) initiative. Under this initiative, Research & Technology Development in AI is being promoted & implemented in the country through a network of 25 technology innovation hubs set up under the National Mission on Interdisciplinary Cyber-Physical Systems (NM-

Artificial Intelligence (AI) based product development supported by Biotechnology Industry Research Assistance Council (BIRAC)

S. No.	Product	Application
1.	Agropeeper App	Quality Assessment and Shelf life evaluation of fruits
2.	CervASTRA	Point of care cervical cancer detection system
3.	COGNIABLE	Early detection and intervention in children with developmental disorders
4.	Dozee	Contact-free monitoring of the vital parameters of the patients on a normal bed
5.	FetalLite	Foetal ECG signal extraction for mothers in labour or post 37 weeks of gestation
6.	GAITSENSE	Gait Analysis Technology
7.	Neukelp	Smart Posture Trainer
8.	Robot X 100	Multipurpose Robot for Agriculture
9.	SAVEMOM	IoT based Maternal Healthcare solutions
10.	Seed Vision	Seed classifier and Quality Analyser
11.	SWAASA	Platform for Respiratory Assessment
12.	Thermalytix	Algorithms to interpret thermal images for breast health

Indian companies and their AI-based applications

S. No.	Company	Headquarter	AI-based Application
India			
1	Acuradyne	Mumbai	Preventive healthcare
2	Aganitha Cognitive Solutions	Hyderabad	Accelerate drug discovery and development through Insilco solutions
3	Artelus	Bengaluru	Technologies to support clinicians in diagnosis, prognosis and treatment of diseases
4	Cellix	Balanagar, Hyderabad	Synergix AI a platform aims to create a diversified portfolio of drug candidates for multiple indications
5	DocPlexus	Pune	Knowledge upgradation of Clinicians
6	Dozee	Bengaluru	AI based patient monitoring system for healthcare providers
7	HCL technologies	Noida	AI based medical Science solutions
8	HealthKart	Gurugram	Medical and Nutrition products
9	HealthPlix	Bengaluru	AI and cloud based electronic medical record management solution
10	Infosys	Bengaluru	AI based Medical Solutions
11	Kellton Tech solutions	Gurugram	AI powered platform to provide personalised care to patients
12	Lybrate	Gurugram	Healthcare communication
13	Mfine	Bengaluru	AI-powered telemedicine mobile app
14	Mindtree	Bengaluru	AI based medical Science solutions
15	Muse Diagnostics	Bengaluru	eTaal digital stethoscope and Surr app for listening to, recording, sharing and analysing body sounds
16	Neurosynaptic communication	Bengaluru	High-quality ReMeDi Remote Healthcare Delivery Solutions
17	Nirmai Health Analytix	Bengaluru	Identification of Breast Cancer
18	Oncostem	Bengaluru	Application in oncology
19	Persistent Systems Ltd	Pune	AI based solutions in Healthcare
20	PharmEasy	Mumbai	To provide medicines at affordable rate
21	Predible Health	Bengaluru	Flagship Product 'LungQ' for lung disease diagnosis
22	Qure.ai	Mumbai	AI based decision support tool for diagnostic images
23	Semantic Web India	Bengaluru	Data analysis software for Genomics Diagnostics and Research
24	Sigtuple	Bengaluru	AI platform to perform 'screening & advanced diagnosis of urine, blood, semen samples, along with retinal scans & X-rays'
25	Skyware automation	New Delhi	AI enabled scientific storage solutions for agri-warehouses
26	TCS	Mumbai	AI based medical science solutions
27	Tech Mahindra	Pune	AI based medical science solutions
28	The Gene Box	Mumbai	predictive genetic analysis to identify innate variations
29	Wipro	Bengaluru	AI based medical science solutions
30	Molecule AI	New Delhi	AI based drug discovery
31	Immunito AI	Bengaluru	AI based drug discovery
32	Prescience Insilico	Bengaluru	AI based drug discovery
Multinational			
1	AIRA Matrix	Mumbai	Drug discovery and Development
2	Autonomize	Bengaluru	Human-centred AI company that is democratising access to data to power human health outcomes
3	Bloodsure	Indore	Connecting the blood donors and making blood available
4	ChironX	Gurugram	Computer aided diagnostics
5	Cyient	Hyderabad	Healthcare Software and Life Science Solutions
6	Fitcircle	Mumbai	AI powered fitness training and diet coaching app
7	Orbuculum	Chennai	AI to screen for chronic disease through genomic data
8	Swagene	Chennai	Genetics & molecular diagnostics laboratory, Personalised for precision medicine by providing targeted genetic insights

ICPS). The Ministry of Electronics and Information Technology (MeitY), India has also operationalised a clutch of Centers of Excellence (CoEs) to assist in knowledge management and creating capabilities to capture new & emerging areas of technology.

BIRAC, either alone or in association with MeitY and the National Association of Software and Services Companies (NASSCOM), supports Indian industries in the AI area. Further MietY and NASSCOM jointly initiated a programme 'Futureskills PRIME' – a certification programme for reskilling/upskilling IT professionals in 10 emerging areas including Cloud computing and Artificial Intelligence for making India a Digital Talent Nation. The Department of Biotechnology also implemented a programme on Artificial intelligence under the Niti-Aayog's 'Responsible AI #AIforAll' guidelines to ensure the safe and responsible use of AI (R-AI).

The department is also in the process of initiating a Programme on 'Bio-manufacturing'. This initiative will have an in-built component on establishing Bio-artificial Intelligence (Bio-AI) Hubs. These hubs will support AI-powered platforms for the microbial engineering of small molecules at an industrial scale. The initiative will bring together scientific and technological advancement towards achieving a major goal of the Department's vision of BioE3 (i.e. Biotechnology for Economy, Environment and Employment) for green, clean and prosperous India.

Conclusion

Biotechnology has immense scope and applications of AI in streamlining the bio-manufacturing processing, data generation and analysis, executing detailed repetitive tasks, decision making, etc. Industries have already embraced and started delivering AI-based products. To capitalise on AI, a nurturing ecosystem, with the support of open and responsible inter-state regulatory systems is demanded. BS

Can Knowledge Graphs Revolutionise Pharma R&D?

In life sciences, the adoption of new standards such as Study Data Tabulation Model (SDTM) and Analysis Data Model (ADaM) is proving critical for efficient and effective data management and sharing. SDTM provides a new way of organising human clinical and nonclinical study data tabulations, which is required for data submission to regulatory bodies like the United States Food and Drug Administration (FDA) and Pharmaceuticals and Medical Devices Agency (PMDA) Japan, while ADaM defines dataset and metadata standards for clinical trial statistical analyses, ensuring efficient generation, replication, and review of data. The Clinical Data Interchange Standards Consortium (CDISC) 360 is another important initiative that aims to implement standards as linked metadata to support metadata-driven automation across the entire clinical research data lifecycle, making it easier for researchers to analyse and share their findings. The digital transformation of pharma industry regulatory processes, hence, has started to make data a key tool. However, with the increasing volume and complexity of data generated in drug discovery and clinical research, life sciences R&D practitioners need better ways of organising, structuring and exploiting their data, at scale.

« **Laxman Singh,** Head, ASEAN and India, Neo4j

To address the increasing volume and complexity of data generated in drug discovery and clinical research, the sector is increasingly adopting an innovative data structure approach, the knowledge graph. Graph databases can tackle complex problems in drug discovery, multiomics, and clinical research by allowing researchers to store and analyse complex interconnected data such as relationships between genes, proteins, cells, and tissues, as well as help the sector get better at meeting standards like SDTM and AdaM.

The main advantage knowledge graphs offer is their basic design. Unlike traditional SQL databases that use fixed tables with rows and columns to store data, knowledge graphs represent data as interconnected 'nodes' (or entities) linked by 'edges' (or relationships).

This network (a graph is a mathematical name for a network) of interconnections holds the key to unlocking breakthrough insights. The power of knowledge graphs is evident in their ability to represent complex data relationships. In the Panama Papers work, for example, a knowledge graph helped uncover an intricate network of opaque offshore accounts, shell companies, and individuals allowing investigators to connect the dots and uncover hidden relationships. These insights would have been difficult to detect using traditional data analysis methods.

Owing to their ability to represent intricate data, knowledge graphs have many applications beyond financial investigations. One such area is biological science, where knowledge graphs can capture the intricate interconnections and correlations among diseases, genes, environment, diet, behaviour, and other factors.

Analysis of such connections and correlations leads to a more profound understanding of the domain, enabling faster and more significant deductions. With the advent of modern native graph databases, cross-comparisons involving billions of connections can be carried out at scale, facilitating the identification of hidden patterns and connections. This ability has the potential to revolutionise biotech and medicine.

AI algorithms applied to patient data

AstraZeneca is leveraging the power of knowledge graphs to facilitate reaction and synthesis prediction, streamlining the development of novel organic molecules and even demonstrating the potential of knowledge graphs in reaction and synthesis prediction during drug discovery. The firm is working with a nine-million-node graph featuring 33 million

relationships to do this, with the graph helping identify areas in the chemical space where new reaction networks can be formulated.

According to the firm, graphs are useful in drug discovery because chemical reactions naturally form networks. When a reaction occurs, the product can lead to other reactions, resulting in a graph structure. By utilising path queries between two molecules, data scientists can understand the connections between reactions. This information can help train new lead prediction algorithms, enabling scientists to predict how different molecules will react and improve drug discovery efforts. AstraZeneca's application of graph technology is being supplemented with data visualisation tools so that scientists can recognise important molecules and reactions they want to investigate more quickly.

AstraZeneca is one of many pharma brands benefiting from knowledge graphs. GSK, for example, finds graph techniques and tools are reducing the manual effort required to validate analysis to 'nearly zero' and ensuring compliance with GDPR on informed consent so that the patient's details disappear from downstream renderings of the data.

In addition to using knowledge graphs to enhance GSK's clinical reporting workflows and address emerging regulatory standards, GSK aims to proactively perform risk-based monitoring. Here, the GSK team has developed a Google-like question-and-answer system that enables users to obtain rapid answers from their clinical trial data. GSK is also employing powerful AI algorithms originally developed for pre-clinical data sets which can be applied to patient-level clinical data. To manage the dataset effectively, the company has opted for a clinical knowledge graph that provides a patient-centric data model, which integrates all domain silos and enables everyone involved to understand the clinical data. GSK is on the way to achieving this, says the team, and while this project isn't yet a full industrial process, early results are consistently strong.

Both AstraZeneca and GSK say graph technology was the natural fit for this problem space.

One of the main benefits of knowledge graphs is that they are not restricted by particular data schema or formatting requirements. They can work with native data structures, and queries can be conducted by asking relevant questions. Moreover, these queries can be executed at lightning-fast speeds, often up to 3,000 times faster than SQL database queries, and across dense networks of knowledge. Such speed can enable rapid pinpointing of the best doctor to target for a clinical trial's success, considering not only their area of expertise but their current capacity, access to the necessary equipment, and whether they may be working with a competitor.

Clinical trials can benefit greatly from knowledge graphs in the case of rare conditions where small patient populations can make it difficult to achieve statistical significance. For example, in diabetes research, knowledge graphs can aid in phenotype mapping, where researchers want to understand the relationship between different observable phenotypes in both humans and animals. This can be particularly challenging when the clinical parameters and observations used to measure these phenotypes are not directly comparable between species.

Another use case that shows more of the benefits of knowledge graphs is Novartis, which uses knowledge graphs to connect and navigate the vast amounts of data it has accumulated over the years. By using graph technology to create a central database of biological data, the firm is starting to be able to link genes, diseases, and compounds in patterns that allow researchers to quickly identify and investigate correlations between them.

To take one example, text mining is used at the beginning of the drug development pipeline to extract relevant text data from PubMed, which is then combined with Novartis's historical and image data in a knowledge graph. The team then uses graph algorithms to identify desired triangular node patterns, allowing them to find data linked by the desired node pattern and arrange the triangles according to a metric that gauges the associated strength between each node in each triangle.

Knowledge graphs in pharma R&D

Overall, the Novartis R&D team has found that using knowledge graphs has allowed it to navigate its vast amounts of data more flexibly, helping to accelerate drug discovery and develop the next generation of medicines.

Novartis, AstraZeneca and GSK are far from being alone. As society faces increasingly demanding, complex clinical challenges, understanding the value of relationships between data with the help of advanced tools like a graph-based knowledge graph is emerging as important as the data points themselves. Without the ability to mine correlations for new insights, even the most promising innovations may lack context and researchers may struggle to make much headway. Based on these and other life sciences use cases, it's becoming ever-more evident that, with their ability to uncover insights from complex data sets, knowledge graphs are starting to play an increasingly vital role in pharma R&D. BS

Singapore Institute of Technology offers new programmes in Health Sciences and Engineering

The Singapore Institute of Technology (SIT) is launching new programmes in Health Sciences and Engineering in Academic Year 2024. The University will pioneer the Integrated Bachelor of Science in Nursing (BSN) - Master of Science in Nursing (MSN) programme in collaboration with SingHealth, the largest public healthcare group in Singapore, to nurture highly trained specialist nurses and the next generation of nurses and leaders to keep ahead of the fast-evolving

healthcare landscape. SIT is the first Autonomous University in Singapore to offer a new through-train Bachelor's to Master's pathway in a five-year programme that adopts the Term-In-Term-Out and Work-Study approaches. Developed in collaboration with SingHealth, this Integrated BSN-MSN programme offers a unique, contemporary and innovative training curriculum that closely integrates academic learning and clinical residency to nurture a new calibre of nurses who will be rigorously trained across a spectrum of clinical settings and be practice-ready through authentic learning in actual work environments.

IIT Madras & Deakin University, Australia to launch academy for cutting edge healthcare research

Indian Institute of Technology Madras (IIT-M) and Deakin University, Australia, have announced the launch of 'IIT Madras Deakin University Research Academy.' Through collaborative global research projects, joint supervision and meritorious scholarships, the academy will nurture several highly talented graduate research scholars, representing SAARC and ASEAN countries, ready to address and solve pressing global challenges. The research scholars will pioneer solutions through cutting-edge research in areas of strategic importance to Australia and India encompassing clean energy, critical technologies, sustainability, climate change, healthcare technologies and more, contributing to the socio-economic goals of both nations at a global level. Building on over a decade-long collaboration between Deakin University and IIT-M, the research academy will offer a four-year joint PhD programme with high-value scholarships, joint supervision by esteemed faculty from both institutions and access to world-class research facilities and resources.

HKBU launches life science imaging centre to promote transdisciplinary research

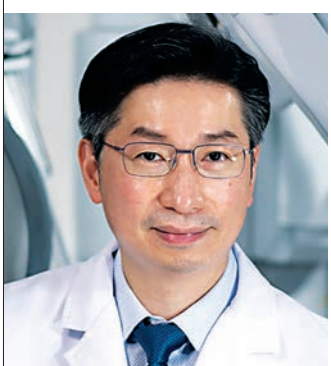
Hong Kong Baptist University (HKBU) recently held the opening ceremony of its Life Science Imaging Centre, a central research facility to support the University's transdisciplinary research endeavours to expand the horizon of knowledge creation in line with its Institutional Strategic Plan. Equipped with advanced brain imaging facilities, covering a 3T Magnetic Resonance Imaging (MRI) scanner, Electroencephalogram (EEG), functional Near-Infrared Spectroscopy (fNIRS), and Transcranial Magnetic Stimulation (TMS) system, the Centre supports academics across different disciplines to translate these cutting-edge facilities into impactful research projects that can address various emerging global issues. As set out in its 10-year Institutional Strategic Plan, HKBU is committed to nurturing future-ready students via transdisciplinary education and research.

Brii Biosciences ropes in Dr Brian Alvin Johns as Chief Scientific Officer

China-based biotech firm Brii Biosciences has announced the appointment of Dr Brian Alvin Johns, as Chief Scientific Officer, effective January 3, 2024. Dr Johns will oversee the discovery programmes at Brii Bio and set the company's future pipeline strategy and priority. Dr Johns brings a wealth of experience from the pharmaceutical industry, with a proven track record of successfully building and leading teams in the discovery and early development of novel medicines. His deep understanding of end-to-end research and development objectives has played a pivotal role in creating and delivering differentiated medicines that have transformed so many patients' lives. Prior to joining Brii Bio, Dr Johns served as the Chief Scientific Officer at HemoShear Therapeutics, Inc., where he led his team to novel targets and platforms in various disease areas. Before that, he was vice president of discovery at ViiV Healthcare and GlaxoSmithKline, where he made huge contributions to ViiV/GSK's HIV franchise with the discovery of groundbreaking medications in dolutegravir and cabotegravir.

CUHK appoints Prof. Philip Chiu as Dean of Medicine

The Council of the Chinese University of Hong Kong (CUHK) has approved the appointment of Professor Philip Chiu Wai-yan as Dean of the Faculty of Medicine, with effect from February 1, 2024. He will succeed Professor Francis Chan, who has been serving CUHK's Faculty of Medicine (CU Medicine) as Dean for over 10 years. Professor Chiu joined CU Medicine in 2005, and is currently Associate Dean (External Affairs) of CU Medicine; Professor and Chief of Division of Upper GI and Metabolic Surgery, Department of Surgery; Director of Multi-Scale Medical Robotics Center supported by InnoHK; Director of Endoscopy Centre, CUHK's Institute of Digestive Disease; Director of CUHK Chow Yuk Ho Technology Centre for Innovative Medicine. Professor Chiu has received numerous prestigious awards for his notable achievements, including the State Scientific Technology and Progress Award from the People's Republic of China; and 2nd class award in Technological Advancement, Ministry of Education of the People's Republic of China. He is an internationally renowned scholar on upper gastrointestinal surgery.



Asieris Pharma picks Sophia Cao to lead women's health business unit

Asieris Pharmaceuticals has announced its set-up of the Women's Health Business Unit for commercialisation. This strategic move is designed to enhance the company's focus on genitourinary diseases and strengthen its position in women's health. The company has appointed Sophia Cao, who brings over 20 years of expertise in pharmaceutical commercialisation, as the Senior Vice President and Head of the Women's Health Business Unit. Sophia's previous roles include serving as the head of women's health at Organon China, where she led long-term business strategy, implemented multi-channel business models, and spearheaded transformative initiatives to propel business growth. She also held the position of Chief Marketing Officer at Sanofi Pasteur China. Prior to that, she dedicated 16 years to Eli Lilly China, serving as Marketing Director, Specialty and Retail, and Commercialisation Head, Osteoporosis, Emerging Market. In these roles, she developed domestic and international commercialisation strategies for various products.

Dr Kuldeep Singh Sachdeva to assume key leadership role at Molbio Diagnostics

India-based Molbio Diagnostics has announced the appointment of Dr Kuldeep Singh Sachdeva to its leadership team. Dr Sachdeva will join as President – Chief Medical Officer and will be responsible for Strategy and Project Management in the company. Leveraging Dr Sachdeva's vast experience and expertise in public health, Molbio aims to further strengthen its mission to facilitate improved and cost-effective healthcare at the Point of Care (POC). Dr Sachdeva is a medical doctor with specialisation in respiratory diseases, tuberculosis and public health. With more than 35 years of experience in public health, he has held senior positions in the Ministry of Health, Government of India (Former head of India's National Tuberculosis Elimination Programme and National AIDS Control Programme). He has served as a nodal officer at The Global Fund for TB, HIV and Malaria and held the position of Regional Director, Southeast Asia at the International Union Against Tuberculosis and Lung Disease. Dr Sachdeva is actively involved as an expert in various committees and technical working groups and has over 95 publications in peer-reviewed journals.

Sosei Group names Toshihiro Maeda as Chief Operating Officer

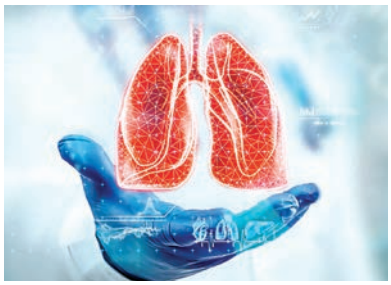
Sosei Group Corporation has announced the appointment of Toshihiro Maeda as Chief Operating Officer (COO). Maeda joins from Bristol Myers Squibb (BMS), where he led a Business Unit and was instrumental in the post-merger integration of Celgene's businesses and commercial strategies for the combined group in Japan. Maeda brings with him a breadth of global management and commercialisation experience and a strong background rooted in the pharmaceutical industry. Prior to BMS, he worked at Merck & Co in both Japan and the US where he held senior partnering and commercialisation roles in its oncology and diabetes business units. He also worked at McKinsey and Company in Japan and the UK where he gained global business experience in the healthcare industry. In this newly created role at Sosei Heptares, Maeda will lead the post-acquisition integration of Idorsia Pharmaceuticals Japan, and global technical operations, including manufacturing, supply chain and quality assurance, for the enlarged business in Japan and the Asia-Pacific region.

Gavi appoints Senator Dr Sania Nishtar as Chief Executive Officer

Gavi, the Vaccine Alliance, has announced the appointment of Dr Sania Nishtar as its new Chief Executive Officer. Dr Sania, currently serving as a Senator in her home country of Pakistan, will assume the role on March 18, 2024. A trained medical doctor, Dr Sania has built an outstanding career over 30 years as a global public health leader. In the national government, she served between 2018 and 2022 as Special Assistant to the Prime Minister on Social Protection and Poverty Alleviation, a role with the status of a Federal Minister. In 2013, during Pakistan's Caretaker Government, she served as a Federal Minister with responsibility for re-establishing the country's Ministry of Health among other roles, winning acclaim for transparency and accountability during her time in office. During her career, Dr Sania has fulfilled several leadership positions in civil society and international organisations. She founded the non-profit NGO think tank Heartfile, which campaigns for health reform in Pakistan. She was the inaugural Chair of the UN Secretary-General's Independent Accountability Panel (IAP) for women's and children's health and Co-Chair of the WHO Independent High-level Commission on Noncommunicable Diseases, among many other roles.

Australia develops tool to identify dust lung disease risk

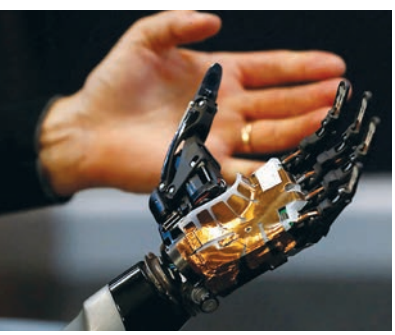
A new dust testing methodology developed by Australia-based University of Queensland researchers offers workers better protection from diseases such as black lung and silicosis. The escalating prevalence of dust lung diseases, especially among young Australians, have made the scientific community realise a new approach was needed. Exposure monitoring for dust and silica is currently based on the weight of particles but this overlooks many details that the scientists



are beginning to understand have significant health effects. The methodology thus developed takes an in-depth look at particle characteristics such as size, shape, and mineral makeup, along with their potential to group together. The scientists have used a Mineral Liberation Analyser which is a specialised type of scanning electron microscope. It can measure the size and shape of individual particles and create a mineral map across them. The new methodology could contribute to research into the connection between the characteristics of particulates and the development of respirable dust diseases.

Korea designs wrist rotation module to enhance usability and efficiency in prosthetic limbs

Robotic assistive devices play a crucial role in supporting the daily activities of individuals with congenital disabilities or those who have experienced unfortunate accidents. Despite their benefits, achieving truly natural movements remains a significant challenge for these robotic assistive devices. Professor Keehoon Kim from the Department of Mechanical Engineering and the School of Convergence Science and Technology and Dr Seoyoung Choi, a research fellow from the Department of Mechanical Engineering at Pohang University of Science and Technology (POSTECH), South Korea, have made a noteworthy contribution to addressing this challenge. They have successfully integrated a wrist rotation module into a robotic prosthesis, allowing for more natural movements without straining the user's body. The innovative prosthetic hand is tailored for a patient who lost their thumb and index finger in a car accident. This advanced prosthesis operates by interpreting signals to the muscles through sensors and determining the motion intention. Unlike conventional prosthetics, it incorporates a wrist rotation module, enabling patients to enjoy unrestricted movement of their wrists.



Chinese medicine drug for myofibrillar myopathy receives orphan drug designation by US FDA

The Centre for Chinese Herbal Medicine Drug Development of Hong Kong Baptist University (HKBU) has developed a new drug using effective components of a Chinese herbal medicine, Chaenomelis Fructus, for the treatment of the rare disease, myofibrillar myopathy. The drug has obtained the orphan drug designation from the US Food and Drug Administration (FDA), and is the first botanical drug in Hong Kong to receive this qualification. Success in obtaining orphan drug (a drug used for treating rare disease) designation will accelerate the approval process of the new drug, including speeding up of the review process, waiver of the marketing authorisation fee, and seven years of market exclusivity for the approved product. The research team plans to submit an Investigational New Drug application to FDA in two years to conduct clinical trials. Myofibrillar myopathy, primarily caused by genetic mutations, including the BAG3 gene, is a rare hereditary neuromuscular disorder with symptoms resembling muscular dystrophy.

Japan demonstrates influence of polyamines on functional profiles of monoclonal antibodies

Consistent manufacturing and production of monoclonal antibodies (mAbs) is critical, and their functional profiles depend on cell culture conditions. Researchers at Tokyo University of Science, Japan have investigated the role of intracellular polyamines on N-glycan profiles of mAbs. They found that polyamine depletion led to an ER stress response in CHO cells, leading to an increase in galactosylation of mAbs. Supplementation of spermidine recovered N-glycan profiles. These findings will contribute to the stable production of antibody-based drugs. Monoclonal antibodies are laboratory-designed proteins that mimic the immune system's antibodies. To date, many therapeutic mAbs belonging to the immunoglobulin G (IgG) class of antibodies, have been approved for the treatment of cancer and autoimmune diseases. Cell lines such as the Chinese hamster ovary (CHO) cells are generally used to produce mAbs. Notably, the production and manufacture of mAbs are regulated by critical quality attributes (CQAs) to ensure their safety and efficacy in treatment.

Indian researchers link ageing of cells with ovarian cancer spread

Researchers at the Indian Institute of Science (IISc) in Bengaluru have found that ovarian cancer cells can spread more easily in tissues that are senescent or aged because these tissues secrete a unique extracellular matrix that attracts the spreading cancer. During the study, the researchers observed that the cancer cells chose to settle down more on the aged tissues; moreover, they settled closer to the aged normal cells in the cell sheets. In particular, the researchers observed that it was proteins secreted by aged cells that settle down as the extracellular matrix (ECM), the base on which the cells adhere and grow, that were called the cancer cells. The team carried out experiments on human cell lines to replicate the predictions of the computer simulations. They noticed that the cancer cells stuck strongly to the extracellular matrix around the aged cells, and eventually cleared the aged cells away. They also noticed that the aged ECM had higher levels of proteins such as fibronectin, laminin and hyaluronan compared to the young cells' ECM, which allowed the cancer cells to bind more strongly. Researchers hope that future studies will build a strong case for using senolytics, drugs that kill senescent cells, as a combination therapy with chemotherapeutics to tackle cancer progression.

Singapore discovers potential nasal COVID-19 vaccine candidate for longer protection

A team of scientists, led by Duke-NUS Medical School in Singapore, has discovered a potential intranasal vaccine candidate that provides improved, longer-lasting immunity against SARS-CoV-2 viruses compared to when given as an injection. By triggering an immune response directly at the point of entry, the intranasal vaccine candidate enhanced long-term immune memory of the virus, which could translate to a reduced need for booster shots. There is growing evidence that intranasal vaccines provide greater protection at mucosal surfaces, making this a vaccination route that could reduce break-through infections and subsequent transmission of the virus. As per the new research, nasal administration of the vaccine candidate boosted mucosal antibody response. Additionally, it enhanced longer-lasting mucosal and systemic immune protection through preferential induction of airway-resident T cells and central memory T cells. A patent has been filed on the discovery which covers the invention of the vaccine composition formulated for mucosal delivery, paving the way for an industry partnership to potentially develop mucosal vaccines against COVID-19 and other pathogens that also target mucosal surfaces.

Thermo Fisher unveils its largest and most ethnically diverse array for pharmacogenomic research

American supplier Thermo Fisher Scientific has launched the new Axiom PangenomiX Array, its largest and most ethnically diverse array to date, offering optimal genetic coverage for population scale disease studies and pharmacogenomic research. The PangenomiX Array is currently the only research solution that combines four assays in one test: SNP genotyping, whole genome copy number variant detection, fixed copy number discovery, blood and HLA typing. The high-throughput array is designed to advance disease risk and detection research, population-scale disease research programmes, ancestry and wellness testing, drug efficacy testing, and drug development research. Inclusive of clinically relevant pharmacogenomic markers and pathogenic variants, the PangenomiX Array offers researchers enhanced whole-genome imputation and a high level of diversity for testing different ethnicities to keep pace with the growing understanding of the genome. The array has already been used to analyse nearly half a million ethnically diverse samples at a predominant biobank in the US to advance more inclusive research studies related to the prevention, diagnosis and treatment of disease.

Qiagen expands biz in Middle East with new regional headquarters and major projects

Qiagen has announced a significant expansion of its business in the Middle East region, which includes three major developments- In early 2024, the company will open its regional headquarters in Riyadh, Saudi Arabia, in order to further strengthen its commercial footprint in the region. It has signed a Memorandum of Understanding (MoU) with the Ministry of Health of Saudi Arabia, addressing various public health and infection control initiatives. The MoU includes establishment of a localised data centre by Qiagen Digital Insights (QDI) to support advanced bioinformatics within the country. Qiagen has been awarded a tender through its Commercial Partner Taiba Medserv LLC from the Ministry of Health of the Sultanate of Oman to provide the country with QuantiFERON-TB Gold Plus tests for its nationwide tuberculosis (TB) screening programme. As a country with a low incidence of TB and a large workforce from high-incidence countries, Oman is expanding its TB testing policy for residency applicants by adding systematic screening for latent TB infection using Qiagen's simple standard-setting QuantiFERON-TB Gold Plus blood test. The Ministry of Health plans to test up to 800,000 people over two years and offer direct medical treatment to those found carrying TB bacteria without symptoms.

Shimadzu automates coating processes of medical systems components

An opening ceremony was recently held for a new building at Shimane Shimadzu Corporation, a manufacturing subsidiary of Japan-based Shimadzu Corporation located in Shimane Prefecture. The new building features various manufacturing digital transformation (DX) measures, including automated coating processes for medical systems components. Coating process automation will increase coating production capacity by 50 per cent at Shimane Shimadzu. Shimane Shimadzu is a manufacturing subsidiary that manufactures X-ray systems developed by the Medical Systems Division of Shimadzu Corporation. With the new building, Shimane Shimadzu will now be able to coat a large number of parts for general radiography systems, fluoroscopy systems, mobile X-ray systems, and other X-ray products on a single production line.

Qure.ai's AI-driven chest X-ray solution gets FDA clearance for enhanced lung nodule detection

Qure.ai, a health tech company that uses deep learning and Artificial Intelligence (AI) tools to make healthcare more accessible, has announced its 13th FDA clearance for its AI-enabled solutions. Qure's chest X-ray based qXR-LN uses AI to identify and localise lung nodules, marking another significant milestone for the organisation, strengthening its standing as a pioneer in the realm of AI-powered advancements for plain film radiography and medical imaging. This also marks the 6th FDA clearance for Qure's

chest X-ray based solutions. Notably, this is the only FDA-cleared solution for detecting and localising lung nodules utilising computer vision to have Radiologists, Pulmonologists and ER physicians as intended users.

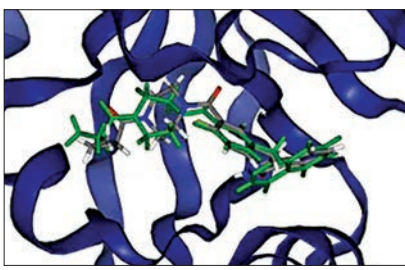
The introduction of AI solutions, such as qXR-LN, presents a remarkable opportunity to cast a wider net to identify potentially malignant pulmonary nodules, thereby boosting the fight against lung cancer. qXR for Lung Nodule (qXR – LN) is a cutting-edge computer-aided detection software designed to identify and highlight regions indicative of suspected pulmonary nodules ranging from 6 to 30 mm in size. Tailored for use in the incidental adult population, this innovative device is a game-changer in diagnostic technology.

Agilent announces New ProteoAnalyzer System

Agilent Technologies Inc. that generated revenue of $6.83 billion in fiscal 2023 and employs approximately 18,000 people worldwide released a new automated parallel capillary electrophoresis system for protein analysis – the Agilent ProteoAnalyzer system – at the 23rd Annual PepTalk Conference, in San Diego. This new platform simplifies and improves the efficiency of analysing complex protein mixtures, a process central to analytical workflows across the pharma, biotech, food analysis, and academia sectors. Capillary electrophoresis (CE) has established itself as an indispensable tool for protein separation, as it offers rapid, high-resolution analysis with minimal sample consumption. The expanding interest of biopharma in monoclonal antibodies and other protein targets of potential therapeutic interest is driving the expected growth in demand for CE solutions. The Agilent ProteoAnalyzer system brings added efficiency, versatility, and reliability, particularly in protein QC workflows. Automating the separation, data processing, and simplifying sample preparation steps streamlines the analysis workflow, which improves efficiency and reduces training and related labour costs. The system also can analyse a wide range of sample types, from crude lysates to purified fractions.

Merck launches first ever AI Solution to integrate drug discovery & synthesis

Merck, a leading science and technology company, launched its AIDDISON drug discovery software, the first software-as-a-service platform that bridges the gap between virtual molecule design and real-world manufacturability through Synthia retrosynthesis software application programming interface (API) integration. It combines generative AI, machine learning and computer-aided drug-design to speed up drug development.



Trained on more than two decades of experimentally validated datasets from pharmaceutical R&D, AIDDISON software identifies compounds from over 60 billion possibilities that have key properties of a successful drug, such as non-toxicity, solubility, and stability in the body. The platform then proposes ways to best synthesize these drugs. Artificial Intelligence (AI) and machine learning models like AIDDISON software can extract hidden insights from huge datasets, thus increasing the success rate of delivering new therapies to patients.

Improving Health Outcomes with C4H

The foundation of public health is strategic communication, which is more crucial than ever in the digital era. Over 1.5 billion people gained access to the internet in the last five years, globally, bringing total users to more than 5.1 billion. Total social media users worldwide topped 4.8 billion in 2023, an increase of over 10 per cent from 2022.

Strategic communication demands knowledge, abilities, and resources to empower healthcare professionals and to provide the best care possible, encourage governments to enact appropriate policies, and persuade individuals to take actions that safeguard and enhance their own health as well as the health of their families and communities. There remains a persistent disparity between the actions people should take to protect their health and the actions they actually take, even with the importance and investments made in various public health communication domains such as health promotion, health literacy, strategic communications, risk communications, and community engagement.

Closing this gap requires a combination of data and analysis, behavioural science and insights, storytelling and other communication-related skills and approaches, and strategic partnerships. This is the basis of Communication for Health (C4H).

In the Western Pacific Region, the World Health Organisation (WHO) has developed C4H, a set of principles and practices to help ensure communication interventions are designed to inform and change attitudes and behaviours in ways that support the achievement of defined public health outcomes.

Since 2019, the WHO, in the Western Pacific has begun using the C4H approach in its communication efforts to improve health outcomes and support countries to do the same. C4H is based on six principles called IMPACT: Informed by data and theory; Measurable; Planned; Audience- and people centred; Collaborative; and Targeted. Application of the C4H approach requires a series of steps to first understand, then plan, develop, test and implement a communication programme or campaign, before evaluating and identifying lessons.

This approach recognises that health communication can play a vital role alongside other public health interventions to improve outcomes and extend lives. The approach builds on a range of disciplines and strategic communications approaches that have been used for decades to inform, change attitudes and behaviours, and help improve health at the individual, community and societal levels.

The WHO's goal is to work with countries and use C4H to contribute to improved health outcomes in the region, to help achieve the shared vision of making the region the world's healthiest and safest.

The C4H approach has already been used with success in several countries across the region. China used it to nudge people to reduce their salt intake, in a series of initiatives from 2018 to 2022. Similarly, Malaysia adopted it to ensure communication was as effective as possible to support COVID-19 prevention. While Papua New Guinea used the C4H approach to address high maternal and newborn mortality. The goal now is to deepen and extend its reach to maximise public health impact.

Hence WHO is building technical capacity and experience in C4H at both regional and country levels, in collaboration with academic experts and other partners. The WHO is committed to using its capacity and experience to support countries in this area. To that end, WHO is investing in C4H technical staff in a growing number of country offices in the region.

Leaders at the WHO Regional Committee for the Western Pacific's 74th session, held in October 2023, endorsed a framework which embraces behavioural sciences within C4H.

The approach brings together varied theories, tools and techniques, including from social and behavioural sciences, storytelling and evidence-based planning, monitoring and learning – to develop communication intended to support improving health-related behaviours.

It underpins the regional C4H resolution, which endorses the Regional Action Framework on C4H: A vision for using communication to improve public health in the Western Pacific Region. This framework guides countries on applying C4H to improve knowledge, change attitudes and shift behaviours for improved health outcomes. BS

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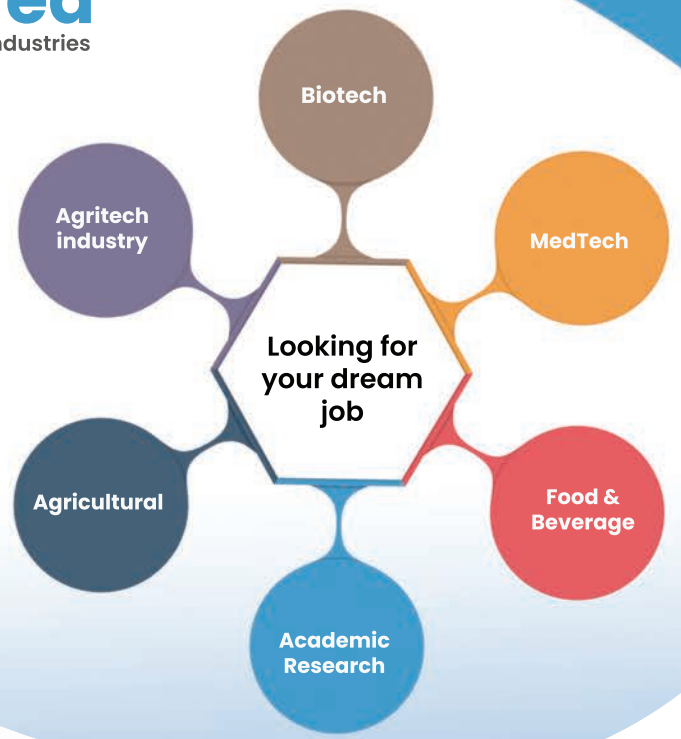

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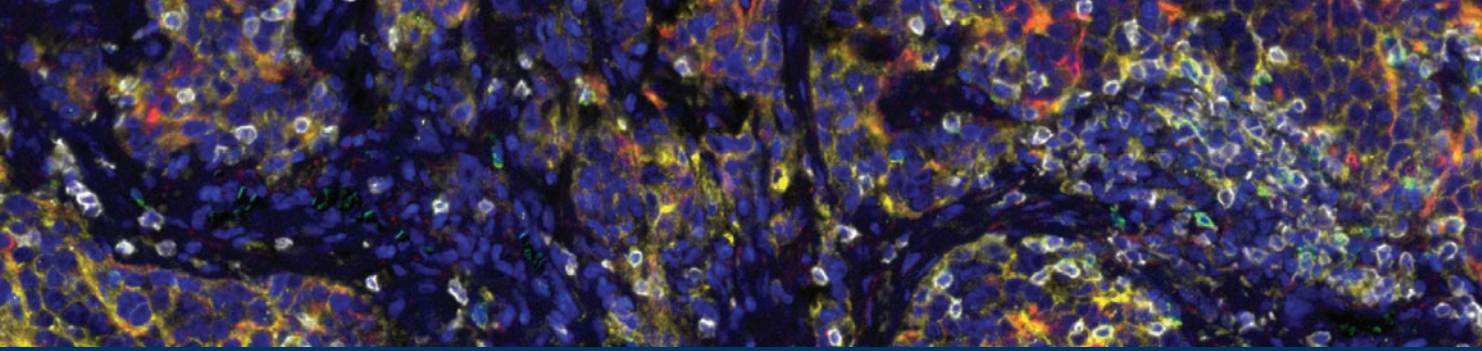

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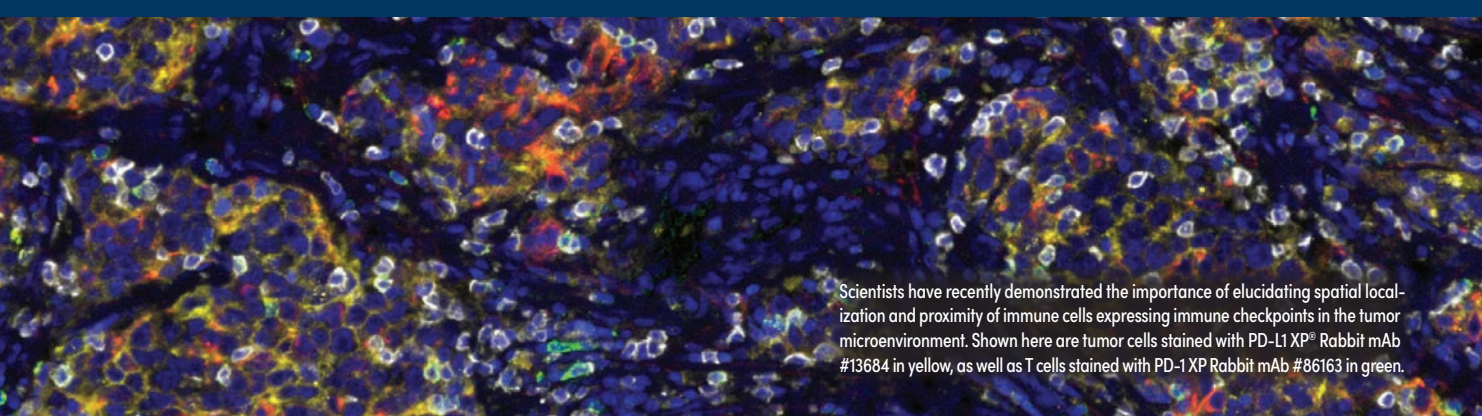

Scientists have recently demonstrated the importance of elucidating spatial localization and proximity of immune cells expressing immune checkpoints in the tumor microenvironment. Shown here are tumor cells stained with PD-L1 XP® Rabbit mAb #13684 in yellow, as well as T cells stained with PD-1 XP Rabbit mAb #86163 in green.

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