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the business of | Bio & Health Sciences
ASIA EDITION

Volume 19 | Issue 4 | April 2024

Addressing Accessibility And Affordability of **Cell & Gene Therapies**

BioSpectrum is an MM ACTIV publication; MCI (P) 028/06/2023

"Because of its specificity and selectivity, ADCs have the potential to reduce adverse side effects & improve patient survival"
- Koichi Morino, Managing Director, Daiichi Sankyo, Singapore - 34

Can Test, Treat, Track Beat Malaria? - 31

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(A Section 8, not-for-profit company (PSU), under the aegis of Department of Biotechnology, Government of India)

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(up to 5:30 pm)

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Thank you BioSpectrum Asia for including Enterprise Singapore in your feature on Singapore deep tech ecosystem, in the March edition.

- Lottie, Singapore

With women comprising 70 per cent of the global healthcare workforce, it is crucial for the pharma industry to champion pay equity. Thank you for the great article on pay parity.

- Nancy, USA

Thank you BioSpectrum Asia for profiling me for your cover feature of the Women's Day issue in March.

- Dr Diana Siew, New Zealand

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Letter from Publisher

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

Dear Readers,

Cell and gene therapies (CGTs) are one of the hottest sectors in the pharmaceutical industry. Quite a few companies in the field are making remarkable advancements toward potentially curative treatments for challenging diseases using groundbreaking science. Globally, 30 gene therapies have been approved (including genetically modified cell therapies). The CGT sector has expanded tremendously, with the number of drugs in development growing nearly six-fold from 511 development-stage candidates in 2013 to just over 3,000 in 2023. By 2025, the US FDA aims to review and approve 10-20 gene and cell therapies annually.

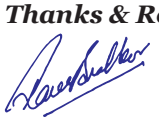
The Asia Pacific region has been leading the field of CGT, with several countries investing significantly in research and development. While China has emerged as an important market for CGTs, particularly CAR-T therapies, surpassing the USA in the number of clinical trials conducted, Singapore is emerging as a top destination for CGT manufacturing, with numerous companies unveiling plans to set up facilities in the country. Our correspondent spoke to industry leaders from across the globe and says in an article that though CGTs offer hope for life-threatening debilitating conditions, access remains out of reach for the patients who need it the most as costs are too high for most of the patient population.

On the other hand, malaria, the oldest disease that has plagued mankind for centuries, continues to wreak havoc globally. The Asia Pacific region also continues to be affected by this enduring fever. India accounted for 66 per cent of malaria cases in the WHO South-East Asia Region in 2022, with nine countries in the region contributing to about 2 per cent of the global burden. Over the past 10 years, only three countries in the region successfully earned their malaria-free status: Maldives in 2015, Sri Lanka in 2016, and China in 2021. China's eradication of malaria in particular was a momentous feat, making it a potential blueprint for other countries in the region. We have covered an article on how China reached this milestone in its fight against malaria in seven decades.

Biotechnology has emerged as one of the key technology enablers of the 21st century, disrupting traditional agri-food systems, diagnostics and therapeutics industries as well. As per the recently published India Deep Science Tech Report by Ankur Capital, more than $900 million were invested into breakthrough deep science biotechnology startups between 2013 and 2023 in India. We are featuring an expert's article that provides a closer look at the investments made in biotechnology in the last decade in India where several first-generation startups are at the stage of scaling up their technology and the next few years will define their success as well as the success of the industry as a whole.

I am sure you will find this edition a great read.

Thanks & Regards,



Ravindra Boratkar
Publisher & Managing Editor

COVER 19

Addressing Accessibility and Affordability of CELL & GENE THERAPIES

Cell and gene therapies (CGT) are one of the hottest sectors in the pharmaceutical industry. Quite a few companies in the field are making remarkable advancements toward potentially curative treatments for challenging diseases using groundbreaking science. With lower R&D development costs than in advanced markets, China is becoming an attractive market for the development of CGT, and therefore may emerge as a strong competitor of overseas-made CGT, notes a GlobalData report. Bayer AG, recently announced the global expansion of its life science incubator network, Bayer Co. Lab, to Shanghai, China and Kobe, Japan. The new site in China will focus on oncology and CGT innovations. While India lags behind China in the production of cell and gene therapies, a wave of new biotech startups is emerging to address this challenge. Immuneel Therapeutics and ImmunoACT are currently developing CAR-T cell therapies. The latter's NexCAR19 therapy received approval from India's Central Drug Standards Control Organisation (CDSCO) for treating relapsed or refractory B-cell lymphomas and leukaemia. Despite a steady stream of regulatory approvals and promising growth prospects, the high manufacturing costs associated with these therapies often render them inaccessible to the majority of patients. To address this issue, companies are actively striving to streamline and optimise the highly intricate and labour-intensive process of cell and gene therapy manufacturing. Let's explore further.

Malaria Burden

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WARY OF THE DRAGON

Dr Milind Kokje
Chief Editor
milind.kokje@mmactiv.com

Biotech appears to be a new turf of rivalry between the US and China. Politics has bearings on every aspect of human life. Technology is no exception as it is being witnessed in the recent developments in the US. Alarmed over the US's entire dependence on China for its biotech supply chain, the former's failure to compete with China in biotechnology and the possession of Americans' genomic data with the Chinese biotech companies, the US lawmakers have initiated legislative steps over the risk to national security and commercial interests caused by Chinese biotech companies.

In March, the US Senate's Homeland Security committee approved forwarding a Bill restricting business with Chinese biotech companies citing national security concerns. Before that, a similar Bill was moved in the US Congress in January seeking to ban federally funded medical providers from using the services of any Chinese biotech company, particularly BGI Group, MGI and WuXi AppTec from accessing genetic information of American people. The Bill was moved by two leading members of the Congressional Select Committee on the Chinese Communist Party (CCP).

Members from both sides, Republicans and Democrats, are together on this particular issue. The legislative approach would include vetting inbound investments, barring federal contracts with designated Chinese firms, curbing outbound investments in China's biotech supply chain and applying export controls. Thus, the passing of the Bills would effectively ban Chinese companies from the US.

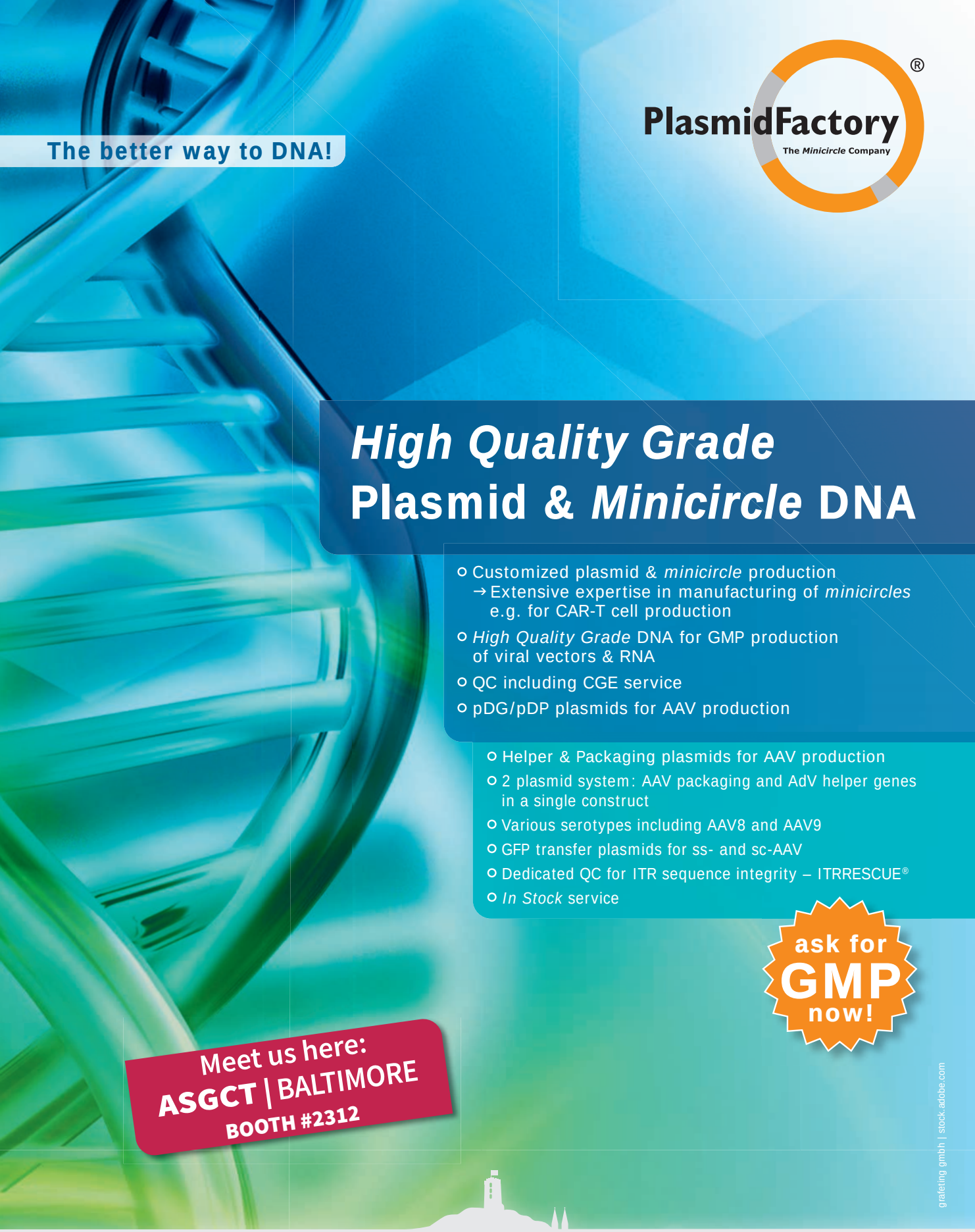
Before that, in February, members of the same committee wrote a letter demanding sanctions specifically against WuXi AppTec, a multinational biotech and medical devices company headquartered in Shanghai. The company has ties to the People's Liberation Army (PLA) and hence represents a threat to national security, the members alleged.

Even a report by the Centre for a New American Security in August 2022 called "Regenerate: Biotechnology and US Industrial Policy", mentioned that the US is at a relative disadvantage in biotechnology compared to China and other rivals, "ceding American leadership over one of the most powerful and transformative fields of technology in recent memory."

But, a major concern of the US lawmakers is that some of the companies are involved in genome sequencing. They feel that handing over the genetic data to these companies constitutes a national security risk due to CCP's legal ability to view private data held by any companies based in its territory. A member of the committee on CCP expressed fears that such data could be used to develop bioweapons against Americans. WuXi AppTec has denied the allegations and has said that it has a strong track record of upholding the highest intellectual property, data and privacy protection standards and maintaining the trust of customers. Even BGI has denied the allegations.

The US and China reportedly share strong biotech ties with China's role in the entire biotech supply chain, from research to sales of products. Understanding biotechnology's strength in revolutionising the life sciences, is now the focus of the conflict. Going by the nature of the current relationship between the US and Chinese biotech companies, experts feel that the legislative actions could disrupt key relationships and supply chains of the US life sciences companies and would ultimately hurt the US. This could damage the drug development supply chain. The policymakers would get too obsessed with the technology's military applications at the cost of hindering efforts to cure disease, opined Abigail Coplin, an assistant professor at Vassar College specialising in China's biotech industry.

Though the US lawmakers' concern over the Chinese biotech companies having the genetic data of Americans is right on the issue of national security and needs some protective actions, they also need to remember what American writer and researcher Evgeny Morozov said about technology. He said, "The global triumph of American technology has been predicted on the implicit separation between the business interest of Silicon Valley and the political interests of Washington." BS



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Taiwan amends regulatory requirements for registration of medical masks

Taiwan Food and Drug Administration (TFDA) has amended regulatory requirements for the registration of medical masks. The "Regulations Governing the Classification of Medical Devices" was amended to change the content in the identification in the classification of I.4040 "Medical apparel" following the amendment of National Standard CNS 14774 (T5017)- Medical face mask and CNS 14755(Z2125)- Disposable dust respirators. With the amendment of the above-mentioned National Standards, "D2 class medical mask" was replaced with "TN95 medical mask". Moreover, for medical masks labelled/claimed to have the equivalent or above effect of TN95 or N95, the sub-micron particulate filtration and exhalation/inhalation resistance of airflow of the mask should be in accordance with TN95 (or higher) performance requirements from disposable dust respirators of the National Standard CNS 14755 (Z2125). Some additives of medical masks, such as some azo colourants, formaldehyde and migratable fluorescent substances, are reported to be hazardous to human health. To minimise the impact of such additives to human health, TFDA requires applicants who apply for the registration of coloured or dyed medical masks to provide relevant evidence to prove that the products to be registered meet the quality requirements for coloured or dyed medical masks of CNS 14774.

Australia releases final report on Aged Care Taskforce

The Australian government has released the Aged Care Taskforce's Final Report, an important next step towards delivering a sustainable aged care system that provides high quality care to all Australians now and into the future. After considering the evidence and meeting several times throughout 2023, the Taskforce has not recommended a new tax or levy to fund aged care. The government has confirmed that it will not impose any increased taxes or a new levy to fund aged care costs or change to the means testing treatment of the family home for aged care. The Taskforce Report delivers 23 recommendations to improve the sustainability of aged care, such as that older people can make a fair co-contribution to the cost of their aged care based on their means; to ensure a strong safety net for low means participants to meet aged care costs. The government will be carefully considering the recommendations of the report.

Bangladesh to develop first national medical education strategy

Bangladesh has set out an ambitious journey path to transform into a Smart-Bangladesh High-Income Country by 2041, as delineated in its Perspective Plan (2021-2041). To achieve this goal, the Ministry of Health and Family Welfare (MoHFW) is working to improve the quality and accessibility of health services and medical education systems, with a focus on developing a competent and motivated health workforce. In partnership with the World Health Organization (WHO), the MoHFW has launched the creation of an extensive national medical education strategy, poised to steer the evolution of medical education within the nation. WHO has been providing technical and financial support to the MoHFW throughout this initiative, by conducting health workforce-related studies, facilitating evidence-based policy dialogue, and mobilising regional and global expertise. WHO Bangladesh has also been instrumental in establishing a technical working group, led by the Directorate General of Medical Education (DGME), which comprises representatives from various relevant organisations and stakeholders. This group will oversee the finalisation and implementation of the strategy.

Kimer Med signs contract worth NZD $1.3M to pioneer antiviral drug advances

Kimer Med, a New Zealand (NZ)-based biotech startup, has signed a contract valued at up to $750,000 (NZD$1.3 million) with Battelle, the world's largest independent, nonprofit research and development organisation. The 12-month contract is funded by the United States government through the Defense Threat Reduction Agency (DTRA), and will fall into Battelle's Accelerated Therapeutics for Combating Acute Viral Epidemics programme. The contract is focused on the discovery and development of new antiviral drug candidates for the treatment of alphaviruses. Spread mostly by infected ticks and mosquitoes, alphaviruses cause significant human and animal disease. Infections that result in encephalitis - inflammation and swelling of the brain - are often fatal and can cause ongoing neurological problems. There is currently no effective antiviral treatment for alphavirus infection. Since the company's launch in 2020, Kimer Med has developed antivirals that have shown in vitro efficacy against 11 different viruses, including the priority viruses Dengue (all four serotypes) and Zika.

Eris Lifesciences acquires Biocon Biologics' India branded formulation biz for Rs 1,242 Cr

Mumbai-based Eris Lifesciences has announced the acquisition of Biocon Biologics' India branded formulation business for a consideration of Rs 1,242 crore thereby jumpstarting its entry into the Rs 30,000+ crore injectables market in India and becoming a leading player in the insulins segment. The acquisition brings two major insulin brands – Basalog and Insugen – into the Eris fold. These are the largest Indian brands in their respective segments with market shares of over 10 per cent. With this acquisition, Eris's Diabetes care franchise will soon reach Rs 1,000 crore in revenue and become the 5th largest diabetes portfolio in India. This acquisition will also mark Eris' entry into Oncology and Critical Care. Eris has signed a 10-year supply agreement with Biocon Biologics as part of this deal. Under this agreement, the Biocon product range will continue to be manufactured and supplied to Eris for commercialisation in India. This acquisition also provides immediate synergies with the recently acquired Swiss Parenterals business.

EurekaBio raises $40M to advance lentiviral vector production system

Shenzhen Eureka Biotechnology Co. (EurekaBio), a leading upstream supplier in the cell and gene therapy field, has announced the completion of its Series B+ financing, exceeding $40 million. The financing was led by Yuexiu Industrial Fund, with participation from numerous well-known Chinese funds, as well as follow-on investments from US funds. The funds will support the commercial implementation of large-scale production

technology for Lentiviral Vectors (LVV), advance research and development around large-scale production technology for Adeno-Associated Viral Vectors (AAV), promote comprehensive solutions for cell therapy manufacturing, accelerate global market expansion efforts, and bolster the overall growth of the company. EurekaBio's core innovation lies in the EuLV Lentiviral Vector Production System, a cutting-edge technology that transforms the large-scale production of lentiviral vectors using stable cell lines and a serum-free suspension system.

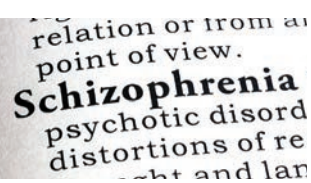
Novartis invests $256M to expand biopharma manufacturing site in Singapore

Novartis recently broke ground for the expansion of its biopharmaceutical manufacturing plant in Singapore. The $256 million investment will facilitate Novartis in deploying digital & automation solutions to enhance manufacturing productivity, improve operational efficiency, and upskill the workforce. The expanded site will focus on manufacturing therapeutic antibody drugs to deliver breakthrough treatments to patients globally. The new facility

will be operational by early 2026. This endeavour will enhance the skills of Novartis' current workforce & is poised to create 100 high skilled new job openings, fostering the expansion of the local life science sector. Novartis acknowledges the significance of investing in talent, & the expanded facility will not only bring in new team members but also provide training for existing employees to thrive in a highly digitalised & automated setting. Novartis has had a strong partnership with Singapore since 1986. The company has invested more than $1 billion as part of its commitment to Singapore & to uplift the pharmaceutical manufacturing capabilities of the nation.

Sosei Heptares inks €750M deal with Boehringer Ingelheim for schizophrenia treatment

German firm Boehringer Ingelheim and Japan-based Sosei Group Corporation have entered a global collaboration and exclusive option-to-licence agreement. At the centre is a joint mission to develop and commercialise Sosei Heptares' portfolio of first-in-class GPR52 agonists, a novel G protein-coupled receptor (GPCR) target, with an intent to improve patient outcomes by simultaneously addressing positive, negative, and cognitive symptoms of schizophrenia.



Sosei Heptares will receive an upfront payment of EUR (€) 25 million from Boehringer Ingelheim upon signing and is eligible for an option exercise payment of EUR 60 million and further development, regulatory and commercialisation milestone payments totaling up to EUR 670 million plus customary tiered royalties for a clinical-stage asset on future Boehringer Ingelheim product sales. Under the terms of the agreement, Boehringer Ingelheim has the exclusive option to licence Sosei Heptares' portfolio of GPR52 agonists following the completion of Sosei Heptares' ongoing Phase 1 and subsequent Phase 1b trial and further Phase 2 enabling activities with HTL0048149, a first-in-class GPR52 agonist.

Australia commits $3M to assist in elimination of dengue fever in Laos

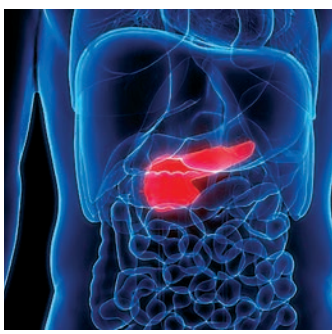
Monash University's World Mosquito Programme (WMP) has received significant funding from the Australian Department of Foreign Affairs and Trade to fund research to manage the spread of mosquito-borne diseases in Laos. The second phase of the project to combat mosquito-borne diseases in Laos, was announced by Prime Minister Albanese and Sonexay Siphandone, Prime Minister of the Lao People's Democratic Republic (PDR) at the ASEAN Special Summit. The signed agreement will strengthen ties between Australia and Laos to a Comprehensive Partnership. The next phase of the World Mosquito Programme's Wolbachia method rollout in Laos will be implemented in partnership between the Lao PDR Ministry of Health and Save the Children to target the country's dengue hotspots. The funding support of $3 million from Australian Department of Foreign Affairs and Trade will enable the project to help protect more communities from mosquito-borne diseases in the capital, Vientiane. It follows a successful deployment of Wolbachia in the Chanthabouly & Xaysettha districts, which helped protect 32 villages with a combined population of 86,000 people. Releases concluded in August 2023, & public acceptance of the mosquito releases was 99 per cent.

Southern RNA joins forces with DKSH to advance biotech collaborations with India

Queensland-based Southern RNA, a leading Contract Development and Manufacturing Organisation (CDMO) specialising in nucleic acid manufacturing, including DNA and mRNA, has announced a strategic partnership with DKSH, a leading market expansion services provider, in India. This partnership marks a significant milestone in Southern RNA's expansion strategies and highlights the burgeoning relationship between the Australian and Indian biotechnology sectors. The partnership, supported by Trade Investment Queensland (TIQ), the dedicated business agency of the Government of Queensland, perfectly aligns with the state's initiatives to boost local exporters and attract investment. Through this partnership both Southern RNA and DKSH will foster innovation and growth in the life sciences industry by leveraging DKSH's extensive network and expertise in the Asia Pacific region to introduce Southern RNA's cutting-edge products and services to India's dynamic pharmaceutical landscape.

BioGate Precision Medicine Corp develops pancreatic cancer therapy

Taiwan-based BioGate Precision Medicine Corp., a member of Powerchip Group, has unveiled an innovative breakthrough in pancreatic cancer drug development. Dr Frank Huang, Chairman and CEO of BioGate, revealed that BioGate through in-house R&D has created a targeted therapy biologic, BGX. This was achieved by developing multi-platform technology combining biochemistry, immunology, and molecular biology. Studies of animals implanted with human pancreatic cancer cells confirm BGX's efficacy in inhibiting tumour growth and antiproliferation in metastasis, while extending survival rates. This achievement represents a major global milestone in pancreatic cancer treatment. BioGate also announced its plan to apply for Taiwan FDA Phase I clinical trials and to seek approval from the US FDA, offering hope and improved care for pancreatic cancer patients in Taiwan region as well as worldwide. Pancreatic cancer affects 500,000 people globally each year, with over 3,000 cases in Taiwan annually.



SK bioscience expands manufacturing facility in Korea for pneumococcal vaccine production

SK bioscience, South Korea-based vaccine and biotech company, has broken ground on a major expansion of its vaccine manufacturing plant, L HOUSE, located in Andong, Gyeongsangbuk-do, South Korea. This expansion aims to strengthen its manufacturing capabilities for global supply by adding two floors to the existing vaccine manufacturing department in L HOUSE, which will create approximately 4,200 sq mt of new space. The new, expanded space will serve as a production base for the next-generation pneumococcal conjugate vaccine candidate 'GBP410' (also known as SP0202), jointly developed by SK bioscience and Sanofi, who are co-investing in the expansion. In addition to facility expansion, SK bioscience plans to quickly obtain cGMP (Current Good Manufacturing Practice) certification for the new facility, which is the standard for pharmaceutical manufacturing and quality management in the United States, to enhance global competitiveness. L HOUSE has already obtained EU-GMP certification from the European Medicines Agency (EMA) in 2021, making it the first domestic vaccine manufacturing facility to do so. SK bioscience and Sanofi plan to utilise the expanded manufacturing facility to accelerate the successful introduction of GBP410 into the global market, including the US, Europe, and South Korea.

Luye Pharma launches Zepzelca drug in Hong Kong and Macao for treatment of Small Cell Lung Cancer

Luye Pharma has launched its innovative drug Zepzelca (lurbinectedin) for the treatment of Small Cell Lung Cancer (SCLC) in both Hong Kong and Macao. Lurbinectedin is a new chemical entity with a novel mechanism of action. It was approved for launch in Macao in November 2023 and in Hong Kong in December 2023 for the treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy. The drug was also approved by the US Food and Drug Administration (FDA) through the accelerated approval process in 2020. To date, lurbinectedin has been approved for launch in 16 countries and regions worldwide. Luye Pharma has been granted the rights to develop and commercialise lurbinectedin in Chinese mainland, Hong Kong, and Macao, to allow Chinese patients to benefit from the innovative therapy as soon as possible. In addition to being approved for launch in Hong Kong and Macao, the drug is also under review for its New Drug Application (NDA) in the Chinese mainland with a priority review designation.

Ginkgo Bioworks launches pathogen monitoring centre in Doha

US-based Ginkgo Bioworks, which is building the leading platform for cell programming and biosecurity, has announced the signing of an agreement with Qatar Free Zones Authority (QFZ) and Doha Venture Capital (DVC) to build the first Centre for Unified Biosecurity Excellence in Doha (CUBE-D) within Qatar Free Zones. CUBE-D's advanced platform is expected to serve as a nucleus for global pathogen monitoring efforts and be a key hub in Ginkgo's bioradar network. Supporting global programmes modelled in part after the US Centers for Disease Control and Prevention (CDC) Traveler Genomic Surveillance (TGS) programme, which tracks and analyses pathogens collected at seven international airports in the US, CUBE-D will be a foundational piece of biosecurity and health security infrastructure in Ginkgo's multi-continent, integrated early warning system for biological threats. CUBE-D plans to support analysis of data collected from pathogen monitoring stations in both Qatar and partner countries, such as airports, municipalities, and agricultural sites by leveraging cutting-edge analytical platforms powered by artificial intelligence and developed by Ginkgo.

Takeda accelerates dengue vaccine access through manufacturing partnership with Biological E

Japanese pharmaceutical company Takeda has announced a strategic partnership with Biological E, a leading vaccines and biologics company in India, to manufacture Takeda's dengue vaccine, TAK-003. The partnership marks a crucial step in the fight against the global public health threat of dengue fever, aligning with the disease-specific target set by the World Health Organization (WHO) to achieve zero case-fatality rate due to dengue by 2030. The partnership will substantially enhance manufacturing capabilities to ensure a sustainable global supply of the vaccine. Biological E will scale up its production capacity to potentially reach 50 million doses annually, accelerating Takeda's efforts to manufacture 100 million doses annually within the decade. The recent recommendations made by WHO's Strategic Advisory Group of Experts (SAGE) on Immunisation recommended Takeda's dengue vaccine for introduction in settings with high dengue burden and high transmission intensity to maximise public health impact.

Pulsenmore expands application of home ultrasound solution for pregnant women

Israel-based startup Pulsenmore has announced its new clinical study collaboration with Michigan Medicine. The study will examine the ability to conduct a remote biophysical profile (BPP) test, by using the Pulsenmore home ultrasound with the guidance of a remote clinician, potentially reducing the clinical burden. The Pulsenmore prenatal home ultrasound, empowers pregnant women to connect their personal smartphones to a dedicated device and application, allowing them to perform ultrasound imaging scans from the comfort of their homes. These scans are seamlessly transmitted to the hospital for evaluation, focusing on essential fetal vitality parameters. The results are then communicated back to the patients. Clinicians can engage with patients asynchronously or in real-time, significantly reducing the necessity for in-clinic visits. Traditional antenatal testing, like the biophysical profile (BPP), typically conducted in clinical settings, involves assessing foetal parameters such as movement, tone, breathing, and fluid levels using ultrasound, and sometimes combined with a non-stress test.

Sanyou Biopharma launches advanced intelligent R&D service platform

Sanyou Biopharmaceutical Co., a contract research organisation based in China, has announced the launch of the 'Sanyou Intelligent Innovative Biologics R&D Service Platform', representing a transformative advancement in biopharmaceutical research and development. The platform encompasses ten meticulously designed systems aimed at optimising processes for customers.

These include robust tools for managing customer projects, organising, and tracking samples, coordinating internal projects, and automating report generation. Additionally, advanced capabilities for sequence analysis, primer design, experimental data processing, and drug development are integrated into the platform. With sophisticated modelling and predictive drug resistance analysis functionalities, researchers can make informed decisions and accelerate innovation in biopharmaceuticals. Furthermore, customer map management feature enables visualisation and analysis of customer data, facilitating strategic decision-making and customer relationship management.

Lunit expands AI medical imaging solutions in East & Southeast Asia

Lunit, a leading provider of artificial intelligence (AI)-powered solutions for cancer diagnostics and therapeutics, has announced two supply contracts that mark its strategic expansion into the East and Southeast Asian region. South Korean startup Lunit will supply its Lunit INSIGHT CXR for chest abnormality detection and Lunit INSIGHT MMG for mammography analysis to the Chung Shan Medical University (CSMU) in Taiwan and Gleneagles Hospital in Singapore,

respectively. Gleneagles plans to enhance screening accuracy and operational efficiency by seamlessly integrating Lunit's cutting-edge technology into its breast screening workflow.

Compared to Taiwan's current screening programme, which relies on low-dose computed tomography (LDCT) for screening high-risk individuals such as smokers or those with a family history of lung cancer, CSMU aims to validate Lunit INSIGHT CXR for potential integration into the national cancer screening programme. The goal is to assess its ability to detect individuals more accurately and efficiently, potentially expanding the screening to a broader group beyond high-risk individuals.

Nippon Express acquires stake in Japanese startup expanding 3D-printed prosthetics biz

Nippon Express (NX) Holdings has acquired an equity stake in Japan-based startup Instalimb, which is expanding its 3D-printed prosthetics business in the Philippines, India and elsewhere overseas. Through this investment, NX will be assisting Instalimb's business expansion from a logistics perspective and supporting the provision of prosthetic limbs in Asian countries such as the Philippines and India and, in future, emerging countries in Africa and other regions as well. Instalimb develops new digital manufacturing solutions using 3D-printing and artificial intelligence (AI) technology, employing these to manufacture and sell 3D-printed prosthetic legs overseas at one-tenth the conventional price and with a shorter delivery time. The company began operating in the Philippines in 2019 and in India in 2022, and has already received positive feedback from more than 2,500 users.

C-CAMP & Indegene help life science startups in India accelerate innovation and growth

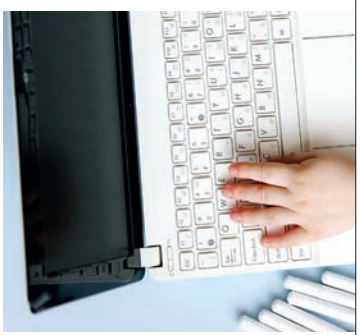
Bengaluru-based Centre for Cellular and Molecular Platforms (C-CAMP), India's premier not-for-profit enabler organisation in the deep tech innovation space, and Indegene, a digital-first, life sciences commercialisation company, have joined hands to help early-stage life sciences startups accelerate technology innovation, product development, and go-to-market. The multi-year agreement will see Indegene bring in financial assistance, mentorship via highly skilled and specialised experts, and a digital service suite, supporting C-CAMP's efforts in nurturing at least 5-7 early-stage deep-science startups with a 360-degree ecosystem. This initiative aligns with Indegene's philosophy of enabling future-ready healthcare globally. The goal of the partnership is to leverage C-CAMP's incubation programme to strengthen the life sciences innovation ecosystem in India and help bring new drugs/therapies to market faster.

Digital health startups to enhance women's health across MENAT region

Organon, a global healthcare company dedicated to improving women's health, in partnership with Flat6Labs, MENA's leading seed and early-stage venture capital firm, has announced the launch of the second cycle of the Women's Health Accelerator Programme. Building on the success of the inaugural cycle and the incredible momentum witnessed across the region, this initiative aims to empower digital health startups with solutions to enhance women's health across the Middle East, North Africa, and Turkey (MENAT) region. The second cycle will hone in on three main focus sectors critical to women's health- Family Planning; Fertility Planning and Women's Wellness. The initiative aims to accelerate the growth of 15 startups, and engage with various stakeholders, ultimately graduating startups that are ready to launch and address current challenges in women's health. Additionally, the programme will include virtual and on-ground community events such as info sessions, roadshows, pitchathons, and webinars to strengthen outreach, scouting, and selection efforts.

WHO and UNICEF launch free online course to address children's environmental health

Recognising the urgent need to empower all healthcare providers to safeguard children's health amidst the challenges of environmental pollution and climate change, the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) have collaborated to create a new free online course. In an era where pollution and climate change are increasingly jeopardizing children's health, development and their future, this course aims to equip healthcare providers with essential knowledge and resources to recognise and mitigate these risks effectively. This course provides an in-depth exploration of children's environmental health, covering key topics of global concern such as air pollution, climate change, e-waste, lead, pesticides and other hazards affecting children's well-being. Participants will gain valuable insights and practical strategies to enhance their capacity in this critical area of healthcare.

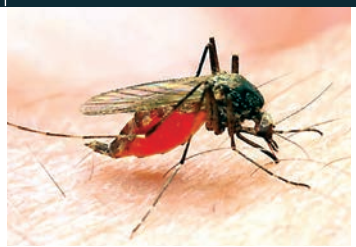


WHO launches new manual to support delivery of psychological interventions

The World Health Organization (WHO) has launched a new manual to support the implementation of psychological interventions. By providing practical guidance on how to implement psychological interventions, this guide will help increase access to evidence-based interventions so that more people can benefit from them. The manual focuses on evidence-based psychological intervention manuals delivered by a non-specialist workforce. Globally, 1 in 8 people experience a mental health condition, with depression and anxiety among the most common. Yet most receive no treatment. This might be because of a lack of services or because services are limited in capacity, inaccessible or unaffordable. Often stigma stops people from seeking help in the first place. Psychological interventions have a crucial role in helping to reduce the vast treatment gap between the high prevalence of mental health conditions and limited access to adequate care.

WHO unveils mobile app for biosafety risk assessment

The World Health Organization (WHO) has launched the Risk Assessment Tool (RAST) for Biosafety and Laboratory Biosecurity, developed to help with laboratory risk assessment. Laboratory workers are reported to be up to 1000 times more vulnerable to infections compared to the general population. RAST is designed to complement the WHO Laboratory biosafety manual's (LBM4) risk- and evidence-based approach. It reflects the first two steps of the risk assessment framework outlined in the LBM4: gather information and evaluate the risks. The app aims to increase understanding of hazards and risks, and to promote thorough assessment and adherence to biological safety practices for laboratory staff. While many biosafety/biorisk assessment apps tend to be informational, the app developed by WHO is logic-based and capable of performing complex risk calculations. It allows the user to gather information about the hazards associated with their intended work in either a research laboratory, diagnostics laboratory or field work settings.



African health ministers commit to end malaria deaths

Ministers of Health from African countries with the highest burden of malaria have committed to accelerated action to end deaths from the disease. They pledged to sustainably and equitably address the threat of malaria in the African region, which accounts for 95 per cent of malaria deaths globally. The ministers signed a declaration committing to provide stronger leadership and increased domestic funding for malaria control programmes; to ensure further investment in data technology; to apply the latest technical guidance in malaria control and elimination; and to enhance malaria control efforts at the national and sub-national levels. The ministers further pledged to increase health sector investments to bolster infrastructure, personnel and programme implementation; to enhance multi-sectoral collaboration; and to build partnerships for funding, research and innovation. In signing the declaration, they expressed their unwavering commitment to the accelerated reduction of malaria mortality and to hold each other and countries accountable for the commitments outlined in this declaration.

International Vaccine Institute opens country office in Kenya

South Korea-based International Vaccine Institute (IVI) has opened a Country and Project Office in Kenya dedicated to the operations of its Advancing Vaccine End-to-End Capabilities (AVEC) initiative in Africa as well as other collaborations with Kenyan partners such as Kenya BioVax Institute across vaccine research, development, and training. AVEC Africa is an accelerator of the regional vaccine ecosystem through the implementation of end-to-end research and development projects in Africa. The grassroots model activates public-private partnerships to drive projects based on local and regional need while promoting hands-on training and experience to develop the products, people, policy, and infrastructure needed to power an integrated and sustainable vaccine ecosystem in Africa. The IVI Board of Trustees (BOT) approved the decision to pursue AVEC Africa as part of a regional strategy and to establish a Country and Project Office in Kenya to oversee the initiative during an Executive Committee meeting in February 2024. The Country and Project Office in Kenya will manage the implementation of the AVEC Africa initiative and its project portfolio. The Global Council, a representative body composed of IVI's State Parties, welcomed this expansion as well as the AVEC Africa concept (previously referred to as the African Vaccine Alliance model), as outlined in a joint statement for stronger global vaccine ecosystems. The Global Council encourages IVI's leadership, governments around the world, and partners to support this critical initiative.

PAHO seek to establish intersectoral commission to prevent & control avian influenza

In order to strengthen surveillance, prevention and control of avian influenza in both animals and humans, the Pan American Health Organisation (PAHO) convened its 35 member states in Brazil recently to establish a regional commission to combat the disease. The meeting took place at a time when the world is experiencing high levels of transmission of the virus among birds and mammals, which poses a potential risk to public health. Participants agreed on the need to create an intersectoral commission to strengthen detection, prevention and response to zoonotic influenza. The Inter-sectoral Commission for the Prevention and Control of Avian Influenza in the Americas will enable public, animal and environmental health sectors to exchange updated information on surveillance, epidemiological risk and evolution of circulating viruses. The commission is also expected to promote strategies at the national, sub-regional and regional levels and strengthen coordination.

Addressing Accessibility and Affordability of CELL & GENE THERAPIES

Cell and gene therapies (CGT) are one of the hottest sectors in the pharmaceutical industry. Quite a few companies in the field are making remarkable advancements toward potentially curative treatments for challenging diseases using groundbreaking science. With lower R&D development costs than in advanced markets, China is becoming an attractive market for the development of CGT, and therefore may emerge as a strong competitor of overseas-made CGT, notes a GlobalData report. Bayer AG, recently announced the global expansion of its life science incubator network, Bayer Co. Lab, to Shanghai, China and Kobe, Japan. The new site in China will focus on oncology and CGT innovations. While India lags behind China in the production of cell and gene therapies, a wave of new biotech startups is emerging to address this challenge. Immuneel Therapeutics and ImmunoACT are currently developing CAR-T cell therapies. The latter's NexCAR19 therapy received approval from India's Central Drug Standards Control Organisation (CDSCO) for treating relapsed or refractory B-cell lymphomas and leukaemia. Despite a steady stream of regulatory approvals and promising growth prospects, the high manufacturing costs associated with these therapies often render them inaccessible to the majority of patients. To address this issue, companies are actively striving to streamline and optimise the highly intricate and labour-intensive process of cell and gene therapy manufacturing. Let's explore further.

The most sought-after and hot sector in the pharmaceutical industry, which has witnessed an outpouring of billions and record-breaking approvals in recent times, is cell and gene therapy. Last year, the United States Food and Drug Administration (US FDA) approved seven cell and gene therapy products, including the world's first approved CRISPR gene editing therapy, Casgevy, two cell therapy products, and the first oral faecal microbiota product, Vowst.

Globally, 30 gene therapies have been approved (including genetically modified cell therapies). The cell and gene therapy sector has expanded tremendously, with the number of drugs in development growing nearly six-fold from 511 development-stage candidates in 2013 to just over 3,000 in 2023, according to Citeline's Pharmaprojects.

By 2025, the FDA aims to review and approve 10-20 gene and cell therapies annually. With an increasing number of products obtaining regulatory approval in the coming years, the market size for CGT is projected to reach $94 billion by 2030, according to Precedence Research. Oncology is anticipated to maintain its lead as the primary indication and area of significant advancement for cell and gene therapies, projected to account for 44 per cent of the CGT market by 2029. Other therapeutic areas poised to derive benefits from CGT include neurodegenerative, autoimmune, and cardiovascular diseases.

Asian Scenario

The Asia Pacific region has been leading in the field of cell and gene therapies, with several countries investing significantly in research and development. China, in particular, has emerged as an important market for CGTs, particularly CAR-T therapies, surpassing the USA in the number of clinical trials conducted. The industry is considered a strategic priority by the government, with CAR T-cell therapy clinical trials in China accounting for over 50 per cent of registered CGT studies worldwide. Currently, there are over 200 ongoing CAR-T trials in China covering a wide range of targets and indications, from haematology-oncology to solid tumours, according to reports from Nature.

Yescarta, developed by Fosun Kite, and relma-cel, from JW Therapeutics, stand as China's first regulatory-approved CAR T-cell therapies, heralding a new era for the industry. A notable achievement is cilta-cel, developed by Legend Biotech, which has successfully gained FDA approval, marking its global recognition.

With lower R&D development costs than in advanced markets, China is becoming an attractive market for the development of CGT, and therefore may emerge as a strong competitor of overseas-made CGT, notes a GlobalData report. Adding to this momentum, Bayer AG announced the global expansion of its life science incubator network, Bayer Co. Lab, to Shanghai, China. At the new site in China, Bayer will collaborate with Shanghai Pharmaceuticals to focus on oncology and CGT innovations.

While India lags behind China in the production of cell and gene therapies, a wave of new biotech startups is emerging to address this challenge. Immuneel Therapeutics and ImmunoACT are currently developing CAR-T cell therapies. ImmunoACT's NexCAR19 therapy received approval from India's Central Drug Standards Control Organisation (CDSCO) for treating relapsed or refractory B-cell lymphomas and leukaemia. This approval positions ImmunoACT to lead India's indigenous CAR-T cell therapy efforts, with NexCAR19 undergoing Phase II trials for

other lymphomas and leukaemia types. Similarly, Immuneel Therapeutics' IMN-003A CAR-T is in Phase II trials for B-cell lymphomas and leukaemia. The successful completion of these trials holds promise in meeting the critical need for effective cancer therapies in India. Recently, German biotech firm Miltenyi Biotec launched operations in India, planning to establish a centre in Hyderabad.

Singapore is emerging as a top destination for CGT manufacturing, with numerous companies unveiling plans to set up facilities in the country. SCG Cell Therapy is among those, announcing the establishment of a manufacturing facility and R&D centre in Singapore. Concurrently, Biosyngen inaugurated a new cell therapy GMP facility in Singapore, further bolstering the city-state's position in the field. Adding to this momentum, the Advanced Cell Therapy and Research Institute Singapore (ACTRIS) recently opened a new 2,000 sqm cell therapy facility to address the growing clinical demand for CGT treatments in Singapore. Thermo Fisher Scientific has also contributed to Singapore's CGT landscape, launching a Cell Therapy Collaboration Center Program aimed at advancing cell therapy initiatives across the Asia-Pacific region.

Australia also aims to become a hub for these therapies. AusBiotech and Medicines Australia are driving the Cell and Gene Catalyst initiative to accelerate development and commercialisation in Australia, with a focus on strengthening the ecosystem and collaborating with industry leaders. The country also launched Australia's National Cell and Gene Manufacturing Blueprint, outlining a strategic approach to establish the country as a regional leader. The blueprint emphasises infrastructure and workforce development to bolster manufacturing capabilities and capacity.

CDMOs enhancing capabilities

CDMOs are elevating their game by enhancing their capabilities and capacities, investing in facilities exclusively dedicated to CGT manufacturing. Avid Bioservices, Inc., a biologics CDMO, has recently completed construction of cGMP manufacturing suites within its new CGT-focused facility located in Orange County, CA. Forecyte Bio, a CGT CDMO, has inaugurated a brand-new GMP facility in Shanghai to bolster its manufacturing capabilities. Lonza is also expanding its global presence in cell and gene therapy, with expansions in the US and The Netherlands, including nearly doubling the size of its Cell and Gene Therapy Development laboratories in Houston. AGC Biologics is ramping up its Milan site to support viral vector development for large-scale clinical and commercial demands. Additionally, AstraZeneca plans to establish a major R&D centre in Hong Kong dedicated to developing cell and gene therapy drugs. In the US, Thermo Fisher Scientific has unveiled a new viral vector manufacturing facility in Plainville, MA, expanding its CGT capabilities. In the APAC region, Fujifilm is investing $200 million into cell therapy development and manufacturing in the U.S., while Catalent adds cryogenic capabilities in Japan to support cell and gene therapy development. OBiO Technology has opened a super factory in China to accelerate cell and gene therapy, and Curocell has launched a 'CAR-T Manufacturing GMP Facility' in Korea. SK pharmteco is also expanding its capabilities with the acquisition of a controlling interest in a U.S.-based Center for Breakthrough Medicines.

Addressing Prohibitive Costs

Cell and gene therapies offer hope for life-threatening debilitating conditions, but access remains out of reach for the patients who need it the most. Scaling CGT operations is critical to meet the growing demand for treatment. 20 per cent of cancer patients who are eligible for CAR-T therapies pass away while waiting for a manufacturing slot.

"We have to challenge the status quo, because therapies can't just be approvable – they need to be accessible too. More therapies approved do not automatically translate into increases in the number of patients treated. Today, it is estimated that less than 3 per cent of patients who could benefit from CAR-T therapies (to name just one category) have been able to access them," said ***Jason C. Foster, CEO, Ori Biotech.***

Ori Biotech, based in London and New Jersey, has developed a proprietary, full-stack manufacturing platform that closes, automates and standardises CGT manufacturing. Ori is set to commercially launch its platform this year.

Manufacturing poses the biggest obstacle in the field of gene therapy. According to SK Pharmteco, the expenses for manufacturing and cost of goods can range from $500,000 to $1 million for gene therapy, excluding research and clinical trial expenses, ultimately burdening patients with hefty costs. The approval of CSL Behring's Hemgenix, the first FDA-approved gene therapy for haemophilia B, marked a significant milestone but also set a record for its price tag — an eye-popping $3.5 million for a single treatment, making it the world's most expensive drug. Similarly, Bluebird's Zynteglo, carries a list price of $2.8 million, further escalating drug pricing. Analysis by the Institute for Clinical and Economic Review suggests that gene therapy's average cost falls between $1 million and $2 million per dose, highlighting the financial challenges associated with accessing these innovative treatments.

The manufacturing process for CGTs is not only daunting, time-consuming, and laborious, but there is also a significant shortage of skilled personnel to handle the sophisticated processes required. According to BioPlan Associates' 20th Annual Report and Survey of Biopharmaceutical Manufacturing, 51.3 per cent of the industry is facing critical shortages in manufacturing staff, more than doubling from just 21.2 per cent in the past three years. This substantial increase underscores the severity of the staffing shortages within the cell and gene therapy contract manufacturing industry.

"The first manufacturing bottleneck faced by cell and gene therapy startups as they scale up production is difficulty in hiring and retaining manufacturing talent who can navigate the certification process, and eventually translate to GMP manufacturing. The global competition for highly qualified manufacturing talent is evident. The biopharma industry has long grappled with this challenge, and it's more challenging for startups to attract experienced talent and train new hands in the biotech sector compared to multinational companies. Data from Cytiva's 2023 Global Biopharma Resilience Index shows that only 24 per cent of biopharma executives are positive about having access to manufacturing talent capable of working in GMP environments in the Asia Pacific," said ***Krishna Karnati, Commercial General Manager, Genomic Medicine, APAC, Cytiva.***

Contract Development and Manufacturing Organisations (CDMOs) are also not fully equipped to handle CGT manufacturing. According to Top1000bio.com database of global biologics facilities, only a handful of the CDMOs can produce either late-stage clinical, or commercial-scale therapies.

"Other bottlenecks include the manufacturing facilities themselves – designing or upgrading these so they can accommodate large-scale production of cell and gene therapies that adhere to regulatory standards, guarantee product quality, and support adaptable production processes – and securing cell lines with the required purity, viability, and genetic stability," said ***Thomas Carlsen, CEO of the Novo Nordisk Foundation Cellerator, Denmark.***

The Novo Nordisk Foundation Cellerator – a facility for the further development and manufacture of cell therapies for use in clinical trials, and a hub within the Nordic cell therapy ecosystem – is being developed to address all these challenges. For example, the company is working to secure cell lines at an early stage and construct a facility that is specifically designed for the large-scale production of high-quality cell therapies.

Unfortunately, manufacturing advancements have failed to keep pace with the rapid innovations seen in cell and gene therapies.

"The speed of innovation in the cell and gene therapy space presents a double-edged

sword as developers bring academic-developed small-scale processes into commercial-scale, quality-driven manufacturing environments in highly compressed timelines. As companies try to scale production without compromising safety and efficacy, they face three intertwining issues: scarce talent pool, starting material variability and immature processes. Particularly in autologous therapies, starting material is a primary source of variability impacting manufacturing success and often heavily relies on expert personnel to tweak process parameters; yet, this process flexibility complicates the development of a robust manufacturing strategy that can scale across operators and geographies," said ***Dr Wenyan Leong, Strategy Lead, Asia Pacific and Japan, Cell Therapy Technologies, Terumo Blood and Cell Technologies.***

Terumo launched the Quantum Flex bioreactor platform, one of the first systems that enables cell therapy commercialisation from process development through manufacturing.

Though there isn't a singular solution to enhance the accessibility of CGTs, refining manufacturing processes to facilitate their large-scale production can effectively lower their costs and ensure they reach individuals in dire need of these treatments.

Digitising CGT manufacturing

By automating and standardising manufacturing processes, we can initiate large-scale production and truly industrialise CGTs. This requires the implementation of platforms designed for flexible process discovery and smooth translation to a commercial scale. Automation addresses key challenges such as the inefficiency of manual processes at scale, elevated costs, and high rates of process failure.

"Additionally, automation cuts costs by 50 per cent and enhances quality, as process failure rates plummet by 75 per cent due to reduced operator errors and minimise contamination through closed processes," said ***Fabian Gerlinghaus, Co-Founder and CEO, Cellares, USA.***

Celares is set to launch its proprietary modular cGMP platform, the Cell Shuttle, designed for industrial-scale cell therapy manufacturing. The Cell Shuttle offers an automated manufacturing solution, slashing labour and facility size requirements by up to 90 per cent. Bristol Myers Squibb is presently utilising Cellares' Cell Shuttle platform for the automated proof-of-concept manufacturing of its CAR-T therapies.

With the current manual or semi-automated manufacturing systems, production space and the need for highly skilled operators are barriers to production capacity. Closed and automated systems address both of these bottlenecks. To that effect, Cytiva has partnered with robotics technology company Multiply Labs to design a robotic system that would automate the manual portions of cell therapy production. Lonza's platform for autologous cell therapy manufacturing, the Cocoon, is a functionally closed, automated system that is currently being used to support clinical trials in Europe and North America.

"While it is known that automated and closed processing platforms will enable scale, it has been a longstanding debate on when to adopt these sophisticated platforms. It is preferable to choose a scalable platform early in development to understand the parameters, and then scale rapidly as needed. One can scale-up or scale-out depending on their manufacturing strategy. Advanced electronic management software can help to ease scale-out strategies through integrated data reporting and protocol management across multiple devices," said Dr Leong.

While the biopharma industry has embraced technology, the primary bottleneck hindering the scale-up of cell and gene therapy (CGT) production is the absence of comprehensive 'end-to-end' solutions.

"As an industry, we are still building very large facilities full of people, using islands of automation run by and connected by people and producing data recorded by people. There is very little 'whole process' automation and limited scope for mechanisation and industrialisation, limiting productivity and constrained by the resulting high cost of goods. To achieve production scale up, we can take inspiration from other highly automated industries, and focus on developing the missing links that will enable us to use these technologies in the CGT industry and thereby achieve scale of tens of thousands of therapies a year. Those at the more commercial end of CGT are already acutely aware that step-change innovations are essential in order to provide these life-saving therapies to all of the patients that can benefit from them," said ***Jason Jones, Global Business Development Lead at Cellular Origins, UK.***

Cellular Origins is working on bringing

Approved Gene Therapies

Product Name	Company	Disease(s)	Locations approved	Year first approved
Gendicine	Shenzhen SiBiono	Head and neck cancer	China	2004
Oncorine	GeneTech	Head and neck cancer; nasopharyngeal cancer	China	2005
Rexin-G	Epeius Biotechnologies	Solid tumors	Philippines	2006
Neovasculgen	Human Stem Cells Institute	Peripheral vascular disease; limb ischemia	Russian Federation, Ukraine	2011
Imlygic	Amgen	Melanoma	US, EU, UK, Australia	2015
Strimvelis	Orchard Therapeutics	Adenosine deaminase deficiency/ Acute lymphocytic leukemia; diffuse	US, EU, UK, Japan, Australia,	2016
Kymriah	Novartis	large B-cell lymphoma; follicular lymphoma	Canada, South Korea,Switzerland	2017
Luxturna	Spark Therapeutics (Roche)	Leber's congenital amaurosis; retinitis	US, EU, UK, Australia, Canada, South Korea, Japan	2017
Yescarta	Kite Pharma (Gilead)	Diffuse large B-cell lymphoma; non-Hodgkin's lymphoma; follicular lymphoma	US, EU, UK, Japan, Canada,China, Australia	2017
Collategene	AnGes	Critical limb ischemia	Japan, US, EU, UK, Japan, Australia,	2019
Zolgensma	Novartis	Spinal muscular atrophy	Canada, Brazil, Israel,	2019
Tecartus	Kite Pharma (Gilead)	Mantle cell lymphoma; acute	US, EU, UK. Australia	2020
Libmeldy	Orchard Therapeutics	Metachromatic leukodystrophy	EU, UK, Switzerland	2020
Breyanzi	Celgene (Bristol Myers Squibb)	Diffuse large B-cell lymphoma; follicular lymphoma	US, Japan, EU, Switzerland, UK, Canada	2021
Abecma	Bluebird bio	Multiple myeloma	US, Canada EU, UK, Japan, Israel Switzerland	2021
Delytact	Daiichi Sankyo	Malignant glioma	Japan	2021
Relma-cel	JW Therapeutics	Diffuse large B-cell lymphoma	China	2021
Skysona	Bluebird bio	Early cerebral adrenoleukodystrophy (CALD)	US, EU, UK, Japan,	2021
Carvykti	Legend Biotech	Multiple myeloma	Australia, China	
Upstaza	PTC Therapeutics	Aromatic L-amino acid decarboxylase	EU, UK	2022
Roctavian	BioMarin	(AADC) deficiency, Hemophilia A	EU, UK, US	2022
Hemgenix	uniQure	Hemophilia B	US. EU, UK, Canada	2022
Adstiladrin	Merck & Co	Bladder cancer	US	2022
Elevidys	Sarepta Therapeutics	Duchenne muscular dystrophy	US	2023
Vyjuvek	Krystal Biotech	Dystrophic epidermolysis bullosa	US	
Fucaso	Nanjing IASO Biotechnology	Multiple myeloma	China	2023
Casgevy	CRISPR Therapeutics	Sickle cell anemia; thalassemia	US, UK	2023
Inaticabtagene autoleucel	Juventas Cell Therapy	Acute lymphocytic leukemia	China	2023
Lyfgenia	Bluebird bio	Sickle cell anemia	US	2023

Source: Pharmaprojects | Citeline, and The American Society of Gene & Cell Therapy (ASGCT) January 2024

advanced robotics automation to cell therapy for the first time. Cellular Origins' platform is a configurable robotic automation solution that enables scalable, cost-effective, and space-efficient cell therapy manufacture that is designed for adaptability.

"Technology alone will not solve the issues in a vacuum. To stride forward, we need further collaboration between leaders in the space, to make sure that solutions are data-driven and grounded in excellence in biology. This huge unmet need has inspired us to partner with academics, therapeutics developers, investors to build solutions that can help bring more therapies to more people in urgent need," signs off Jason Foster. BS

Ayesha Siddiqui

"We anticipate India will adopt decentralised models for managing CGTs, ensuring closer proximity between patients and treatment facilities"

Cell and gene therapy (CGT) expert from Germany, Miltenyi Biotec has recently announced its entry into the Indian market to provide researchers, scientists and clinicians easier access to expertise, research, and manufacturing solutions. The company is well poised to enable local development and manufacturing in India to drive affordable and accessible CGTs by academia and industry for Indian as well as global patients. In conversation with BioSpectrum Asia, Dr Boris Stoffel, Chief Executive Officer and Managing Director of Miltenyi Biotec, talks about the real challenges associated with the use of CGT, and the way forward. ***Edited excerpts:***

« **Dr Boris Stoffel,** Chief Executive Officer and Managing Director, Miltenyi Biotec, Germany

Could you elaborate on the narrative behind Miltenyi Biotec's invention of the groundbreaking technology that has led to the development of new procedures for treating diseases through Cell and Gene Therapy? How was this achieved?

Miltenyi Biotec, being a private entity, stands as the pioneer in next-generation technology within the field of Cell and Gene Therapy (CGT). The significance of this technology persists even after 35 years, as it emerged in 1989 at a time when the concept of disruptive technology was still nascent. Looking back 35 years, it's evident that our innovation was disruptive because, at that time, only a handful of labs worldwide utilised large-scale cell sorters. Specialised operators were required to sort immune cells from blood, making it a cumbersome process.

The invention of MACS technology revolutionised this landscape by enabling every researcher to utilise a simple column and antibodies coupled with small microbeads in a magnetic field to separate cells within a short timeframe. This democratisation of technology meant that researchers were no longer reliant on expensive, specialised equipment available only in select labs. At that time, Germany, for instance, had only two such sorters, one of which was located at the Institute of Genetics of Immunology, where Stefan Miltenyi, the founder, was a student.

In the realm of CGT today, much revolves around the MACS Prodigy platform. This instrument, though appearing conventional, serves as a cornerstone in autologous cell therapy. It facilitates end-to-end processing of patient cells, starting from sample collection to final cell product delivery.

Could you provide an overview of cell manufacturing for personalised medicine with the CliniMACS Prodigy?

The core of this platform, reminiscent of our innovation 35 years ago, lies in the isolation of specific immune cells, crucial for therapies such as Chimeric Antigen Receptor (CAR) T cells. These cells are then transferred into a cultivation chamber, forming a closed system. Within this chamber, cells can be manipulated and expanded for weeks, culminating in the final product packaged in a culture bag ready for re-implantation.

However, as a global community by facility operations by streamlining processes and leveraging advanced analytics, we can collectively enhance the efficacy of cell manufacturing technologies like the CliniMACS.

How did you translate the new technology into pharmaceutical settings for distribution in patient treatment, and what are the associated costs? Do you believe that cell and gene therapy treatment is affordable for the Indian population, and what is your philosophy in introducing this new technology to India?

As we observe the pricing trends in the US and Europe, where these treatments are offered at substantial costs ranging from $300,000 to 400,000, it raises questions about accessibility, particularly in regions like the APEC where efforts seem minimal.

We believe that these transformative therapies should be accessible to all, regardless of geographic location or socioeconomic status. Traditionally, high-tech innovations tend to first benefit countries with advanced infrastructure, with others reaping the benefits later. However, we challenge this notion. Miltenyi Biotec has had a presence in India for nearly two decades, initially through distribution channels. However, a strategic shift occurred about a year and a half ago. Recognising the global demand for equitable access to therapies, we decided to overhaul our approach. With the support of our network of physicians worldwide, our goal is to make these therapies available to every hospital in India at affordable and reasonable costs, for this we are talking to government agencies, research institutions and other funding agencies that can make it happen.

With your direct entry into the India market, how do you plan to tackle the existing infrastructure, regulatory, and quality control challenges in India?

Miltenyi Biotec has always prioritised quality control, leveraging flow cytometry for product validation. We have developed Benchtop flow cytometry and curated one of the largest collections of recombinant antibodies, ensuring precise and repeatable analyses.

To simplify quality control procedures, we developed MACS-Quant software with express modes, streamlining flow cytometry analyses. This user-friendly approach ensures that even individuals without extensive laboratory experience can conduct quality control assessments effectively. Our aim is to integrate these components seamlessly, enabling individual hospitals to establish units for providing these therapies to patients with ease.

What factors have led to India's unique approach in advancing technology and bringing it to market, particularly in the context of regulatory standards and the emergence of autologous cell and gene therapies like CAR-T treatments?

We believe that India has chosen a unique path in terms of advancing technology and bringing it to market. Historically, India has aligned itself with regulatory standards set by entities such as the US FDA and EMEA. However, the emergence of autologous cell and gene therapies, particularly CAR-T treatments, is altering traditional paradigms.

Moving forward, we anticipate India will adopt decentralised models for managing these therapies, ensuring closer proximity between patients and treatment facilities. Our aim is to facilitate progress in oncology hospital infrastructure by leveraging state-of-the-art CAR-T therapies.

Furthermore, we offer comprehensive training and support to hospitals and research institutions. Our approach encompasses education on manufacturing processes, quality control, and medical discussions. Additionally, we intend to establish excellence centres across India to cater to the diverse needs of different regions. Hyderabad has been identified as an initial location, with plans for further expansion in key cities like Bangalore, Delhi, and Mumbai.

Could you please provide an overview of your global operations?

Our global headquarters is near Cologne, Germany, under the ownership of our founder and innovator, Stefan Miltenyi. Currently, our workforce totals approximately 5,000 employees worldwide, with around 900 based in the United States, which serves as our largest business hub for several reasons.

Primarily, the United States remains a hotbed for research and innovation, making it crucial for us to have a presence there. Additionally, significant investments, particularly in CAR-T cell therapy, have originated from the US, with Novartis being a notable example. While our manufacturing primarily takes place in Germany, we've also established facilities in California and on the East Coast to meet market demands, largely through acquisitions of smaller companies.

In Europe, we have marketing, sales, and support organisations spread across various countries. However, all manufacturing operations are centralised in Germany, emphasising the "Made in Germany" quality standard. Looking ahead, we anticipate a shift in the importance of regions like India and China for biotech manufacturing due to geopolitical factors and population size. Consequently, we may explore manufacturing solutions in these regions in the future.

Overall, our approach in the APAC region differs slightly from other areas, as we adopt a more focused and strategic approach in defining markets and partnering with specific entities to serve our objectives. As we continue to expand globally, we will remain adaptable to market dynamics and explore opportunities for further growth and collaboration. BS

Amguth Raju
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Addressing Challenges in Cell Therapy Manufacturing

Even with significant advancements, there are still a number of issues with cell therapy manufacturing that need to be resolved as production grows.

« **Dr Federica Tomay,** Field Application Scientist, Cell Analysis, Agilent Technologies

Cancer research has come a long way. Along with technology advancements, the basic options for treating cancer, such as surgery, radiation, and chemotherapy, have expanded their mainstays when immunotherapy is developed. Individualised CAR-T cell therapy uses a patient's immune system to fight specific types of cancers or a broad spectrum of immuno-oncology and infectious diseases. Cell-based therapies aim to treat diseases by altering or restoring certain sets of cells or using cells to carry a therapy through the body.

Despite substantial progress in this field, cell therapy manufacturing presents multiple challenges that must be addressed as production scales up. At Agilent, our cell analysis team works closely with cell therapy manufacturing companies to explore innovative technologies that can overcome some of these challenges locally, regionally, and globally.

Complexity of Production: Cell therapies involve complex biological processes that are difficult to standardise and scale. These include manipulating living cells and viral vectors, which can be highly variable and sensitive to environmental conditions. Building on automation and closed-system technologies can help reduce the complexity and variability of production processes and standardise procedures while reducing the risk of contamination and increasing manufacturing efficiency. Agilent offers specific instruments like the Bravo Automated Liquid Handling Platform for high-throughput and precise liquid handling to facilitate the automation and optimisation of various processes in cell therapy production.

Quality Control and Regulatory Compliance: Ensuring consistent quality and compliance with regulatory standards is a significant challenge due to the personalised nature of many cell-based therapies. Employing advanced analytics and real-time monitoring technologies can enhance quality control over the manufacturing process and quicker adjustments when issues are detected.

Agilent supplies professionals with essential tools such as guide RNA (gRNA) sequences and comprehensive oligonucleotide libraries, which are instrumental in refining the process of genetically modifying patient cells. By utilising advanced technologies like Flow Cytometers, xCELLigence systems, Seahorse XF analysers, and BioTek instruments, specialists can monitor and enhance the engineering of these cells with greater precision and efficiency.

Each of these tools offers unique capabilities, from the detailed analysis of cell characteristics and populations and facilitating real-time monitoring of cellular functions to providing insights into cellular metabolism and versatile solutions for cell imaging and analysis. Together, these innovative technologies support the optimisation of T-cell engineering, paving the way for innovative treatments in personalised medicine.

Supply Chain and Logistics: The supply chain for cell therapies is complex, involving transporting temperature-sensitive materials and products, often across long distances. Companies are exploring improved cryopreservation techniques and logistics solutions to enhance the stability and viability of products during transportation. Blockchain technology is also being considered to improve traceability and security throughout the supply chain.

Scalability: Due to the nature of cell therapies, scaling up production while maintaining quality and efficiency is a significant challenge. Companies are exploring modular and flexible manufacturing systems that can easily be scaled up or adapted to different therapies. Continuous manufacturing processes are also being developed to replace batch-based processes, potentially increasing scalability and efficiency.

Cost of Production: The high cost of manufacturing cell therapies can hinder their widespread adoption. To address this, process optimisation and the use of more cost-effective production methods, including leveraging synthetic biology to reduce the cost of raw material expenses and enhancing viral vector production methods, are crucial. BS

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Engineering CAR T cell sharpshooters

« **Brian Huber,** Vice President, Therapeutic Areas, Drug Development and Consulting, ICON

Approved CAR T-cell therapies have shown remarkable results in patients with certain types of blood cancers. However, further innovations are needed before the technology can reach its full potential. In principle, CAR T-cell therapies work because they are engineered with a chimeric antigen receptor (CAR) that is designed to recognise a cancer antigen expressed on the surface of that patient's cancer cells. When the CAR T-cell therapy is administered to the patient, these CAR T-cells coordinate a targeted immune response against the patient's cancer.

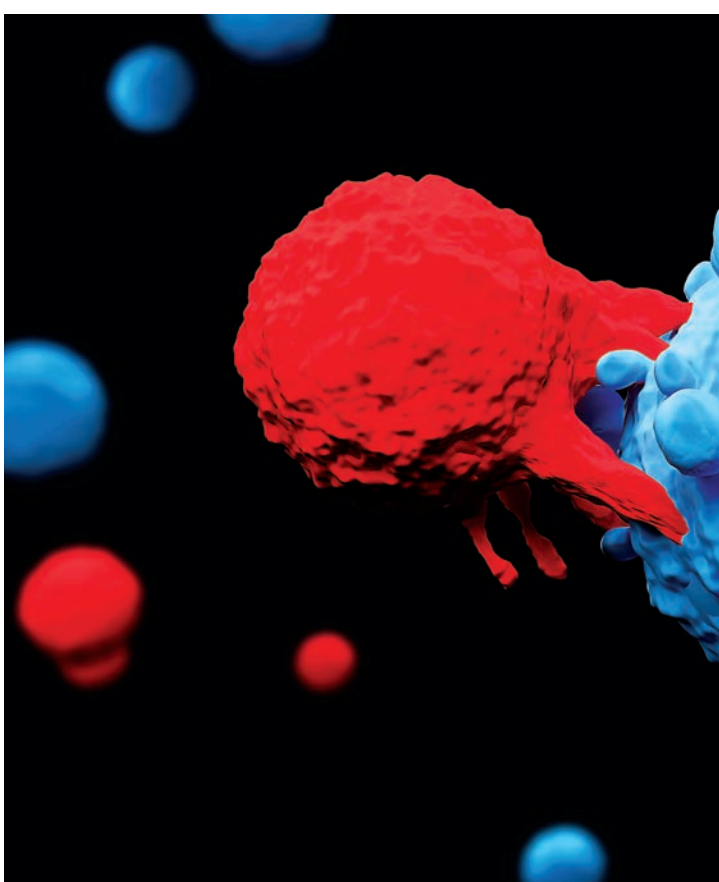
Ideally, the antigen for a traditional CAR T cell (or a T cell) would be universally and homogeneously expressed on cancer cells, but never expressed on healthy cells. In practice, this "perfect" cancer antigen likely does not exist for solid tumors where antigen expression is heterogeneous, and where overlap between antigen expression on cancer and healthy cells is common.

Two acceptable antigen candidates have been identified for blood cancers (CD19 or B-cell maturation antigen). These antigens are highly expressed in some blood cancers, but they are not cancer-specific. Additionally, in an immune evasion strategy, known as antigen loss, some patients who have received approved CAR T-cell therapies relapse because some of their cancer cells either lack or stop expressing the antigen targeted by their CAR T-cell therapy.

Ongoing challenges with CAR T-cell safety and efficacy reflect fundamental limitations of the initial aim of CAR T-cell development – to engineer cancer-targeting T cells that mirror the function of T cells. Now, efforts to develop more targeted and controlled CAR T-cells reflect a new aim: to engineer CAR T-cells with capabilities that give them distinct advantages over T-cells and first-generation CAR T-cell therapies.

CAR T-cells need to be targeted

To survive, cancers must continuously evade the immune system. Often, cancer cells achieve this by co-opting the immune system's mechanisms of self-regulation that are intended to prevent an overly strong immune response or an immune response against healthy cells. This means that if a cancer has survived long enough to do harm to the body, it has



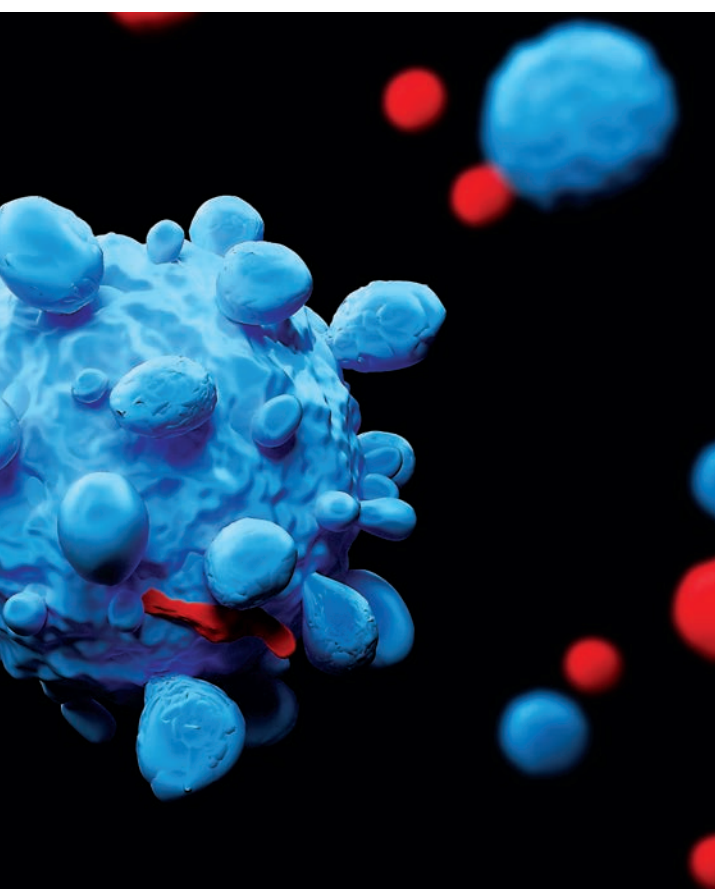
already successfully evaded the efforts of T cells, which normally recognise and then coordinate a targeted immune response against the cancer.

Ongoing efforts are now focused on engineering CAR T-cells with novel functionalities, such as logic gating and expression switches, that anticipate and help to counter mechanisms of immuno-suppression and evasion that have limited the efficacy of T cells and contemporary CAR T-cell therapies.

CAR T cells need to be controlled

While many limitations of efficacy are shared with T-cells, some critical differences between the first generation of CAR T-cells and T cells contribute to the toxicity of approved CAR T-cell therapies. Because CAR T-cells are engineered outside the body, they are not subject to the mechanisms that the immune system has in place to eliminate T cells that are able to identify antigens expressed on healthy cells. This means that unlike natural T cells, CAR T-cells can be designed to target antigens that are present on cancerous and healthy cells. The resulting auto-immune response from "on target, off tumor" T-cell activity can be fatal.

In addition, CAR T-cell expansion and proliferation are not subject to the same careful control that the immune system normally has over T cells to prevent them from provoking an immune response that is dangerously strong. While the dose of CAR T-cell therapies can be specified when the therapy is administered, the expansion and proliferation of CAR T-cells following administration are poorly controlled. As a result, severe complications from CAR T-cell therapy are common, including cytokine release syndrome and neurotoxicity. Many new CAR T-cell therapies in development are now being engineered so that clinicians retain better control over CAR T-cell activity and proliferation after the therapy has been administered.



Engineering future CAR T-cell sharp-shooters

The most promising elements that can be added to CAR T-cells effectively increase precision and control. Future CAR T-cell therapies may need to be engineered with multiple functionalities at once to improve precision and control. The following methods of CAR T-cell engineering are especially promising:

Multiple receptors

CAR T-cells can be engineered with multiple different antigen-specific receptors to create "logic gates" which can either activate or deactivate the CAR T- cell based on their combined activity. Engineering CAR T-cells with "OR," "AND" or "NOT" logic gates could provide a solution to a number of the challenges presented by CAR T-cells designed to be activated upon recognition of a single antigen.

By making CAR T-cells less specific, "OR" logic gating has the potential to protect against antigen heterogeneity between cancer cells and the likelihood of antigen loss. The "OR" logic gate functions by increasing the number of antigens that can activate a CAR T cell. Meanwhile, by increasing the specificity of CAR T-cells, "NOT" or "AND" logic gates make it possible to safely target a CAR T-cell against a cancer antigen that is expressed on healthy cells, as long as the logic gate prevents the T-cell from activating when it interacts with healthy cells. (In AND gating, a CAR T-cell needs to be activated by more than one antigen at once. While in NOT gating, the CAR T-cell can be deactivated by a receptor bound to a healthy-cell antigen).

Modularity

Modular CAR T-cells aim to improve the control over CAR T-cell activity following administration. This control is accomplished by engineering a CAR T-cell that can be separated into multiple modular pieces. Instead of directly recognising cancer antigens, a CAR T-cell is engineered to recognise a "middleman" – an antibody which is engineered to

CAR T-cells can be engineered to have altered expression of cytokines – small proteins that immune cells use to signal each other and orchestrate the immune response – or cytokine receptors. Expression of the cytokine IL-2 has been used to increase CAR T-cell proliferation following administration. CAR T-cells engineered to express other immunostimulatory cytokines may be able to counter local immunosuppression. Increased expression of cytokine receptors could improve CAR T-cell penetration of solid tumors, if the CAR T-cells were engineered with receptors for cytokines that are highly present in the tumor microenvironment.

bind the cancer antigen. The CAR T-cell becomes functional when it binds to the engineered antibody that is bound to the cancer antigen.

In practice, modular CAR T-cells allow a clinician to control the degree of CAR T-cell activation based on how much of the engineered antibody is administered. When that engineered antibody is naturally eliminated and no longer present in the body, then the CAR T-cells become inactive, making the pharmacodynamics analogous to a normal drug. In September of 2022, a first-in-human trial using a modular CAR T-cell therapy in blood cancer patients demonstrated that adjusting the engineered antibody dosage shortened the duration and severity of cytokine release syndrome and neurotoxicity events compared to approved CAR T-cell therapies.

Suicide genes

Another way to control CAR T-cells following administration is engineering them with a suicide gene, which, when triggered by a small molecule, induces the death the of CAR T-cells.This is a more severe method of control than modularity, because it is not fine-tunable. However, the effect of suicide genes are rapid, allowing clinicians to terminate a CAR T-cell therapy in case of severe complications. Suicide genes may prove especially useful in early trials of CAR T-cells, where the safety of the therapy is difficult to predict.

One commonly used suicide gene system relies on the modified protein caspase-9, which can trigger the death of a T-cell when it is cross-linked by a small molecule with another protein. Rimiducid, one of the small molecules that can trigger the caspase-9 suicide gene, has recently been demonstrated as an effective "safety switch" in a phase 1/2a trial of a novel CAR T-cell therapy for advanced neuroblastoma. In the trial, one patient who experienced especially severe side effects received two infusions of rimiducid, which rapidly eliminated the CAR T-cell therapy and resolved life-threatening toxicities.9

Cytokine expression

CAR T-cells can be engineered to have altered expression of cytokines – small proteins that immune cells use to signal each other and orchestrate the immune response – or cytokine receptors. Expression of the cytokine IL-2 has been used to increase CAR T-cell proliferation following administration. CAR T-cells engineered to express other immunostimulatory cytokines may be able to counter local immunosuppression. Increased expression of cytokine receptors could improve CAR T-cell penetration of solid tumors, if the CAR T-cells were engineered with receptors for cytokines that are highly present in the tumor microenvironment.

Expression switches

Expression switches also offer a mechanism for regulating the activity of CAR T-cells by engineering a mechanism that makes CAR T-cells respond to specific conditions – including anoxia, which is characteristic of the tumor microenvironment – or small molecule drugs such as rapamycin.The combination of multiple drug-induced switches within a single CAR T therapy could allow for the fine-tuning of multiple elements of CAR T-cell proliferation and activation. For example, one research team led by Dr Ahmad Khalil of Boston University, has engineered CAR T-cells with two expression switches that use different small-molecule inducers to first control T-cell proliferation, and then induce antitumor activity. Control of T-cell proliferation was achieved through the induced expression of the cytokine IL-2, that helps T-cells grow and survive, followed by induced expression of the chimeric antigen receptor by a second small molecule.

The limitations of a CAR T-cell engineered with a single cancer-specific antigen have become increasingly clear. Although it is not yet evident what the future of CAR T-cells will be, ongoing research efforts suggest that the next wave of CAR T-cells are likely to include additional elements that make them more precisely controlled and adaptable than T-cells and CAR T-cell predecessors. BS

Can Test, Treat, Track **Beat Malaria?**

Malaria has long been a major public health concern in the Asia Pacific region, particularly in South East Asia (SEA) affecting millions of people. While Asia Pacific has been very successful in drastically reducing the malaria burden, over the past 10 years only three countries in the region successfully earned their malaria-free status: Maldives in 2015, Sri Lanka in 2016, and China in 2021. China's eradication of malaria in particular was a momentous feat, making it a potential blueprint for other countries in the region. Let's examine the lessons we can learn from China's malaria elimination strategy.

Malaria, the oldest disease that has plagued mankind for centuries, continues to wreak havoc globally. The World Health Organisation (WHO's) 2023 World Malaria Report revealed that global malaria cases in 2022 surpassed pre-COVID-19 levels. The Asia Pacific region also continues to be affected by this enduring fever. India accounted for 66 per cent of malaria cases in the WHO South-East Asia Region in 2022, with nine countries in the region contributing to about 2 per cent of the global burden. Notably, Myanmar experienced a seven-fold increase in cases between 2019 and 2022 due to political and social instability, impacting neighbouring countries like Thailand, where cases doubled. Bangladesh and Indonesia also saw increases in malaria cases between 2021 and 2022.

Understanding China's Approach

The WHO certified China as malaria-free in 2021, marking a significant achievement. Malaria had been endemic in China for many years, with an estimated 30 million cases annually and a 1 per cent fatality rate in 1949. The elimination of malaria in this populous nation represents a major milestone not only for Chinese public health but also for global efforts towards malaria eradication.

"Seventy years ago, China was reporting 30 million malaria cases annually. Moving from 30 million to zero malaria cases required decades of consistent political will and concerted efforts to innovate, strengthen health infrastructure, and enable 13 different ministries and departments across the country to work in tandem in a whole-of-government approach to defeat this deadly disease," said ***Dr Sarthak Das, CEO, Asia Pacific Leaders Malaria Alliance.***

The Asia Pacific Leaders Malaria Alliance (APLMA) unites 22 governments in Asia-Pacific who have committed to eliminating malaria in the region by 2030. APLMA is a partner of the RBM Partnership to End Malaria (formerly known as Roll Back Malaria), the largest global platform for coordinated action against malaria.

China Strategies

China has adopted strategies such as The 523 Project, ITNs, 1-3-7 approach and Collaborations in the last seven decades and emerged successful in eradication of malaria as WHO certified China as malaria free nation in 2021.

The 523 Project: In 1967, the Chinese Government launched the '523 Project' – a nation-wide research programme aimed at finding new treatments for malaria. This effort, involving more than 500 scientists from 60 institutions, led to the discovery in the 1970s of artemisinin – the core compound of artemisinin-based combination therapies (ACTs), the most effective antimalarial drugs available today.

ITNs: In the 1980s, China was one of the first countries in the world to extensively test the use of insecticide-treated nets (ITNs) for the prevention of malaria, well before nets were recommended by WHO for malaria control. By 1988, more than 2.4 million nets had been distributed nation-wide. The use of such nets led to substantial reductions in malaria incidence in the areas where they were deployed. By the end of 1990, the number of malaria cases in China had plummeted to 117,000, and deaths were reduced by 95 per cent.

1-3-7 approach: China's 1-3-7 approach required suspected malaria cases to be confirmed and reported to the central health authorities

Vaccination and malaria elimination

In October 2023, the World Health Organization (WHO) recommended a new vaccine, R21/Matrix-M, developed by The University of Oxford and the Serum Institute of India, for the prevention of malaria in children. This marks the second malaria vaccine recommended by WHO, following the RTS,S/AS01 vaccine developed by GlaxoSmithKline (GSK), which received WHO approval in 2021. Both vaccines have demonstrated safety and efficacy in preventing malaria in children.

However, the necessity of vaccines in the Asia Pacific region is debatable, given that countries like China, Sri Lanka, and the Maldives have achieved malaria elimination without relying on vaccines, instead employing established strategies such as early diagnosis, treatment, and vector control. While vaccines are a welcome development, they come with unique challenges. The R21/MM vaccine is primarily designed to reduce Plasmodium falciparum malaria mortality in young African children, potentially limiting its effectiveness in regions where Plasmodium vivax is prevalent (such as Asia). Additionally, while Serum Institute of India has the capacity to produce more than 200 million doses of the R21/MM vaccine annually, the production capacity for RTS,S/AS01 is limited, with only 18 million initial doses allocated to 12 countries for 2023–25.

Though optimistic about the success of Oxford's R21/MM vaccine, East Asia Forum, which is the academic research network of the East Asian Bureau of Economic Research (EABER) says that Oxford's R21/MM could be a historic breakthrough for children in Africa, but it may have limited impacts on the elimination of malaria in the Asia Pacific. Asia is capable of reaching this goal, but it needs tools suited to its fundamentally different malaria problem.

In areas where limited accessibility hinders regular surveillance and vector control, vaccines could serve as another critical tool. While no single tool will be a silver bullet, vaccines are vital weapons in our arsenal as we strive to put an end to the world's oldest fever, stated APLMA.

(China Information System for Diseases Control and Prevention) within one day, verified and investigated by trained staff within three days, and finally a focus investigation and response had to be conducted within seven days through house-to-house visits to eliminate possible sources of transmission. This strict timeline was developed to break the chain of malaria transmission by detecting secondary malaria infections and preventing further spread of the disease. The 1-3-7 approach has also proved effective at prevention of re-establishment, protecting communities from imported cases.

Collaborations: China's historic achievement in eliminating malaria did not happen in isolation. The country actively collaborated with various ministries, underscoring the significance of effective multi-sector cooperation in attaining success. In 2010, an agreement was signed involving 13 ministries, including those overseeing health, education, finance, research, development, public security, the military, police, commerce, industry, information technology, media, and tourism. Together, they united to combat malaria nationwide, culminating in the formulation of the 'China Malaria Elimination Action Plan (2010-2020)', which served as the cornerstone of the national malaria elimination programme. This collaborative effort, guided by provincial, county, and township administrators, played a crucial role in malaria elimination and will continue to be pivotal in preventing its resurgence in China.

Scaling up Lessons for APAC

APAC countries can draw inspiration from China's experience and adapt its successful strategies to their own contexts. Investing in scientific research, intra and inter collaborations, smart surveillance, and the utilisation of tried and tested tools such as ITNs can all contribute to the fight against malaria.

"For over two decades, the Asia Pacific (APAC) region has made impressive progress against malaria. As the most populous country and the third in APAC to achieve malaria-free certification from WHO, China's strong commitment to eliminating this deadly disease is an important part of the region's success story. Employing an innovative and whole-of-government approach among other strategies, China has shown a clear path towards malaria elimination which other countries in APAC have learned from,"Dr Das added.

Recognising this important impact, the WHO included the 1-3-7 approach in its reference manual for surveillance to national malaria programmes around the world. Most malaria-endemic countries in Asia Pacific have now adopted the 1-3-7 approach or a modified version as part of their national strategic plans for malaria. Application of the 1-3-7 approach in Thailand played a role in controlling

a malaria outbreak in 2017, and also in helping Cambodia improve their timeliness and response rate. Myanmar also adopted the strategy but faced considerable challenges such as human resource availability and transportation.

"While the 1-3-7 approach has seen great success, it is a resource-intensive approach that requires strong health infrastructure and sustained high-level political commitment to ensure the financing and systems required run smoothly. Local conditions also play an important role, as the 1-3-7 approach role-out in Myanmar was more mixed due in part to limited training of health workers as well as limited access to supplies, internet, and transportation which delayed response times," said Dr Das.

Apart from these factors, China's commitment to universal health coverage has also been crucial to its success. The country's poverty reduction programme, along with unwavering political commitment at all levels of government over a 70-year period, underpinned China's success in eliminating malaria and was a key factor in its achievement.

"Vector control is another essential component of malaria prevention, with the scale-up of insecticide-treated nets (ITNs) or long-lasting insecticidal nets (LLINs), and expansion of indoor residual spraying (IRS) as key contributing factors. While the majority of malaria transmission occurs indoors, there are increasing concerns around the magnitude of outdoor transmission, where more investment in scientific and technological breakthroughs is much needed," said ***Dr Zhi-Jie Zheng, Director, China Country Office, Bill & Melinda Gates Foundation.***

In collaboration with Chinese partners, the Gates Foundation has supported initiatives to share China's malaria elimination experience and innovations with African and Southeast Asian countries. Since 2018, the foundation has funded a malaria control pilot project in southeastern Tanzania, which adapted China's elimination approach to include rapid reporting and follow-up to halt transmission, resulting in a 60 per cent reduction in malaria prevalence. The WHO is piloting this approach in other African countries like Zambia, Senegal, and Burkina Faso.

The foundation also collaborates with the Global Health Drug Discovery Institute (GHDDI) to biosynthesize artemisinin, a promising drug candidate showing potential in reducing drug resistance. Moreover, the foundation assists Chinese partners in improving manufacturing facilities to ensure access to artemisinin-based drugs worldwide. Furthermore, the foundation and the National Natural Science Foundation of China (NSFC) announced funding for research proposals on outdoor malaria vector control, aiming to provide technical support for field trials in countries like Sudan and other Asian nations.

In the Asia Pacific, we are in the final stage of malaria elimination, but this doesn't mean the threat is completely eradicated. While the last mile of malaria elimination is challenging, China's experience shows that combining tried-and-true tools with innovative approaches tailored to local conditions can lead to significant success. The Asia Pacific must learn from China's example, maintaining vigilance and sustaining rigorous efforts to fight this deadly disease until the very end. BS

Ayesha Siddiqui

How China Combated Malaria

China pioneered innovative measures and drugs to effectively arrest the spread of malaria. The three critical innovations that made China's historic achievement possible include:

Artemisinin-based combination therapies (ACTs): Artemisinin is a compound discovered by Chinese Nobel laureate Tu Youyou and her team in 1972 that has since become the WHO-recommended standard treatment for malaria globally.

Long-lasting insecticidal nets (LLINs): Bed nets treated with insecticides can effectively block transmission of the disease by female mosquitoes. In the 1980s, China was one of the first countries in the world to test the use of these nets, even before WHO recommended it.

'1-3-7' malaria surveillance and response approach: This strategy entails reporting confirmed cases within one day, investigation of specific cases within three days, and targeted control measures to prevent further transmission within seven days. China developed the approach in the early 2000s and it quickly proved effective in its own national malaria elimination programme. Thereafter it was highlighted as an effective surveillance model in WHO's Malaria Surveillance, Monitoring & Evaluation: A Reference Manual (2018).

Source: Bill & Melinda Gates Foundation

“Because of its specificity and selectivity, ADCs have the potential to reduce adverse side effects and improve patient survival”

« **Koichi Morino,** Managing Director, Daiichi Sankyo, Singapore

Japan-headquartered Daiichi Sankyo, the global healthcare company, launched its subsidiary Daiichi Sankyo Singapore Pte. Ltd. to bridge unmet needs in oncology. The new Asia Pacific regional hub will be a centre of excellence, providing excellence in Research & Development, Pharmacovigilance, Medical Affairs and key processes and systems across the region. The Singapore subsidiary will be home to the RDPV QA (Research & Development, Pharmacovigilance, and Quality Assurance) function. In addition, the Singapore subsidiary will focus on antibody-drug conjugates (ADCs), a class of drugs that offer targeted precision and potent drug delivery to certain tumour types. ADCs deliver potent cancer-killing agents directly to cancer cells to eliminate them, whilst limiting damage to healthy surrounding cells. Koichi Morino, Managing Director at Daiichi Sankyo Singapore shares more details with BioSpectrum Asia. ***Edited excerpts:***

How does Daiichi Sankyo leverage antibody-drug conjugates (ADCs) to execute precision therapeutics?

Daiichi Sankyo has a proprietary ADC technology called DXd. Daiichi Sankyo’s portfolio currently consists of six DXd ADCs in clinical development across multiple types of cancer, with one of them now in commercialisation. Each of our Daiichi Sankyo DXd ADCs pairs deruxtecan, our unique, stable linker and potent payload with a monoclonal antibody. This allows for versatility across a wide range of cancer types, each directed toward a specific antigen on the surface of cancer cells.

Engineered with precision, our DXd ADC technology has seven distinct features including a unique, high-potency payload, optimised drug-to-antibody ratio and a stable, selectively cleavable linker. DXd ADCs induce selective tumour cell death and are specifically designed to reduce systemic exposure to the payload. The released payload is cell membrane permeable, enabling a bystander antitumor effect resulting in the elimination of cells expressing the tumour-associated antigen and neighbouring cells in the tumour.

Where do your clinical development portfolios stand presently, and how do you perceive the commercialisation perspectives?

We are tackling some of the most challenging diseases, with the highest unmet medical needs through innovative treatment modalities in oncology and within these disease areas, we want to go beyond making incremental differences – we want to transform clinical practice and truly redefine standards of care.

Our over 120 years of heritage in pioneering science, starting from the first adrenaline crystalised and the first discovery of vitamin B1 in the early 1900s, inspires us to rise to new challenges with continuous innovation. To date, we have over 15 novel compounds in development across multiple types of cancer in more than 70 clinical trials, primarily focused on breast and lung cancer initially, but also exploring gastric, ovarian, prostate, and haematological cancers, with oncology compounds that are targeting HER2, TROP2, HER3, B7-H3, CDH6, EZH1/2, and FLT3-ITD.

In the near term, we are focused on delivering five DXd ADCs. Our longer-term innovation will come from our post-DXd ADC platforms and new technologies beyond ADCs in oncology to deliver cancer treatments for a sustainable society and company. But we cannot do all this on our own. Success relies on partnership – between our people, scientists, researchers, health care providers, payers, policy decision-makers, advocates, and patients and we are grateful for the support of our partners who are working to enable rapid delivery of these medications to patients who

need them the most.

In Singapore, we are a part of nine global clinical trials across breast cancer, gastric cancer and non-small cell lung cancer, with the potential to expand to other tumour types. The first medicine to emerge from our significant Research and Development efforts – the HER2-directed ADC called ENHERTU – has already received approval in Singapore for indications in selected types of breast, gastric and lung cancers.

How can DXd ADC technology improve cancer management?

Our DXd ADC technology, developed in-house, has led to new hope for thousands of patients – and has begun showing impact on changing the standards of care. DXd ADC portfolio, which offers an updated view into the clinical activity of these potential medicines for patients with various types of advanced or metastatic non-small cell lung cancer.

DXd ADCs are a result of a passion project from our dedicated scientists and ultimately, we bring that same passion to all of our innovative endeavours. Because of its specificity and selectivity, ADCs have the potential to reduce adverse side effects and improve patient survival and well-being.

Our lead DXd ADC medicine alone has earned multiple breakthrough therapy designations and standing ovations at ASCO. Furthermore, pioneered HER2 low BC and HER2 mutant NSCLC as new clinically meaningful patient segments, revolutionising treatment for patients that previously did not have a HER2-directed treatment option available.

DXd ADCs have demonstrated clinical benefit in multiple tumour types and have the potential to transform the health outcomes for people living with cancer.

How will the new RDPV QA set up in Singapore contribute to the APAC pharma sector?

As part of the Daiichi Sankyo Quality Assurance organisation, the newly set up RDPV QA (Research & Development, Pharmacovigilance, and Quality Assurance) function in Singapore is a strategic way forward to reinforce our commitment to patients, customers, and rigorous quality assurance in all that we do. This Asia Pacific regional hub will be a centre of excellence, driving the mission of 'Patient first, Quality Always' while ensuring the highest quality standards in Research & Development, Pharmacovigilance, Medical Affairs and key processes and systems across the region.

Our DXd ADC technology, developed in-house, has led to new hope for thousands of patients – and has begun showing impact on changing the standards of care. DXd ADC portfolio, which offers an updated view into the clinical activity of these potential medicines for patients with various types of advanced or metastatic non-small cell lung cancer. DXd ADCs have demonstrated clinical benefit in multiple tumour types and have the potential to transform the health outcomes for people living with cancer.

With the launch of the Daiichi Sankyo Singapore entity, what would be the impact on the oncology market in Singapore?

In November 2021, Daiichi Sankyo announced the establishment of its wholly-owned subsidiaries in Australia, Canada, and Singapore. With the establishment of these three subsidiaries, there are now 27 countries in which the Daiichi Sankyo group of companies are present. The subsidiaries will contribute to healthcare in countries where Daiichi Sankyo operates and strengthen the foundation for its global business, including oncology products. In addition to our current portfolio of medicines for cancer and cardiovascular disease, Daiichi Sankyo is primarily focused on developing novel therapies for people with cancer as well as other diseases with high unmet medical needs.

Continuing the efforts, the Daiichi Sankyo Singapore will be dedicated to bridging unmet needs in oncology. We hope to extend and improve the lives of cancer patients, with cancer accounting for almost 30 per cent of all deaths in Singapore. The launch has strengthened Daiichi Sankyo's commitment to creating new employment and treatment opportunities in Singapore while bringing forward new methods of drug delivery to the oncology market.

In the first few years of our launch, our focus will be to make sure that we are reaching out to partners and collaborators so that we can better understand and highlight patient voices and needs, as well as work together with partners and the relevant stakeholders to bring faster access to cancer medicines in Singapore. BS

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“AI will be integrally involved in not only the diagnosis of cancer but also in determining the prognosis and best therapeutic option”

« **Sun Woo Kim,**
CEO,
Deep Bio, Korea

South Korea based Deep Bio, a pioneering artificial intelligence (AI) healthcare firm focused on cancer pathology, is making waves in the industry. Their recent involvement in the innovative CancerX initiative, part of the White House Cancer Moonshot programme, marks a pivotal moment. Spearheading advancements in deep learning and cancer pathology, Deep Bio aims to revolutionise cancer diagnosis and prognosis. Sun Woo Kim, CEO, Deep Bio sheds light on their transformative mission, AI-driven healthcare, data privacy, among others. ***Edited excerpts:***

What inspired Deep Bio to focus on developing in vitro diagnostic software for cancer pathology?

With the advancement of AI like deep learning, AI can distinguish images and classify them for the first time, just as the human eyes can. I found that cancer detection and diagnosis were very subjective at that time. Pathologists have difficulty providing the exact tumour measurements using a microscope because human pathologists estimate the tumour area and provide the proportion of cancer information. Moreover, interobserver and intraobserver variability in the grading of tumours can impact therapy selection and patient outcomes. It would be good to apply AI technology for cancer pathology for accuracy and consistency.

How does Deep Bio leverage deep learning in its in vitro diagnostic software for cancer pathology?

Identifying diverse tissue morphological patterns related to tumour malignancy, differentiation levels, and prognosis in cancer pathology is crucial.

Deep learning proves highly effective in recognising specific patterns within large datasets, as demonstrated by its surpassing human recognition in the ImageNet challenge.

Leveraging this capability, Deep Bio is developing in vitro diagnostic software for cancer pathology. This software employs deep learning-based image analysis for various tasks, such as identifying tissues and cancerous lesions, distinguishing between cell nuclei and cell membranes, classifying and grading histologic tumour types, estimating gene mutations, and predicting patients' prognoses.

The goal is to enhance the precision and efficiency of cancer diagnostics by harnessing the power of deep learning to analyse intricate tissue patterns and provide valuable insights into various aspects of cancer pathology.

What are some of the challenges that Deep Bio has faced in developing and implementing its AI healthcare solutions?

The efficacy of deep learning hinges on access to substantial datasets to achieve high accuracy. However, acquiring such extensive datasets challenges medical data and sensitive personal information.

This difficulty is compounded by the intricate nature of obtaining significant annotation data from pathology experts for various organs and cancer types. The demand for pathological diagnosis is rising while the number of pathologists is declining, exacerbating the challenge of building comprehensive datasets.

Complicating matters further is the issue of inter-observer variability, making both data collection and performance evaluation exceptionally challenging. To address these complexities, our diagnostic AI applications undergo rigorous comparisons with pathologists, measuring accuracy and speed.

The expectation is that these AI applications will match and surpass pathologists in terms of accuracy and speed, meeting user expectations. Achieving this while ensuring cost-effectiveness poses a formidable engineering task, requiring innovative solutions to overcome the hurdles associated with limited data

access, inter-observer variability, and the evolving landscape of pathology demands.

What collaborative efforts does Deep Bio engage in with healthcare providers or institutions to implement and refine its technology solutions?

Deep Bio's medical AI solutions are developed based on extensive medical data and expert knowledge. Collaborating with healthcare professionals, particularly pathologists, is indispensable for developing and delivering optimal solutions. We engage closely with domestic and international healthcare institutions and pathologists to ensure compliance with data regulations, construct essential datasets, assess performance, and pinpoint areas for refinement. Our principal collaboration entails partnering with providers of digital pathology platforms to ensure the stable delivery of our solution and perpetually enhance its efficacy through resolving engineering challenges.

How does Deep Bio address concerns regarding data privacy and security when dealing with sensitive patient information?

Deep Bio implements strict data security measures to prevent unauthorised access to medical data. Our research systems operate on segregated networks, and access to research data is restricted to designated researchers; We hold ISO 27001 certification for our information security management system.

Deep Bio's solutions feature robust security measures in line with the South Korean Ministry of Food and Drug Safety (MFDS) cybersecurity checklist. For example, all data communication is encrypted, and unauthorised access attempts are promptly blocked. Our cloud services comply with HIPAA regulations, ensuring secure storage, transmission, and processing of protected health information (PHI).

How does Deep Bio perceive the current and future trends in AI-driven healthcare, particularly in the context of cancer pathology?

Deep Bio perceives the current and future trends in AI-driven healthcare, particularly in cancer pathology, amid a notable shift from analog to digital pathology. This transformation involves moving from traditional glass slide reviews to evaluating digitised images captured by high-definition scanners viewed on computer monitors.

This change allows pathologists to conduct remote reviews, fostering accessibility for patients in underserved areas. Concurrently, it fuels the development of AI-assisted pathology, utilising digitised images to train algorithms that assist pathologists in making more accurate diagnoses, prognoses, and predictions of therapeutic responses.

Deep Bio anticipates digitising nearly all pathology cases in the envisioned future. These digitised images would play multifaceted roles, serving as pre-screen analyses before pathologist reviews, real-time support during consulting reviews, or post-sign-out quality control (QC) reviews to detect misdiagnoses or discrepancies. This trajectory reflects a broader trend of seamlessly integrating AI into healthcare workflows, enhancing diagnostic precision, efficiency, and accessibility in cancer pathology.

Are there any upcoming projects or products that you are particularly excited about?

We believe that AI will be integrally involved in not only the diagnosis of cancer but also in determining the prognosis for the patient and predicting the best therapeutic option – essentially, the realm of precision medicine. In the case of prostate cancer, many men do not require definitive treatment and are candidates for surveillance. AI can be used to identify those cases that may require more definitive therapy versus those that can be safely monitored. Much of this will be done based on the analysis of morphologic images captured from the hematoxylin and eosin (H&E) stained slides. In addition, the future holds a more comprehensive integration of AI, incorporating additional layers of information such as genetic sequencing data and population or metadata. This holistic approach aims to significantly improve the precision and effectiveness of diagnosis, prognosis, and predictive medicine.

As for our expansion plans, our DeepDx Prostate product is CE-marked for distribution throughout the European Union. In addition, our DeepDx Prostate product is available through our channel partner's image management systems (IMS). Many image management vendors are already embedded within hospitals and pathology labs worldwide. So, one mechanism for widespread adoption is to make our algorithms available across multiple platforms. We currently have various customers in the United States that utilise our algorithm as a Laboratory Developed Test (LDT). These laboratories have rigorously validated our algorithm in their laboratories under Clinical Laboratory Improvement Amendments (CLIA). Over the next several months, we will add channel partners and expand our distributor network worldwide. BS

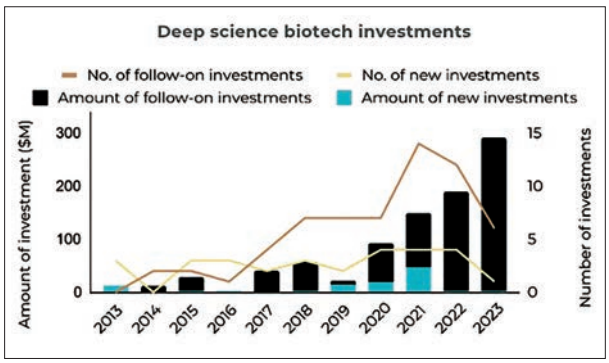
Ayesha Siddiqui

How Indian Biotech Investments are on a Doubling Spree

« **Suraj Nair,**
Lead, TechSprouts,
Ankur Capital

A latest report by Ankur Capital provides a closer look at the investments made in biotechnology in the last decade in the country. Several first-generation startups in India in the biotechnology sector are at the stage of scaling up their technology and the next few years will define their success as well as the success of the industry as a whole.

Biotechnology has emerged as one of the key technology enablers of the 21st century, disrupting traditional agri-food systems, diagnostics and therapeutics industries as well. As per the recently published India Deep Science Tech Report by Ankur Capital, more than $900 million were invested into breakthrough deep science biotechnology startups between 2013 and 2023 in India. Driven by a need to develop solutions against COVID-19 and Antimicrobial Resistance (AMR), the period between 2020 and 2023 saw growth stage investments into multiple diagnostics as well as therapeutics startups to scale their solutions.



Source: India Deep Science Tech Report

The past two decades have seen three key breakthroughs which have paved the way for biotechnology-led solutions to become a reality.

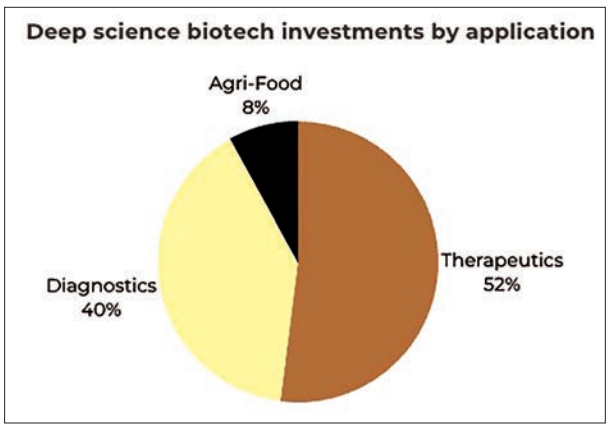
Next Generation Sequencing: Faster sequencing of genomic information (whole genome, exome, and genes) has led to an explosion of genomic data and novel biomarkers.

The cost of sequencing has fallen even faster than the exponential increase of computing power dictated by Moore's law.

CRISPR gene editing: The 2012 discovery of the CRISPR-Cas9 genome-editing toolkit opened doors for highly targeted genetic modifications to address challenges in therapeutics, diagnostics as well as other industries.

AI-based multi-omic modelling: New machine learning and deep learning models such as AlphaFold for protein sequences, and structures is accelerating the discovery of novel Biomolecules.

The therapeutics industry has seen a shift in the last few years towards biotechnology-based products. Monoclonal antibodies such as Humira and Keytruda are some of the largest selling drugs in the world with sales of $14 billion and $24 billion each in 2023. Four of the top six biopharmaceutical products sold worldwide were large molecules such as antibodies, mRNA vaccines and peptides. The availability of genomic data and relevant biological DNA/RNA/protein disease markers have made personalised medicine such as cell and gene therapy a reality. India, which has traditionally been a large market for biosimilars and bio better drugs, has also seen an uptick in novel drug development over the last decade. Companies such as Bugworks, Zumutor Biologics, Eyestem Research, ImmunoACT are developing novel biological products and have taken significant strides towards commercialising their products. Eyestem is developing a scalable cell therapy solution for treating Dry-AMD (Age-related Macular Degeneration). Zumutor has received IND approval for its first-in-class anti-LLT1 monoclonal antibody against prostate cancer, B-cell lymphoma and Glioma.



Source: India Deep Science Tech Report

Scaling up in biotech is another challenge. Processes need to be optimised at different scales, purification needs to be standardised and product characteristics have to be studied before commercialisation. Several first-generation startups in India are at the stage of scaling up their technology and the next few years will define their success as well as the success of the industry.

Molecular diagnostics came of age in 2020 and was the technology of choice to diagnose COVID-19 at an early stage. Novel DNA amplification and editing enzymatic systems such as Cas-9 are now being used to develop highly sensitive and specific molecular diagnostics solutions for early diagnosis of infectious diseases, cancers and other life-threatening diseases. MolBio Diagnostics, which has developed a Truelab Real-Time quantitative micro PCR system became the first molecular diagnostics company in India to be valued at over $1 billion. Startups such as DNome, CRISPR Bits, and Adiuvo Diagnostics are developing disruptive molecular diagnostics solutions, using protein engineering, synthetic biology and advanced gene editing technologies.

India is emerging as a manufacturing hub for specialty chemicals, an industry valued at $32 billion. The industry is looking for sustainable process alternatives to meet its net zero targets, and biological processes using either fermentation or enzymes are a viable solution. Startups such as Quantumzyme, KCat Enzymes, and Fermentech Labs are developing novel enzymes to replace the existing chemical-based processes while also improving the conversion efficiencies and reducing the carbon footprint of the processes.

The opportunities are massive, but challenges exist. Grants like Biotechnology Industry Research Assistance Council (BIRAC) - Biotechnology Ignition Grant (BIG), and Startup India help in the early stage of product development and prototyping, however, private venture capital is still relatively nascent in the country. While seed-stage capital for early technological derisking has been readily available of late, later capital at the Series A stage and beyond has been limited to a few key sectors and investors. Secondly, there is limited participation from domestic corporates and strategic investors. Regulations also need to keep pace with technological advancements. Finally, startups particularly at the early-stage face challenges in attracting key personnel who can drive engineering, strategy and sales. There is a need for techno-commercial talent from the industry to take the plunge and join these startups to accelerate commercialisation.

Engineering Derisking & Tech

Biotechnology companies need to have technology-derisking strategies before commercialising the products.

As a biotech company scales, its innovation is approaching market-readiness. At this point, the company's priority is to secure early revenue; to do so, the company needs to show efficacy and economic viability at the scale of real-world deployment as well as in manufacturing. This usually involves engineering de-risking. In some cases, the product will also need to go through regulatory or qualification processes, extensive clinical trials, third-party pilot validation and IP protection for the core technology before market readiness. Companies such as String Bio, after developing the products at the lab scale or at 50 litre fermenter capacity, have carried out extensive pilots for their products in the fields as well as in collaboration with reputed universities to generate pilot field data on the performance of the products. The company also has 15 granted patents with another 38 filed, showcasing a robust patenting strategy for their technology.

Scaling up in biotech is another challenge. Processes need to be optimised at different scales, purification needs to be standardised and product characteristics have to be studied before commercialisation. Several first-generation startups in India in the biotechnology sector are at the stage of scaling up their technology and the next few years will define their success as well as the success of the industry as a whole. BS

Chief Minister of Telangana, A Revanth Reddy, along with Western Australia's Minister for Health and Mental Health Amber-Jade Sanderson, industry leaders and dignitaries unveiling EY Parthenon's report entitled "From volume to value: Indian pharma's transformation with data and AI" at the 21st edition of BioAsia 2024 held in Hyderabad.

BioAsia 2024

Ushering Fourth Industrial Revolution in Telangana

Taking advantage of the 21st edition of BioAsia 2024 at the Hyderabad International Convention Centre (HICC) in Madhapur, the Government of Telangana, a southern state in India, leveraged the confluence of the global platform to spearhead initiatives aimed at propelling the state into the forefront of the Fourth Industrial Revolution (C4IR).

Termed as Asia's largest life sciences event, BioAsia 2024 showcased the convergence of pharma, biotech, healthcare and other allied companies adopting new cutting-edge technologies such as Artificial Intelligence (AI) and Big Data Analysis, catalysed fostering partnerships, collaborations, and new investments in the industries.

The three-day global bio event starting from February 26, was marked by the presence of more than 200 leading delegates from across 50 countries including, the USA, UK, France, Germany, Canada, Switzerland, and Australia, among others. The event also witnessed a footfall of over 10,500 participants from across various pharma, biotech, healthcare and other allied sectors.

Telangana Chief Minister Revanth Reddy, who inaugurated the BioAsia event made a significant announcement about the unveiling of the Genome Valley Phase-II expansion on February 27, the second day of the event. The Genome Valley project which is proposed to come up over an extent of 300 acres is expected to attract Rs 2000 crore investment. The facility is set to span across Greenfield pharma clusters located in Vikarabad, Medak, and Nalgonda districts. Highlighting the project's significance, CM Reddy accentuated its strategic placement near the Hyderabad International Airport, highlighting the convenience it provides for global entrepreneurs.

This ambitious venture apart from attracting thousands of crore rupees of investment is also expected to generate employment opportunities to 500,000 individuals in the state.

The second day of the event witnessed leading international speakers Amber Jade Sanderson, Minister of Health, Government of Western Australia, Dr Christopher Boerner, CEO of Bristol Myers Squibb (BMS), Professor Greggg Semenza, Nobel Laureate from Johns Hopkins School of Medicine and Dr Rod Hochman, President and CEO of Providence delivering the keynote address.

The Genome Valley Excellence 2024 Award, presented to Nobel Laureate Professor Gregg L Semenza, further underscores the Government

of Telangana's commitment to encouraging the scientific community striving to advance healthcare and life sciences.

The event witnessed the highlights of the ground-breaking research work of Prof. Gregg Semenza. His discovery of hypoxia-inducible factor 1 or HIF-1 protein that controls gene expression in response to the fluctuations in oxygen availability attracted the attention of industry leaders and the scientific community present at the event. The pioneering research of Prof. Semenza is said to help understand the molecular mechanism of oxygen regulation and the pivotal role of the HIF proteins in treating diseases such as cancer, anaemia, blinding eye disease and cardiovascular diseases.

Outlining the state government industrial policies and initiatives taken up by the government to further encourage industries to set up their bases in Telangana, the Industries and IT Minister, D. Sridhar Babu, highlighted that the government is planning to create over 10,000 new job opportunities in health-tech, alongside nurturing emerging companies and startups in the sector. As part of this, the state government is moving with a plan to provide technical and professional skill training programmes to nearly 50,000 graduates over the next few years, equipping them with industry-ready capabilities to drive research, development, and manufacturing in the life sciences domain.

The BioAsia community also recognised the immense contribution of the startups which are coming up with innovative and new ideas to resolve the complex healthcare and other problems facing society. Of the noted more than 75 new startups floated across the country, BioAsia 2024 recognised five startups for their groundbreaking innovative contributions to healthcare.

Startups such as Plebc Innovations, ZedBlox ActiPod, UR Advanced Therapeutics, Descign, and Lamark Biotech were honoured for their incredible work in revolutionising healthcare access, technology, and patient care. These startups exemplify the transformative potential of technology in shaping the future of medicine and healthcare delivery.

Telangana as Investment Hub

BioAsia, which was launched way back in 2003, in the past 20 years had been an attractive platform for the Pharma, Biotech, Healthcare and Medical Tech companies not just from India, but also from across the globe. Ever since then, the forum has constantly increased its pitch and today has become a global conglomeration platform. Addressing the audience at the event, B P Acharya, former Secretary, Industries and Commerce, who was behind the creation of BioAsia said,"The event had now reached a stage where it has become a more mature global forum, attracting thought leaders and delving into the contemporary issues and new advancement by lead scientists, industry leaders, policymakers, regulators and partnering International players to bring out solutions not just to problems of Indian industry but also to the entire global community".

Overall, BioAsia has attracted a large number of international players to invest in Telangana over the past 20 years. Acknowledging this, Jayesh Ranjan, the Industries & Commerce Department, Principal Secretary, said, "BioAsia has played a vital role in showcasing the Telangana state's solid industrial infrastructure to the global community which in turn had helped attract a large chunk of global investment to the state in the past two decades".

Highlighting Telangana state's emergence as a prime investment hub, Chief Minister Revanth Reddy, urged investors to explore opportunities beyond Hyderabad, particularly in Tier-2 cities. With initiatives like the Regional Ring Road project (RRR) and the development of transport infrastructure, the state government is committed to facilitating seamless operations for domestic and international organisations.

In a testament to Hyderabad's appeal as a destination for investment, the Chief Minister of Telangana also highlighted the substantial investments garnered during the recent World Economic Forum at Davos, amounting to Rs 40,232 crore.

Notably, he welcomed the collaboration between Japanese multinational pharmaceutical company Takeda and Indian vaccine maker Biological-E to produce five crore Dengue vaccine doses annually, further enhancing Hyderabad's reputation as a

Top 5 Startup Awardees

1. **Plebc Innovations Pvt Ltd:** Revolutionising healthcare access in rural areas with their teleoperated robotic ultrasound system.
2. **ZedBlox ActiPod:** Leading the way in unbreakable cold chain solutions for healthcare.
3. **UR Advanced Therapeutics Pvt Ltd:** Innovating biomaterials for tissue engineering, focusing on endoregenerative cornea.
4. **Descign:** Powering life sciences and healthcare with their AI-enabled digitalisation platform.
5. **Lamark Biotech:** Bringing life-saving medicines within reach globally.

Indian Pharma's Evolution with Data and AI

EY Parthenon (EY-P), a premier strategy consulting firm, joined hands with BioAsia to unveil a groundbreaking report entitled "From volume to value: Indian pharma's transformation with data and AI". This report heralds the profound impact of Gen AI on revolutionising drug discovery, R&D, and pharmaceutical operations.

Signifying a pivotal shift in India's pharmaceutical landscape, the report underscores the convergence of data and Artificial Intelligence (AI) as a catalyst for unprecedented advancements. By embracing these transformative technologies, India is poised to lead global pharmaceutical innovation, fostering a resilient ecosystem for industry growth.

Suresh Subramanian, Partner & National Life Sciences Leader at EY Parthenon India, emphasised the seismic impact of Gen AI, citing projections that it will contribute $4-5 billion to the Gross Value Added (GVA) of the Indian pharma sector by 2030.

Gen AI's transformative potential extends beyond patient care, impacting various facets of healthcare such as R&D, manufacturing, and supply chain management. However, amidst these gains, ensuring robust data governance and regulatory compliance remains paramount.

Shakthi Nagappan, Director of Life Sciences, Government of Telangana, and CEO of BioAsia, lauded the transformative era of Data and AI in healthcare. This technological fusion is revolutionising drug discovery, clinical trials, precision medicine, and healthcare delivery mechanisms.

The report outlines key imperatives for Indian pharma's transformation with data and Gen AI, including leveraging AI in drug discovery, shifting to value-centric R&D, building resilient supply chains, and embracing digital upgrades in manufacturing, quality, and compliance.

By harnessing Gen AI's capabilities in reshaping R&D through Machine Learning (ML) and Natural Language Processing (NLP), Indian companies are accelerating drug development for various diseases, including cancer, Alzheimer's, and rare diseases.

Furthermore, Gen AI offers opportunities for early-stage development cost savings, target identification, pharmacology analysis, and safety monitoring, positioning India as a frontrunner in pharmaceutical innovation.

To bolster India's pharmaceutical sector by 2030, the report emphasises the need for large-scale plant setups, reduced human intervention, and embracing Industry 4.0 technologies to ensure high-quality standards and manufacturing efficiency.

In conclusion, the report paints a picture of a transformative future where data and AI converge to unlock unprecedented possibilities, positioning India at the forefront of global pharmaceutical advancements.

leading vaccine production hub of the world.

In a strategic move, Queensland-based Southern RNA forged a partnership with DKSH to expand into the Indian biotech market, showcasing the growing relationship between the Australian and Indian biotechnology sectors. This collaboration announced at BioAsia 2024, reflects the global significance of the event as a platform for driving innovation, collaboration, and investment in the life sciences industry.

During a meeting held at BioAsia with Jeremy Jurgens, Managing Director, World Economic Forum & Head of the Forum's Centre for the Fourth Industrial Revolution, Chief Minister Revanth Reddy advocated for investments in not just pharma, biotech and healthcare sectors, but also encouraged investment in the agriculture sector in the state. Additionally, the Chief Minister unveiled the state government's initiative to develop digital health profiles for all residents, further underlining Telangana's commitment to leveraging technology for comprehensive healthcare solutions.

Furthermore, CM Reddy urged Didier Vanderhasselt, Ambassador of Belgium to India, to explore investment prospects in the green hydrogen sector. This initiative aligns with Telangana's vision for sustainable development and renewable energy solutions. Moreover, expressions of interest were received from industrialists keen on investing in the semiconductor sector. The Chief Minister provided assurances regarding the provision of requisite infrastructure, including land at affordable prices, to facilitate seamless operations and encourage investments in this burgeoning sector.

Overall, Telangana's initiatives at BioAsia 2024 have set the stage for the state to emerge as a leader in the Fourth Industrial Revolution, harnessing the power of technology and innovation to propel growth, create employment opportunities, and drive advancements in healthcare and life sciences. BS

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National University of Singapore builds partnership with universities in Vietnam

National University of Singapore (NUS) has signed a Memorandum of Understanding (MoU) with the Vietnam National University-Ho Chi Minh City (VNU-HCMC), Vin University (VinUni) and Hanoi University of Science and Technology (HUST) respectively, deepening its continued cooperation with the higher education sector in Vietnam to promote joint research, as well as greater collaboration in teaching, innovation and enterprise. The new partnership

between VNU-HCMC and NUS aims to provide pathways for VNU-HCMC students who have completed the first three years of their Bachelor's programmes, to pursue their Master's degrees at NUS. Those who demonstrate academic excellence will receive a scholarship to pursue a four-year doctoral programme at NUS, completing the entire academic journey in eight years. In Hanoi, VinUni and NUS inked an MoU for both universities to jointly expand learning opportunities for talented students through new academic pathways, engage in interdisciplinary research, particularly in the areas of smart cities and solutions for community health, as well as explore opportunities to exchange scientific and academic knowledge.

IIT-Guwahati strengthens international collaboration with Universities in Canada & Japan

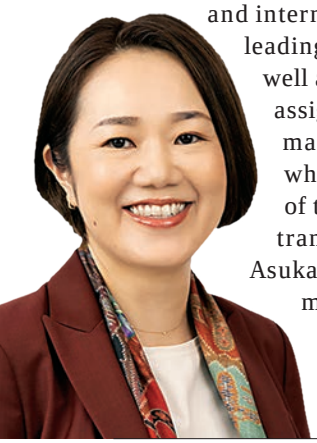
The Indian Institute of Technology (IIT) Guwahati has bolstered its global partnerships by signing four Memorandums of Understanding (MoUs) with renowned international educational institutions. On March 3, 2024, the institute took a significant step towards enhancing knowledge exchange by formalising collaborations with Dalhousie University, Canada and Gifu University, Japan. All the MoUs have been signed for a period of five years and may be further extended based on mutual understanding. The key highlight of the MoU with Dalhousie University, Canada, is to establish a Joint Doctoral Programme. This innovative collaboration marks the inception of joint doctoral programmes designed to foster dynamic research collaborations between scholars and students from both institutions. By facilitating exchange programmes for students and academic staff, fostering joint research activities, and promoting the sharing of research materials, this partnership aims to cultivate a rich academic environment conducive to ground breaking discoveries and academic excellence.

Samsung Biologics signs MoU with Seoul National University to foster bio experts

South Korea-based Samsung Biologics and Seoul National University (SNU) have signed a Memorandum of Understanding (MoU) to foster bio experts as part of industrial-academia collaboration. Under the MoU, Samsung Biologics and the School of Biological Sciences at SNU will establish a programme to nurture bio talent, as well as offer Master's scholarship for top performing undergraduate students and an opportunity to work at Samsung Biologics after completing their degree. The latest MoU is part of Samsung Biologics' efforts to strengthen the local bio talent pool and drive innovation. The company plans to expand collaboration with other universities that have bio-related majors.

Takeda Pharma appoints new President for Japan Pharma Business Unit

Takeda Pharmaceutical has announced that Asuka Miyabashira has been appointed as President of the Japan Pharma Business Unit (JPBU), effective April 1, 2024. Asuka was previously the head of the Neuroscience Business Unit within JPBU and a member of the JPBU leadership team. She will succeed Milano Furuta, who has become Takeda's new chief financial officer from April 1, 2024. Asuka will report directly to Christophe Weber, President and Chief Executive Officer, and will join the Takeda Executive Team (TET). Asuka started her career at Takeda 20 years ago and has served in roles of increased responsibility in marketing and medical in Japan and internationally. These include leading regional sales in Japan as well as important international assignments, such as country manager at Takeda Vietnam, where she led the development of the local business strategy and transformation. Prior to this role, Asuka served as business operation manager at Takeda Indonesia to build the foundation for Takeda Oncology's new product launch and access strategy.



Thermo Fisher names Devi Darmadi as Country GM in Indonesia

American firm Thermo Fisher Scientific will significantly expand local operations in Indonesia with the opening of its first official office. To lead its growth and operations in Indonesia, Thermo Fisher has appointed Devi Darmadi as the country's general manager (GM). In this role, Devi will spearhead strategic initiatives and go-to-market evolution, geared toward expanding the company's footprint in Indonesia. Devi has over 10 years of experience in product and sales management in the pharmaceutical and medical equipment industry, with a strong background in medicine and a bachelor's degree in medicine. Her core competencies include new business development, customer relationship management, analytical skills, and hospital operations. She has a proven track record of achieving significant revenue growth, exceeding sales targets, and expanding market share for leading global brands such as Philips and Johnson & Johnson.

Dr Darren Patti steps in as Group COO at Telix Pharma

Australia-based Telix Pharmaceuticals has announced the appointment of Dr Darren Patti as Group Chief Operating Officer (COO). Dr Patti joined Telix in March 2021 to lead the company's United States (US) operations. Over the past three years as US Chief Operating Officer & General Manager for the Americas region, he has overseen the successful launches of Illuccix in the US and Canada, has led ongoing market development for Telix in Brazil & the Latin America (LATAM) region, & has been a key figure in the launch preparations for Telix's follow-on imaging products Zircaix and Pixclara. Prior to joining Telix, Dr Patti held a variety of roles at Sofie Biosciences over a period of 15 years, most recently as Vice President of Operations leading the operationalisation of the Sofie-Lantheus PSMA-PET imaging programme. Dr Pattin's deep experience in radiopharmacy network management & operations, combined with an intricate understanding of the Telix business makes him the ideal leader for global operations function as the company expands into new commercial markets & bolster manufacturing capabilities to support therapeutic and imaging programmes.

Lubrizol names Bhavana Bindra as MD - India, Middle East and Africa

The Lubrizol Corporation, producing multiple grades of high molecular weight polymers for the pharmaceutical market, has announced the appointment of Bhavana Bindra as Managing Director (MD), India, Middle East & Africa (IMEA). The newly created role will support Lubrizol's aggressive growth goals and ongoing commitment to the region. With over two decades of experience in the manufacturing industry and working with renowned companies in this space like REHAU and Cummins India, Bhavana will apply her leadership and industry expertise to drive Lubrizol's growth in the region. As Lubrizol IMEA Managing Director, Bhavana will be responsible for leading the company's IMEA team to deliver regional growth for Lubrizol and its customers, based on a local-for-local approach. Bhavana will work closely with Lubrizol leaders across the company to support localised market opportunities and strengthen relationships with in-region customers, suppliers and stakeholders. She also will provide oversight of a new Global Capability Center in Pune, which will serve as a regional hub that enhances Lubrizol's capabilities for regional growth.

Jenny Zheng joins Illumina as Senior VP and GM of Greater China

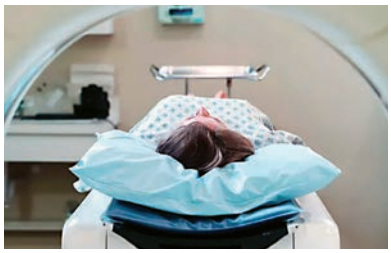
Illumina Inc., a global leader in DNA sequencing and array-based technologies, has announced that Jenny Zheng joins Illumina as Senior Vice President (VP) and General Manager (GM) of Greater China, and a member of the global executive management team. Jenny has more than 25 years of international experience in the healthcare and pharmaceutical sector. Prior to joining Illumina, she served as Chairman and President of Xian Janssen Pharmaceutical. In her multiple leadership tenure, she has led teams across countries and regional markets to achieve double-digit topline and bottom-line growth for her organisation, and managed multiple strategic projects' successful operations. During this time, Jenny has led an innovation-focused development strategy that has resulted in accelerated access and availability of innovative medicines.

Veeda Clinical Research appoints Dr Mahesh Bhalgat as Group CEO

Veeda Clinical Research has announced the appointment of Dr Mahesh Bhalgat as the Group Chief Executive Officer (CEO). Dr Bhalgat is an accomplished leader and professional with more than three decades of a successful career in developing business strategies, driving growth, spearheading multiple initiatives across several verticals, and managing operations in diverse businesses including Biopharmaceuticals, Vaccines, Contract Research Organization (CRO), Contract Development and Manufacturing Organization (CDMO), Agricultural Biotechnology, and Research reagents and services space. Dr Bhalgat has vast experience of being in senior leadership roles. Prior to joining Veeda, he was the Chief Operating Officer (COO) for Syngene International (Biocon Group Company). Prior to that, he was the COO and Executive Director for Sanofi in Hyderabad, where he was responsible for initiating the first-ever Indian manufacturing operation for injectable polio vaccine. Dr Bhalgat started his India career with Biological E, which he joined after 20 years in North America pursuing his study and working with multi-national drug development companies, which include Amgen and Monsanto and Thermo Fisher.

Australia designs 5-minute full body MRI scanner using AI

In a study published in Computers in Biology and Medicine, researchers at Monash University in Australia have shown how their novel artificial intelligence (AI) technology, McSTRA, outperformed state-of-the-art methods, producing enhanced clinical imaging in record time. Magnetic Resonance Imaging (MRI) scans can take up to 60 minutes, depending on the size of the area being scanned. The new software is capable of completing scans 10-times faster



than current MRI technology, giving it the potential to reduce scan times to just minutes and boost the number of patients accessing diagnostic services. If further validation of the method is successful, the researchers hope to see it incorporated by manufacturers into next generation MRI equipment for use in patient settings. McSTRA uses superior deep-learning technology to simultaneously enhance MRI image quality and enable unprecedented scan times. The study was a collaboration between researchers from Monash Biomedical Imaging and the Department of Electrical and Computer Systems Engineering at Monash University.

Korea develops medical waste sterilisation technology for hospitals

A medical waste treatment system, which is capable of 99.99 per cent sterilisation by using high-temperature and high-pressure steam, has been developed for the first time in Korea. The Korea Institute of Machinery and Materials (KIMM), an institute under the jurisdiction of the Ministry of Science and ICT, has succeeded in developing an on-site-disposal type medical waste sterilisation system that can help to resolve the problem caused by medical waste, which has become a national and social issue as the volume of medical waste continues to increase every year. This project was launched as a basic business support programme of KIMM and was expanded into a demonstration project of Daejeon Metropolitan City. Then, in collaboration with VITALS Co., a technology transfer corporation, the medical waste treatment system was developed as a finished product capable of processing more than 100 kilograms of medical waste per hour, and was demonstrated at the Chungnam National University Hospital. As the size and structure of the installation space varies for each hospital, installing a standardised commercial equipment can be a challenge.

Hong Kong invents non-invasive diagnostic device for chronic kidney disease

A team of scientists at the Department of Health Technology and Informatics at the Hong Kong Polytechnic University (PolyU), in collaboration with The Fifth Affiliated Hospital of Sun Yat-sen University, has invented Smart-CKD (S-CKD), a non-invasive computer-aided diagnostic tool. It integrates ultrasound data and selected clinical variables to provide clinical insights and assesses the risk of moderate-to-severe renal fibrosis progression in chronic kidney disease (CKD) patients with a promising diagnostic efficiency of 80 per cent. This device offers a cost-effective solution for guiding patient management, thereby contributing notable clinical advantages. By leveraging machine learning, S-CKD integrates three pivotal clinical parameters - age, ultrasonic renal length and end-diastolic flow velocity of the interlobar renal artery, to assist medical practitioners in assessing renal fibrosis risk in CKD patients during routine clinical practices. It plays a crucial role in guiding treatment decisions and improving patient prognosis. S-CKD is accessible through an online web-based platform or in offline document-based format, making it a user-friendly auxiliary instrument for flexible clinical applications.

Japan designs new tool to decipher gene behaviour

Scientists have extensively researched the structure and sequence of genetic material and its interactions with proteins in the hope of understanding how our genetics and environment interact in diseases. This research has partly focused on 'epigenetic marks', which are chemical modifications to DNA, RNA, and the associated proteins (known as histones). While researchers can identify and compare epigenetic marks, understanding the correlation between specific modifications and how genes work has remained challenging. To help overcome this, scientists at Kyoto University in Japan have created a new tool called epidecodeR. The user-friendly tool enables biologists to quickly check if a modification affects how a gene responds in specific situations. The team used statistical methods to categorise groups of genes based on how many modifications they had. They showed that EpidecodeR can predict the role of specific modifications, such as altering certain proteins or using drugs, and how these could impact gene activity. They also found epidecodeR to be effective in identifying substances that can block another protein, called RNA demethylase, and explored how changes in proteins called histones might be related to drug abuse.

Singapore develops ultra-thin semiconductor fibres for use in healthcare wearables

Scientists from Nanyang Technological University (NTU), Singapore have developed ultra-thin semiconductor fibres that can be woven into fabrics, turning them into smart wearable electronics. They have developed a mechanical design and successfully fabricated hair-thin, defect-free fibres spanning 100 metres, which indicates its market scalability. Importantly the new fibres can be woven into fabrics using existing methods. To demonstrate the feasibility of use in real-life applications, the team built smart wearable electronics using their newly created semiconductor fibres, such as a smartwatch. A smartwatch with a wrist band integrated with the fibres functioned as a flexible and conformal sensor to measure heart rate, as opposed to traditional designs where a rigid sensor is installed on the body of the smartwatch, which may not be reliable in circumstances when users are very active, and the sensor is not in contact with the skin. Moreover, the fibres replaced bulky sensors in the body of the smartwatch, saving space and freeing up design opportunities for slimmer watch designs.

India unveils new insights into working mechanism of cholesterol lowering drugs

An important study by researchers at the Indian Institute of Technology (IIT) Kanpur's Department of Biological Sciences and Bioengineering has led to new insights into understanding how cholesterol-lowering drugs like Niacin work at a molecular level. Utilising the cutting-edge cryogenic-electron microscopy (cryo-EM) technology, the team, led by Prof. Arun K. Shukla, was able to visualise the key target receptor molecule activated by Niacin and other related drugs. The research, which has the potential to lead to the development of new drugs to lower cholesterol with fewer side effects, has been published in the international journal, Nature Communications. Niacin is a commonly prescribed drug to lower bad cholesterol and triglycerides while increasing good cholesterol. However, in many patients, the drug causes side effects such as skin redness and itching, referred to as flushing response.

Revvity introduces new workflow to accelerate newborn sequencing research

American firm Revvity, Inc. has announced the introduction of a flexible end-to-end workflow solution for newborn research, enabling users to utilise different instruments, reagents and databases based on a lab's needs. The research-use only (RUO) offering from Revvity culminates in analysis and report, covering essential steps in the sequencing process. The solution enables identification of variants in more than 350 genes, complemented by a large database of carefully pre-curated variants. The offering includes dried blood spot collection and processing devices, Chemagic kits and instruments for nucleic acid extraction, liquid handlers and reagents for library preparation, VICTOR2 D Instrument for sample quality control, and software capabilities. The workflow is compatible with the Element AVITI system and other leading NGS platforms.

Cytek Biosciences opens new facility in China for cell analysis solutions

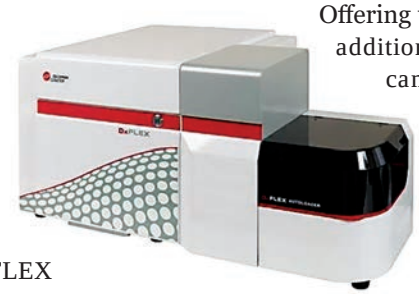
US headquartered Cytek Biosciences, Inc. has opened a new 50,000-square-foot facility in Wuxi, China. This strategic move increases the company's manufacturing capacity to meet the growing worldwide demand for comprehensive cell analysis solutions. The Wuxi facility offers the advantage of fostering unique vendor relationships and further facilitates Cytek to manufacture its own components, distinguishing the company from other industry players. In addition to bolstering Cytek's manufacturing capabilities, the facility also accommodates Cytek Wuxi operations, research and development, marketing, human resources, and sales teams. Recognised as a pioneer in spectral flow cytometry, Cytek is the creator of the first commercialised fluorescence-based flow cytometry platform to achieve 40 colours, effectively shifting the paradigm of what scientists thought was possible in flow cytometry. Cytek's portfolio of comprehensive solutions empower scientists, allowing them to go even further with their research, all with greater ease and shorter time to insights.

Shimadzu launches connected service business for diagnostic X-Ray imaging systems

Japan-based Shimadzu Corporation has launched Shimadzu Connected, a connected service business for diagnostic X-ray imaging system parts. Shimadzu Connected is the collective name for various businesses that generate recurring revenues from offering continuous service contracts, parts, and software licences to healthcare institutions that are Shimadzu customers and businesses that offer new service solutions based on the operating status of equipment at those customers. Shimadzu Connected businesses use technology for remotely monitoring the operating status of customer equipment. As a first step, Shimadzu will launch Smile guard, a service for replacing X-ray tubes before they fail. The service will be offered in Japan through Shimadzu Medical Systems Corporation, a subsidiary of Shimadzu Corporation. Under the service contract, Shimadzu will recommend the replacement of parts before they fail, based on the operating status of Shimadzu angiography systems for which at least one year has elapsed since the purchase date. From Spring 2025, Shimadzu plans to expand the Smile guard service by offering it in the United States and China regions and by including product lines other than angiography systems.

US FDA clears Beckman Coulter Life Sciences DxFLEX Flow Cytometer

Beckman Coulter Life Sciences, a global leader in laboratory automation and innovation, has received 510(k) clearance from the US Food and Drug Administration (FDA) to distribute its DxFLEX Clinical Flow Cytometer in the United States (US). Launched regionally in 2020, this advancement brings the popular benchtop IVD flow cytometry system to American labs while expanding testing capabilities.



Offering up to 13-colours, additional detectors can be activated as laboratory needs evolve without the need to purchase additional hardware. Praised for its superior sensitivity and resolution, the compact DxFLEX Flow Cytometer makes multicolour flow cytometry less complex by using avalanche photodiode (APD) detector technology instead of traditional photomultiplier tube (PMT) technology. The use of APD technology simplifies compensation procedures and delivers richer content analysis with higher sensitivity to find dim populations. By comparison, running compensation on a conventional PMT flow cytometer involves significant hands-on time, even when features like auto-compensation setup are available in the software.

MGI Tech and Eurofins Genomics elevate precision health with sequencer technologies

China-based MGI Tech has announced a milestone collaboration with Eurofins Genomics Europe Genotyping A/S, which has placed a corporate order of the revolutionary DNBSEQ-T20×2 (T20), ultra-high throughput sequencer, along with the genomics data centre ZTRON Appliance and a range of MGI's state-of-the-art laboratory automation products and systems. This marks the first corporate order of the T20 in the Europe region, signalling a significant advancement in precision health initiatives across the continent. Powered by MGI's proprietary DNBSEQT technology, T20 represents a breakthrough in genetic sequencing by significantly reducing sequencing costs to below $100 per genome when running 50,000 whole genome sequencing (WGS) per year, garnering global attention. Specifically designed to address the most challenging sequencing scenarios, T20 caters to a wide array of high-throughput sequencing needs in scientific and clinical research, including WGS, WGBS, stLFR, single-cell sequencing, Stereo-seq, and more.

Thermo Fisher opens new office in Indonesia

Thermo Fisher Scientific has significantly expanded the local operations in Indonesia with the opening of its first official office, signifying a key milestone as the company transitions from its current representative office to a larger workspace. Over the past year, Thermo Fisher has taken significant steps to strengthen its presence in Indonesia, including the establishment of a legal entity in the country. This strategic move aims to enhance customer proximity and deepen relationships with Indonesian stakeholders. The establishment of the new office in Jakarta is set to nurture local talent and support scientific advancements within the community. The company has previously also forged a strong partnership with National Research and Innovation Agency of Indonesia (BRIN, Badan Riset dan Inovasi Nasional) to strengthen research infrastructure and capabilities in the country.

Overcoming HIV DR with Vigilance & Surveillance

On March 5, the World Health Organization (WHO) released a HIV Drug Resistance (HIVDR) Report which stated that drug resistance is growing and issued recommendations for countries to monitor and respond to the potential challenges. The report highlights high levels of HIV viral load suppression (>90 per cent) in populations receiving dolutegravir (DTG)-containing antiretroviral therapy (ART). However, observational and country-generated survey data indicate that levels of HIVDR to DTG are exceeding levels observed in clinical trials.

The WHO has recommended use of DTG, since 2018, as the preferred first- and second-line HIV treatment for all population groups. It is more effective, easier to take, and has fewer side effects than other drugs currently in use. It also has a high genetic barrier to developing drug resistance. However, among the four surveys reported, levels of resistance to DTG ranged from 3.9 per cent to 8.6 per cent, and reached 19.6 per cent among people experienced with treatment and transitioned to a DTG-containing ART while having high HIV viral loads. To date, only a few countries have reported survey data to the WHO.

HIV remains a major global public health issue, having claimed 40.4 million lives so far with ongoing transmission in all countries globally; with some countries reporting increasing trends in new infections when previously on the decline. There were an estimated 39.0 million PLHIV at the end of 2022. In 2022, 630,000 people died from HIV-related causes and 1.3 million people acquired HIV.

The WHO noted that by 2025, 95 per cent of all people living with HIV (PLHIV) should undergo a diagnostic test, 95 per cent of those should be taking life saving ART and 95 per cent of PLHIV who are on treatment should achieve a suppressed viral load for the benefit of the person's health and to reduce onward HIV transmission. In 2022, these percentages were 86 per cent, 89 per cent and 93 per cent respectively.

The world has witnessed an unprecedented increase in the use of ART, which has saved the lives of tens of millions of people living with HIV/AIDS. At the end of 2021, 28.7 million people, out of an estimated 38.4 million PLHIV, were receiving ART globally. Increased use of HIV medicines has been accompanied by the emergence of HIV drug resistance – the levels of which have steadily increased in recent years.

The WHO has recommended oral preexposure prophylaxis (PrEP) as a prevention option for those at risk of acquiring HIV. In 2021, more than 1.6 million people received oral tenofovir disoproxil fumarate + emtricitabine (TDF + FTC) PrEP, and in the past two years the PrEP arsenal expanded to include two new ARV drugs recommended by the WHO: dapivirine containing vaginal rings (DPV-VR) and injectable long acting cabotegravir (CAB-LA).

The use of CAB-LA PrEP reduces the risk of acquiring HIV. However, there are concerns about the potential emergence of integrase-strand transfer inhibitors (INSTI)-resistant HIV. INSTI resistance has been observed in some cases with recent CAB exposure, and delayed detection and confirmation of HIV infection can increase the risk of selection of INSTI drug resistance–associated mutations. Despite the risk, the roll-out of CAB-LA PrEP should not be hindered. Since limited quantities of CAB-LA are anticipated to be available over the next 3–5 years, there is an opportunity to carefully monitor for the emergence of CAB drug resistance and to characterise the potential risk of DTG cross-resistance in well-defined populations using CAB-LA PrEP.

The introduction of DTG-containing regimens coupled with the expansion of PrEP for preventing HIV infection, including new drugs such as CAB-LA, promises to revolutionise HIV care and prevention. However, early signals of DTG resistance among people for whom DTG-containing regimes fail to achieve viral suppression highlight the ongoing need for vigilance and intensified efforts to optimise the quality of HIV care delivery to maximise individual and population-level outcomes coupled with standardised routine surveillance of HIV drug resistance to prevent, monitor and respond to the potential threat of HIV drug resistance. BS

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