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the business of Bio & Health Sciences
ASIA EDITION

Volume 19 | Issue 5 | May 2024

What's APAC's Recipe of Success in CLINICAL TRIALS MARKET?

"We are exploring opportunities to collaborate with startups and incubators"
- **Padraig McDonnell, CEO-elect & Chief Operating Officer (COO), Agilent Technologies** - 37

Australia's quest for ethical AI - 32

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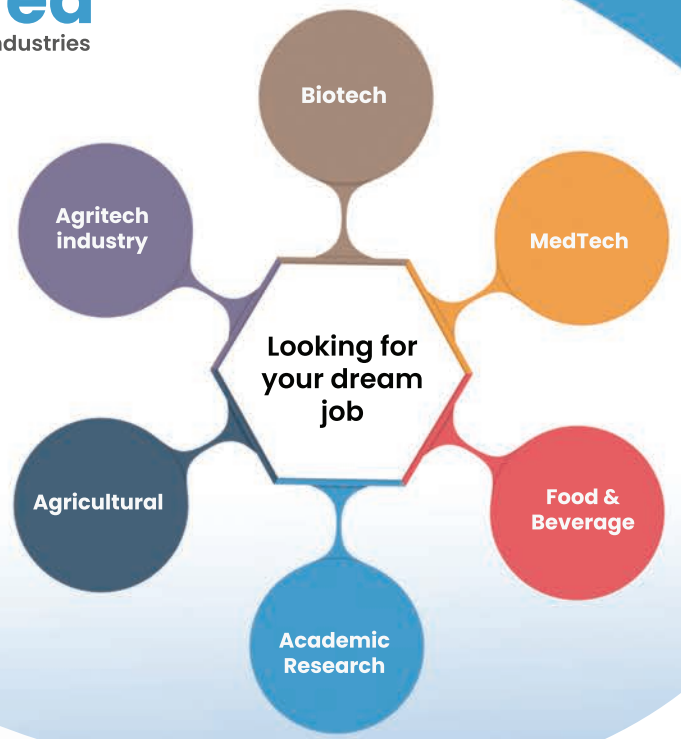

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Acknowledgement/ Feedback

Thank you for the interview feature on Deep Bio in the April 2024 edition.

- Diane, Korea

Biotech companies need to have technology-de risking strategies before commercialising products. Thank you for the feature on Ankur Capital.

- Suraj Nair, India

A challenge faced by cell and gene therapy startups as they scale up production is difficulty in hiring and retaining talent.

- Krishna Karnati, Singapore

Vol 19; Issue 5; May 2024

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Photo: istockphoto

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Printed and published by Ravindra Boratkar on behalf of MM ACTIV Singapore Pte Ltd.

Printed at Times Printers Private Limited
16 Tuas Avenue 5, Singapore 639340
Tel : +65-63112888

Reprinted in India for private Circulation

Chief Editor: Dr Milind Kokje

MCI (P) 028/06/2023

Letter from Publisher

Ravindra Boratkar
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Communications Pvt. Ltd.

Dear Readers,

The APAC region remains the dominant player in clinical trials, with rapidly outpacing growth rates in comparison with the US and Europe. The region is emerging as a major clinical trial hub and about half of all studies worldwide are currently carried out in the region, according to various reports. Pre-stage trials are increasing; these were formerly thought to be the hub for late-stage international trials. In terms of cumulative annual growth rates, the APAC region outgrew both Europe and the US by four times between 2013 and 2022, making it the fastest-growing market for early-stage clinical trials.

By 2022, APAC accounted for 58 per cent of all global phase I clinical trials. This indicates higher levels of innovation within the region, focusing on the development of novel therapies. Our team has put together an overview story on the clinical trials landscape in the APAC region as the lead for this issue touching upon various aspects such as regulatory issues, adoption of technology, focus areas for CROs, and enhancing reach through networking, as the region offers lucrative opportunities for all stakeholders to innovate and grow.

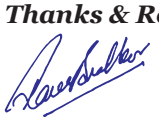
Recognising the potential of AI in the public health system, Australia has established a new task force dedicated to guiding its use. The country has also launched a National Policy Roadmap for AI in Healthcare that identifies current gaps in Australia's capability to translate AI into effective and safe clinical services. Our team has covered an article that unearths Australia's initiatives to promote the appropriate and ethical application of AI in healthcare and life sciences space.

While global expansion is a natural trajectory for any startup, expanding into international markets is not easy. Biotech startups face numerous challenges worldwide, including policy, regulatory, talent, technology, and cash flow obstacles. Touching upon how these issues can be overcome, to create a market for Asian biotech startups in the developed world, namely the US and Europe, our correspondent has covered a story noting that scaling up is essential to fulfill their commitment of delivering innovative medicines to patients. By cultivating local expertise and navigating regulatory landscapes adeptly, these companies can effectively address unmet medical needs and make significant contributions to healthcare globally.

Cell and gene therapies continue to revolutionise the field of medicine, offering new treatment options for patients with various diseases that, by type of disease or severity, were considered untreatable until a few years ago. The domain experts in an article pointed out that CAR-T therapy is poised to make a significant impact on the lives of more patients with improved treatment options as companies are expected to receive more approvals for their therapeutics in the near future.

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

Thanks & Regards,



Ravindra Boratkar
Publisher & Managing Editor

COVER 20

What's APAC's Recipe of Success in CLINICAL TRIALS MARKET?

Asia-Pacific (APAC) is emerging as one of the most promising and resilient markets for clinical trials. According to a report by Clinical Trials Arena, between 2017 and 2022, the region posted growth in clinical trials of around 10 per cent, outstripping growth in other major regions including the US, Europe and the rest of the world (RoW). Asia's growth far exceeded the overall average figure of 5.3 per cent per year. As of 2023, the number of trials reached 14,346 in APAC. Let's delve into the thriving clinical research landscape in the region and explore the trends driving its growth.

Australia & AI

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CAR-T Therapy

Dr Davide Garrisi,
Vice President, PPD Cell and Gene Therapy Institute

Dr Kim Watanabe,
Executive Director,
Cell and Gene Therapy, PPD Cell and Gene Therapy Institute

REGULARS

UNCLE SAM TAKES ON THE DRAGON

Dr Milind Kokje
Chief Editor
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The US-China tussle on the medicine turf continues with the issue of the US's dependence on China-produced Active Pharma Ingredients (APIs) and bulk drugs along with the phenomenal growth of Chinese biotech companies compared to the US. Moreover, American agencies are already concerned about the Chinese biotech companies gaining access to American genomic data.

The US House Energy and Commerce Oversight and Investigation sub-committee recently held a hearing on the Food and Drug Administration's (FDA) foreign inspection programme. Interestingly, names of Indian pharma companies appear in the tussle as they are suppliers of generic drugs to the US, but sourcing ingredients from China.

At the hearing, the FDA came under fire for a backlog of inspections of foreign drug makers. The sub-committee chief Morgan Griffith pointed out that the drugs and their bulk APIs in the US come from foreign countries, particularly in the case of generic drugs, Chinese and Indian manufacturers comprise a majority of facilities supplying the US market. India, too, is heavily reliant on China for bulk APIs. The US administration does not know the true number of medicines and bulk APIs coming from foreign manufacturers as per the admission of the FDA. A report by the Coalition for a Prosperous America before the hearing claimed that India-based Aurobindo Pharma, which supplies the most generic drugs by volume to the US, gets 55 per cent of raw ingredients from China. A sub-committee member has pointed out that till foreign facilities remain uninspected, they pose a risk to quality and safety. This is important since 58 per cent of drug makers supplying drugs to the US market are located abroad.

A major problem appears to be conducting unannounced and short-term notice inspections in China. The FDA performed a record number of inspections of manufacturing facilities in India and China. It postponed the inspections due to COVID-19-related public health concerns in 2020. Since March 2022, it has conducted 35 such inspections in India, but none in China. The bone of contention as per the US claim is that China is preventing the US-FDA officials from inspecting the facilities and also, the latter's new interpretation of National Security law that criminalises the sharing of routine business records, which the FDA requires for inspections.

Another major challenge seems to be the recruitment and retention of the overseas inspection workforce, despite the FDA's initiatives to boost recruitment. That is affecting the number and level of inspections. Sensing the growing tensions on the medical turf, even private companies have started considering producing drugs for two (the US and China) markets separately from one another. In a recently published interview with Bloomberg, AstraZeneca's CEO has said that the company is organising itself so that medicines to the US and Europe can be supplied to Chinese patients independently. This is due to geopolitical tensions threatening the disruption of pharma supply chains. The company has announced a $300 million cell therapy facility in the US and a $1 billion acquisition of Chinese CAR-T biotech Gracell Biotechnologies.

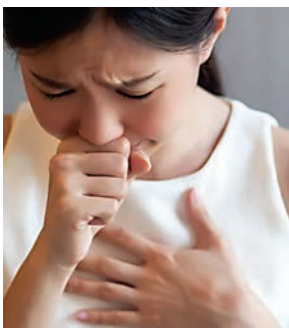
However, by unveiling a new drug initiative, the US administration has embraced India's strategy of diminishing China's dominance in APIs. As Sino-American bilateral relations deteriorate, the US is leaning towards India as it feels that the diplomatic relations are far more favourable than China. This can be an opportune time for Indian pharma to strengthen its presence in the US market further. However, it appears that the US wants even Indian companies to reduce their dependence on the Chinese APIs as well if they wish to export their drugs to the US. The process of Indian companies reducing dependence on China has begun to some extent, particularly due to the government's Production Linked Incentive (PLI) scheme, with the Indian companies producing APIs, key starting materials (KSMs) and intermediates. Still, self-sufficiency appears to have not reached a sufficient level. Proper steps in that direction may open more opportunities for Indian pharma and API-producing companies. Considering the proceedings at the recent sub-committee meetings, even more in-depth and unannounced FDA inspections are expected. BS

Korea to institute 4 healthcare reform tasks

The Ministry of Health and Welfare (MoHW), Government of the Republic of Korea has announced its 2024 Action Plan for Key Policies. This year, under the vision of "Healthcare Reform and Welfare for the Weak to Open up the Future," the Ministry will focus on implementing the four core tasks. The Ministry will increase the medical workforce by expanding medical school seats and innovating education and training, and overhaul delivery systems and networks to strengthen local healthcare. It will also build a medical accident safety net to reassure both physicians and patients, including the enactment of the Act on Special Cases Concerning Medical Accident, and inject more than KRW 10 trillion by 2028 for fair compensation for essential healthcare services. Second, the MoHW will implement Welfare for the Weak 2.0 to provide tighter yet wider protection. Third, the Ministry will increase patient care to reduce the burden on families. The Ministry will also build a tight-knit support system so that all citizens can access the care services they need. Fourth, the MoHW will secure future growth engines by innovating healthcare and welfare. The Ministry will reduce the burden of childbirth and childcare by increasing support for infertility and fertility tests, and expand the First Meeting Voucher and Parental Allowance for greater support for childcare expenses.

Singapore approves new asthma indication for GSK's Trelegy Ellipta

GSK Singapore has announced that the Health Sciences Authority (HSA) has approved a new indication and a new strength for Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol 'FF/UMEC/VI') for the maintenance treatment of asthma in patients aged 18 years and older who are not adequately controlled with a combination of a long-acting beta2-agonist (LABA) and an inhaled corticosteroid (ICS). This adds to its current license for use in patients with chronic obstructive pulmonary disease (COPD) and makes Trelegy Ellipta the first once-daily single inhaler triple therapy approved for use in both asthma and COPD in Singapore. This approval is based on the CAPTAIN study which has shown that in patients uncontrolled on ICS/LABA, the additional bronchodilation provided by Trelegy had demonstrated significant improvements in lung function compared with fluticasone furoate/vilanterol (FF/VI), in a single daily dose in an easy-to-use inhaler.



New South Wales government injects $5M for critical research to address Silicosis crisis

The New South Wales (NSW) government in Australia has committed $5 million in critical funding for silicosis research and a patient support programme for individuals and their families navigating the health risks associated with exposure to silica dust. Building on the world-first manufactured stone ban, the NSW Government delivers on its election commitment to support research which centres firmly on silica dust-related disease diagnosis, treatment and care. The grant funding, administered

collaboratively by icare and the Dust Diseases Board, will provide a total of $5 million over 3 years to the Asbestos and Dust Diseases Research Institute (ADDRI). This funding enables research into prevention, diagnosis, therapeutic procedures, and treatment of silica dust-related diseases with the aim of improving outcomes for people diagnosed with silicosis. icare, through the Dust Diseases Board, has grants programme which has delivered investment into dust disease research, including providing funding to the Asbestos Diseases Foundation Australia, the Lung Foundation Australia and research programmes at the University of NSW, the University of Sydney and the University of Technology, Sydney among others in financial year 2022-23.

Indonesia collaborates with Tanoto Foundation to improve primary healthcare services

The Ministry of Health of the Republic of Indonesia is collaborating with Tanoto Foundation to develop digital learning modules aimed at increasing the capacity of 1.5 million Integrated Health Post cadres (Posyandu) in mastering 25 basic competencies. These competencies include the ability to explain the use of Maternal and Child Health (Buku KIA) handbooks for parents of children under five, provide education on breastfeeding and age-appropriate complementary feeding, and improve interpersonal

communication skills to influence the positive behaviours to achieve better health. Tanoto Foundation also supports the acceleration of digital health transformation, especially in improving the Master Data Index to enable integration across systems and applications. Integration with the Aplikasi Sehat IndonesiaKu (ASIK) system is carried out to record health service results and monitor patients and programme participation in all primary care health units (such as community health centres, village health centres and Posyandu) with the SATUSEHAT national health management platform. This integration ensures that health services are increasingly targeted, especially in preventing stunting and improving maternal and child health.

India launches first home-grown gene therapy for cancer

President of India, Droupadi Murmu recently launched India's first home-grown and the world's most affordable gene therapy for cancer at the Indian Institute of Technology (IIT) Bombay. The launch of India's first gene therapy is a major breakthrough in the battle against cancer. As this line of treatment, named 'CAR-T cell therapy', is accessible and affordable, it provides a new hope for the whole of humankind. India's first CAR-T cell therapy was developed through collaboration between the Indian Institute of Technology, Bombay and Tata Memorial Hospital in association with industry partner ImmunoACT. CAR-T cell therapy is considered to be one of the most phenomenal advances in medical science. It has been available in the developed nations for some time, but it is extremely costly, and beyond the reach of most patients around the world.

IDB & Japan enhance digital health services in Latin America and the Caribbean

The Inter-American Development Bank (IDB) and the Government of Japan have joined forces to enhance digital health services in Latin America and the Caribbean through a $5 million contribution from Japan. This marks the first donation to the Pan-American Highway for Digital Health Initiative, led by the IDB, the Pan American Health Organization (PAHO), and countries from the region. The Pan-American Highway for Digital Health is focused on pandemic readiness and the continuity of healthcare building on the advances made further to the COVID-19 pandemic. Through the digitisation of clinical data, it promotes the interoperability and exchange of health information, allowing patients to access and share vital details such as vaccination status, allergies, diagnosis, or prescriptions whenever and wherever required. This fosters quality healthcare services by enabling health teams to make informed decisions regarding a patient's health, consider their medical history, and optimize regional resources. Additionally, this data can assist governments in making better decisions about the health of their population. Furthermore, the Pan-American Highway for Digital Health supports countries in joining the WHO's Global Digital Health Certification Network, which allows for the secure verification of health information.

Eisai divests its French rights of neurology drugs to CNX Therapeutics for € 56.5M

Japan headquartered pharma company Eisai Co. has announced that its French sales subsidiary Eisai S.A.S. has entered into an agreement to transfer the rights in France, the French Overseas Territories and Algeria for the antipsychotic, Loxapac (generic name: loxapine) and the Parkinson's disease treatment Parkinane LP (generic name: trihexyphenidyl hydrochloride) to CNX Therapeutics, based in UK. Following the signature of this agreement, a transition period had opened during which the required implementation steps will be carried out in order for CNX to become able to operate directly the business, including the regulatory steps for the transfer of the relevant marketing authorisations and exploitant status. Under the terms of the agreement, Eisai S.A.S. will receive 56.5 million euro as a lump-sum contract payment upon completing the transaction. Eisai anticipates no changes to its consolidated financial forecast for the period ending March 31, 2024.

Fujifilm to invest $1.2B to expand large-scale cell culture CDMO biz in US

Japan-headquartered Fujifilm Corporation has announced an investment of $1.2 billion in its large-scale cell culture contract development and manufacturing organisation (CDMO) business to further expand the planned Fujifilm Diosynth Biotechnologies end-to-end bio-manufacturing facility in Holly Springs, North Carolina, bringing the total investment in the facility to over $3.2 billion. The expansion adds significant large-scale production capacity to Fujifilm Diosynth Biotechnologies' global network through its United States (US) and Europe manufacturing hubs. The investment will generate an additional 680 jobs by 2031, also bringing the total number of new, highly skilled local jobs to 1400 in Holly Springs. The new investment in Fujifilm Diosynth Biotechnologies' large-scale cell culture facility in Holly Springs will add 8 x 20,000 liters (L) mammalian cell culture bioreactors by 2028, to the already planned 8 x 20,000 L for bulk drug substance as part of the initial investment. This new facility allows for flexibility to expand with additional bioreactors to accommodate new projects to meet the emerging needs of partners, and upon completion will make the site one of the largest cell culture biopharmaceutical CDMO facilities in North America.

Merck expands M Lab in Shanghai with additional €14 M investment

Merck, a leading science and technology company, has expanded its M Lab Collaboration Center in Shanghai, the company's largest in its global network of ten interconnected labs. The €14 million investment adds a new biology application lab, a process development training center and an upstream application lab to the existing M Lab Collaboration Center in Shanghai. Opened in 2020 and strategically located in Pudong, at the heart of the biomedical park in Shanghai, the M Lab Collaboration Center offers customisable solutions tailored for China's life science community to help advance drug development. It includes Pilot Scale and Process Development support labs that offer non-GMP (Good Manufacturing Practice) lab space where pharmaceutical and biopharmaceutical manufacturers can explore ideas, learn techniques and work side-by-side with the company's scientists and engineers to solve critical process development and production challenges.

Singapore supports development of AI-based clinical trial tool with S$50,000

A team of healthcare professionals has received a $50,000 award to transform their idea for an Artificial Intelligence (AI)-powered tool that can match cancer patients with the relevant clinical trials, into reality. They were taking part in the Duke-NUS Health Innovator Programme, a nine-month, first-of-its-kind fellowship in Singapore that assembles a multi-disciplinary team to solve healthcare problems while being guided by industry mentors. Team OncoPATH's project aims to improve clinical

trial accessibility and simplify referrals for local and regional cancer patients to the clinical trial team. The platform, OncoPATH, uses a Large Language Model to match cancer patients to suitable trials. Prospective patients are matched according to the information entered in a short questionnaire (i.e. diagnosis, stage of cancer, mutational profile and sites of disease). Interested patients can forward their details to register for the matched trial(s), and a formal consultation will be arranged at the respective healthcare institution. This year, which marks the second edition of the Duke-NUS Health Innovator Programme, saw five competing teams addressing clinical needs in the fields of "oncology and primary health".

Freudenberg India to invest Rs 350 Cr in 2024 for expansion & growth

Freudenberg India has announced significantly high sales at Rs 3803 crore for the financial year 2023. The operating result for 2023 has been robust and the group has announced investments close to Rs 350 crore in CY 2024 across facilities in Punjab, Karnataka and Tamil Nadu. In Morinda, Freudenberg has invested in a new production facility for its Vibracoustic Business Group and its Freudenberg-NOK India joint venture. The company exports close to Rs 800 crore from India. Freudenberg Group, a global technology conglomerate, which commemorates its 175th anniversary year in 2024, has reported record growth in revenues and operating profits for the financial year 2023. Freudenberg achieved sales of €11,902.8 million, 1.3 per cent higher than the previous year's figure of €11,753.1 million. Freudenberg Group has 11 companies operating across diverse segments such as medical products, automotive, chemical, energy, technical textiles, and cleaning products in the country.

Novo Nordisk invests ¥4 B in China for sterile preparation expansion project

Danish pharma firm Novo Nordisk has announced that it would invest approximately 4 billion yuan (¥) in Tianjin for a sterile preparation expansion project and recently held a groundbreaking ceremony for the expansion project. 2024 is the 30th anniversary of the establishment of Novo Nordisk China. Thirty years ago, Novo Nordisk took the first step to establish roots in China in Tianjin, building a Tianjin production plant and making it one of its global strategic production bases. In the first quarter of 2023, Novo Nordisk invested 1.18 billion yuan to launch a finished product workshop expansion project and introduced a prefilled injection pen production line. The sterile preparation expansion project invested and constructed this time is another important milestone in Novo Nordisk's development in Tianjin. It will further enhance its production capacity in China and meet the needs of Chinese patients for innovative drugs. The expanded sterile preparation production will use the world's leading isolator technology to provide a higher level of sterility guarantee for preparation production. The entire project is scheduled to be completed in 2027.

Boehringer Ingelheim takes cancer therapies to China in partnership with Sino Biopharma

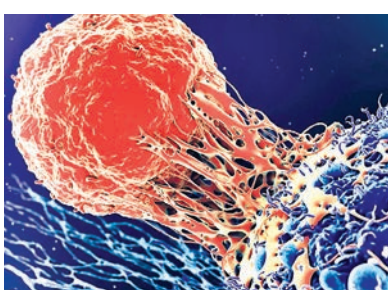
Sino Biopharmaceutical Group has entered into a strategic partnership with Germany-headquartered Boehringer Ingelheim to bring Boehringer Ingelheim's innovative cancer therapies to the market in mainland China. Under the agreement, Sino Biopharma and Boehringer Ingelheim will collaborate to jointly develop and commercialise Boehringer Ingelheim's oncology pipeline in mainland China. The strategic partnership covers multiple assets under clinical development by Boehringer Ingelheim, including three assets brigimadlin, zongertinib, and BI 764532, and multiple early-stage assets. Brigimadlin is a mouse double minute 2 (MDM2)-p53 antagonist which has advanced into the pivotal trial for the treatment of dedifferentiated liposarcoma (DDLPS) and is being investigated for other cancers such as biliary tract cancer (BTC), non-small cell lung cancer (NSCLC), pancreatic cancer and other tumors with MDM2 amplifications; while Zongertinib is a selective human epidermal growth factor receptor 2 (HER2) inhibitor that covalently binds to the tyrosine kinase domain (TKD) of both wild type and mutated HER2 receptors.

World Orphan Drug Alliance expands to Japan & South Korea

The World Orphan Drug Alliance (WODA), a global alliance of commercial distributors dedicated to providing access to treatments for rare diseases and specialty medicines in complex markets around the world, has expanded its reach to include Japan and South Korea, as well as the African subcontinent. The addition of two new members, Nxera Pharma (formerly Sosei Heptares) and Veld Pharmaceuticals, brings the total number of countries covered by WODA to 156 and provides access to 200 million rare disease patients. The Alliance now provides a broad outreach with a local focus through 12 separate entities: Specialised Therapeutics (Australia, New Zealand, and South East Asia), Medis (Central and Eastern Europe & Nordics), RareStone (Greater China), Path Pharma (Greece, Cyprus, Malta), CTS (Israel), OrphanDC (Latin America), Vector Pharma (Middle East, North Africa, and Turkey), Orpharm (Russia and the CIS region), EffRX Pharmaceuticals (Switzerland), Veld Pharmaceuticals (the African subcontinent), Nxera Pharma (Japan, South Korea), and its global consultancy partner Decisive Consulting.

Serum Institute of India partners with Univercells to make personalised cancer treatments more accessible

Serum Institute of India (SII), the world's largest vaccine manufacturer, has joined forces with Univercells, a Belgian biotech innovator, targeting a dramatic increase in accessibility to personalised cancer care. This partnership aims to bring cutting edge treatment options within reach of millions globally. At present, personalised care options such as novel cancer vaccines and specialised immunotherapies are accessible to a few patients only. These new therapies are developed using genetic material



extracted from the patient's tumours, a process which is both time-consuming, and expensive. Besides, due to strict regulatory limitations on the sequence, transfer, and manufacturing of genetic material, these treatments are only available in a handful of countries. This collaboration between SII and Univercells will help in addressing these challenges, with a view to capturing a proportion of the global cancer care market. Longer term, Univercells and SII believe that they may be able to dramatically accelerate the progress of new medicines. At present, the average time for a cancer therapy to go from patenting to use by patients is close to 15 years in the UK.

BioPIPS expands membership to enhance productivity in biologics manufacturing

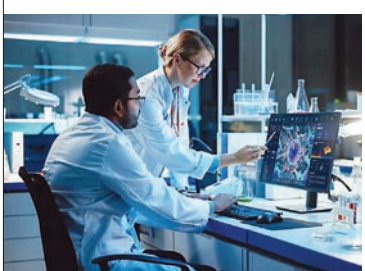
The Biologics Pharma Innovation Programme Singapore (BioPIPS) consortium has expanded with the addition of global immunotherapy company, BioNTech. The company joins global pharmaceutical companies GSK and Sanofi alongside Singapore's research organisations and institutes of higher learning Agency for Science, Technology and Research (A*STAR), Nanyang Technological University, Singapore (NTU) and its innovation and enterprise company, NTUitive, National University of Singapore (NUS), and Singapore Institute of Technology (SIT). The BioPIPS consortium is led by A*STAR and supported by the Singapore Economic Development Board (EDB). It aims to grow Singapore's capabilities in biologics manufacturing, focusing on increasing productivity and sustainability, to transform the existing base of biologics production in Singapore. The consortium will focus on biologics products including recombinant therapeutic proteins, and vaccines, which played a critical role in saving lives and preventing severe disease during the COVID-19 pandemic.

SK bioscience exports influenza vaccine to Thailand, entering Southern Hemisphere market

SK bioscience has shipped approximately 440,000 doses of SKYCellflu to Biogenetech in Thailand from its vaccine manufacturing facility 'L HOUSE' in Andong, South Korea. The vaccine, the company's self-developed cell-cultured influenza vaccine, contains the recommended composition of influenza virus for use in the 2024 Southern Hemisphere influenza season announced by the World Health Organization (WHO). Starting with the export to Thailand, SK bioscience expects to extend its sales not only in the Southeast Asian market but also in the Southern Hemisphere market. Thailand is affected by both the WHO's Northern and Southern Hemisphere flu vaccination guidelines due to its elongated geography from north to south. Recently, Thailand Department of Disease Control has launched a vaccination campaign aimed at workers in 31 major tourist areas in efforts to prevent influenza after the COVID-19 pandemic. SKYCellflu is the world's first cell culture-based influenza vaccine to obtain WHO Pre-qualification (PQ) certification.

Starpharma and Medicxi create Petalion Therapeutics to develop novel dendrimer-based treatments

Australia-based Starpharma has entered into a strategic partnership with UK headquartered Medicxi, a leading life sciences investment firm dedicated to financing companies developing innovative medicines, to co-found a new UK-based company called Petalion Therapeutics. Petalion will initially focus on developing novel targeted dendrimer-drug conjugate therapies in oncology, utilising Starpharma's proprietary DEP dendrimer platform technology. Medicxi will fund Petalion with an initial investment of up to $25 million (~AUD $38 million) to finance the development of a novel oncology drug candidate. Starpharma will license certain intellectual property to Petalion as required for the research, development, manufacture and commercialisation of this potential new therapeutic and, in exchange, will receive an equity holding of 22.5 per cent in Petalion.



National University of Singapore opens new research institute in China to incubate medtech startups

The National University of Singapore (NUS) Guangzhou Research Translation and Innovation Institute (NUS GRTII), a collaboration between NUS, the People's Government of Guangzhou Municipality, and the China-Singapore Guangzhou Knowledge City Administrative Committee, recently held the inauguration ceremony for its new building in Guangzhou, China. The establishment of NUS GRTII, the university's fourth overseas research institute in China, follows three other research institutes set up by NUS – the NUS Suzhou Research Institute, the Tianjin University-NUS Joint Institute in Fuzhou, and the NUS Chongqing Research Institute. NUS GRTII has inked strategic collaboration agreements with 13 partners comprising leading Singapore enterprises, Huangpu District companies and other industry players and organisations. One of the startups which will commence incubation at NUS GRTII is JN Medsys, an innovative Digital PCR technology company in Singapore, founded by Dr Johnson Ng. Another startup, Yimiji Technology, is an artificial intelligence (AI)-based medical image processing analysis platform and smart surgical robotic technology, enabling diagnosing and treating medical conditions during perioperative period.

Kotak and Venture Center launch Investor Readiness Programme in India for healthcare startups

In a significant move to bolster the healthcare startup ecosystem in India, Venture Center, in partnership with Kotak Alternate Asset Managers (KotakAlt), has announced the launch of the second cohort of the Investor Readiness Programme (IRP). This equity-free (and also fee free) 24-week accelerator, supported by KotakAlt under its CSR programme, is designed to connect, mentor, and prepare startups with a working prototype to initiate a Rs 1 to 8 crore fundraise. The high touch programme will offer a customised approach tailored to meet the unique needs of each participating startup. With a track record of success, including fundraising achievements by previous cohort participants, the IRP is an unparalleled opportunity for healthcare startups looking to scale their operations and impact.

Korea leverages JLABS global network to enhance growth of biotech and medtech startups

Johnson & Johnson (J&J) Innovation has commemorated an agreement with the Republic of Korea's Ministry of Health and Welfare (MOHW), to mark the selection of its Operator of the 2024 Global Accelerator Platform. Through this platform, the MOHW aims to leverage the- Johnson & Johnson (J&J) Innovation JLABS global network to enhance the competitiveness of Korean biotech and medtech startups, while attracting overseas

investments and catalysing the country's innovation ecosystem to serve the critical mission of enhancing and saving lives. This collaboration will leverage the expertise and global reach of J&J in both innovative medicine and medtech and the track record of JLABS in accelerating innovation across the globe. Through this agreement with MOHW, JLABS will provide services and innovation resources to early-stage companies, facilitating the acceleration of their discoveries into potential innovative medicines, medical technologies, and healthcare solutions.

VentureBlick forges strategic alliance with T-Hub for guiding healthcare innovators

To promote cross-border cooperation and advance revolutionary healthcare solutions, Singapore-headquartered VentureBlick, a leading global platform for healthcare innovation, has announced the signing of a Memorandum of Understanding (MoU) with T-Hub, the top technology incubator and accelerator in India.

The primary objective of this collaboration is to create an ecosystem that promotes innovation, knowledge exchange between countries, and distribution and marketing support for healthcare startups out of India. Healthcare startups in India can now avail all the intel offered by VentureBlick and T-Hub to propel their global growth. The diverse set of solutions like medical validation, clinical trials, market mapping, regulatory approvals, go-to-market strategies can enable their cross-border expansion. VentureBlick is launching a health tech innovation platform called Discovery to bring together innovators, physicians, investors, distributors and industry experts to advance healthcare innovation and startups in the space.

D3 Bio raises funds to advance innovative oncology pipeline

D3 Bio, a China-based biotechnology startup that focuses on discovery, development, and registration of innovative cancer drugs, has announced closing of Series A+ financing round led by Medicxi, a leading European life sciences investment firm. D3 Bio's existing investors, Matrix Partners China and WuXi AppTec's Corporate Venture Fund also participated. The substantial investment of $62 million in this round underscores D3 Bio's steadfast commitment to advancing its pioneering oncology pipeline. The funding will be allocated to expedite the development of D3 Bio's assets through preclinical and clinical stages, with a particular focus on accelerating the global clinical trial of D3S-001, a new generation small molecule KRAS G12C inhibitor with the best-in-class potential. D3S-001 is currently in phase II development in non-small cell lung cancer, colorectal cancer and pancreatic cancer. D3 Bio has built a pipeline of multiple oncology programmes, which hold significant promise for developing future therapies across various indications.

Seaport Therapeutics receives funding for development of neuropsychiatric medicines

Seaport Therapeutics, a clinical-stage biopharmaceutical company based around a unique drug delivery platform originally developed by Australia's Monash University researchers, has announced the closing of a $100 million oversubscribed Series A financing round. The round was co-led by ARCH Venture Partners & Sofinnova Investments along with Third Rock Ventures & Seaport founder PureTech Health. Using the proprietary Glyph platform which was initially developed by Professor Christopher Porter &

his team at the Monash Institute of Pharmaceutical Sciences (MIPS), Seaport Therapeutics is advancing a clinical stage pipeline of neuropsychiatric medicines in areas of high unmet patient needs including depression & anxiety disorders, currently being held back by key limitations such as negligible oral bioavailability or hepatotoxicity. The Glyph platform solves these limitations by rerouting the mechanism of absorption to enable oral administration & reduce liver exposure. Seaport Therapeutics is built on a proven development strategy & is led by the team that created and advanced the groundbreaking drug candidate KarXT (xanomeline-trospium), which is now poised to be the first new class of medicine in over 50 years for patients living with schizophrenia.

WHO unveils digital health promoter harnessing generative AI for public health

The World Health Organisation (WHO) has announced the launch of S.A.R.A.H., a digital health promoter prototype with enhanced empathetic response powered by generative artificial intelligence (AI). S.A.R.A.H. is a Smart AI Resource Assistant for Health that represents an evolution of AI-powered health information avatars, using new language models and cutting-edge technology. It can engage users 24 hours a day in 8 languages on multiple health topics, on any device. WHO's digital health promoter is trained to provide information across major health topics, including healthy habits and mental health, to help people optimise their health and well-being journey. It aims to provide an additional tool for people to realise their rights to health, wherever they are. S.A.R.A.H., also known as Sarah, has the ability to support people in developing better understanding of risk factors for some of the leading causes of death in the world, including cancer, heart disease, lung disease, and diabetes. She can help people access up-to-date information on quitting tobacco, being active, eating a healthy diet, and de-stressing among other things.

WHO launches CoViNet: a global network for coronaviruses

The World Health Organisation (WHO) has launched a new network for coronaviruses, CoViNet, to facilitate and coordinate global expertise and capacities for early and accurate detection, monitoring and assessment of SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance. CoViNet expands on the WHO COVID-19 reference laboratory network established during the early days of the pandemic. Initially, the lab network was focused on SARS-CoV-2, the virus that causes COVID-19, but will now address a broader range of coronaviruses, including MERS-CoV and potential new coronaviruses. CoViNet is a network of global laboratories with expertise in human, animal and environmental coronavirus surveillance. The network currently includes 36 laboratories from 21 countries in all 6 WHO regions. Data generated through CoViNet's efforts will guide the work of WHO's Technical Advisory Groups on Viral Evolution (TAG-VE) and Vaccine Composition (TAG-CO-VAC) and others, ensuring global health policies and tools are based on the latest scientific information.

WHO sounds alarm on viral hepatitis infections claiming 3500 lives each day

According to the World Health Organisation (WHO) 2024 Global Hepatitis Report, the number of lives lost due to viral hepatitis is increasing. The disease is the second leading infectious cause of death globally, with 1.3 million deaths per year, the same as tuberculosis, a top infectious killer. New data from 187 countries show that the estimated number of deaths from viral hepatitis increased from 1.1 million in 2019 to 1.3 million in 2022. Of these, 83 per cent were caused by hepatitis B, and 17 per cent by hepatitis C. Every day, there are 3500 people dying globally due to hepatitis B and C infections. Funding for viral hepatitis both at a global level or within dedicated country health budgets, is not sufficient to meet the needs. This arises from a combination of factors, including limited awareness of cost-saving interventions and tools, as well as competing priorities in global health agendas. The report outlines a series of actions to advance a public health approach to viral hepatitis, designed to accelerate progress towards ending the epidemic by 2030.

Brazil and Gavi advance equitable immunisation globally

The Brazilian Ministry of Health (MoH) and Gavi, the Vaccine Alliance have signed a landmark Memorandum of Understanding (MoU) to collaborate on vaccine production, innovation and global access. This strengthened partnership reaffirms both partners' commitment to ensuring equitable access to life-saving vaccines. Gavi and Brazil will also promote integrating global health with other critical areas like finance, climate change and digital technology as part of the MoU. Brazil and Gavi's partnership dates to 2006, when Brazil first pledged a regular contribution to Gavi through the International Finance Facility for Immunisation (IFFIm) as the first Latin American donor. In addition, the country supplies yellow fever vaccines to Gavi through Bio Manguinhos, a strategic product that helps prevent outbreaks in Gavi-supported countries. With the new MoU, Gavi and Brazil enter a new phase of this partnership by working together to ensure the world has equitable access to routine immunisation as well as to be better prepared for future disease outbreaks with life-saving vaccines through local and regional production, contributing to the diversification of the global vaccine production.

Nigeria introduces new 5-in-1 vaccine against meningitis

Nigeria has become the first country in the world to roll out a new vaccine (called Men5CV/MenFive conjugate vaccine) recommended by the World Health Organization (WHO), which protects people against five strains of the meningococcus bacteria. MenFive is indicated for active immunisation of individuals aged 9 months to 85 years against invasive meningococcal disease caused by Neisseria meningitidis groups A, C, Y, W, and X. The vaccine and emergency vaccination activities are funded by Gavi, the Vaccine Alliance, which funds the global meningitis vaccine stockpile, and supports lower-income countries with routine vaccination against meningitis. Nigeria is one of the 26 meningitis hyper-endemic countries of Africa, situated in the area known as the African Meningitis Belt. Last year, there was a 50 per cent jump in annual meningitis cases reported across Africa. The new vaccine has the potential to significantly reduce meningitis cases and advance progress in defeating meningitis. This is especially important for countries like Nigeria where multiple serogroups are prevalent. The new vaccine uses the same technology as the meningitis A conjugate vaccine (MenAfriVac), which wiped out meningococcal A epidemics in Nigeria.

Global deployment of rapid diagnostic tests to boost fight against cholera

The recent arrival of rapid diagnostic test (RDT) kits for cholera in Malawi signals the start of a global programme that will see more than 1.2 million tests distributed to 14 countries at high risk for cholera over the next several months. Countries that will receive kits in this largest-ever global deployment include those currently severely impacted by cholera outbreaks, such as Ethiopia, Somalia, Syria, and Zambia. This programme will improve the timeliness and accuracy of outbreak detection and response by boosting routine surveillance and testing capacity and helping rapidly identify probable cholera cases. Critically, it will also help countries monitor trends and build an evidence base for future preventive programmes, supporting the achievement of national cholera control and elimination targets. The global cholera diagnostics programme is funded and coordinated by Gavi, the Vaccine Alliance (Gavi), with procurement and delivery to countries led by UNICEF, and undertaken in collaboration with the Global Task Force on Cholera Control (GTFCC), and WHO.

US FDA approves first gene therapy for children with metachromatic leukodystrophy

The US Food and Drug Administration (US FDA) has approved Lenmeldy (atidarsagene autotemcel), the first FDA-approved gene therapy indicated for the treatment of children with pre-symptomatic late infantile, pre-symptomatic early juvenile or early symptomatic early juvenile metachromatic leukodystrophy (MLD). The FDA has granted approval of Lenmeldy to Orchard Therapeutics. Metachromatic leukodystrophy is a debilitating, rare genetic disease affecting the brain and nervous system. It is caused by a deficiency of an enzyme called arylsulfatase A (ARSA), leading to a buildup of sulfatides (fatty substances) in the cells. This buildup causes damage to the central and peripheral nervous system, manifesting with loss of motor and cognitive function and early death. It is estimated that MLD affects one in every 40,000 individuals in the United States. There is no cure for MLD, and treatment typically focuses on supportive care and symptom management.

AI makes retinal imaging 100 times faster, compared to manual method: Study

Researchers at the National Institutes of Health in the US applied artificial intelligence (AI) to a technique that produces high-resolution images of cells in the eye. They report that with AI, imaging is 100 times faster and improves image contrast 3.5-fold. The advance, they say, will provide researchers with a better tool to evaluate age-related macular degeneration (AMD) and other retinal diseases. Researchers are developing a technology called adaptive optics (AO) to improve imaging devices based on optical coherence tomography (OCT). Like ultrasound, OCT is non-invasive, quick, painless, and standard equipment in most eye clinics. This latest work targets the retinal pigment epithelium (RPE), a layer of tissue behind the light-sensing retina that supports the metabolically active retinal neurons, including the photoreceptors. The team has developed a novel AI-based method called parallel discriminator generative adversarial network (P-GAN), a deep learning algorithm. By feeding the P-GAN network nearly 6,000 manually analysed AO-OCT-acquired images of human RPE, each paired with its corresponding speckled original, the team trained the network to identify and recover speckle-obscured cellular features. When tested on new images, P-GAN successfully de-speckled the RPE images, recovering cellular details.

Global collaboration to combat chronic lung infection

Scientists have discovered a target for the development of a drug to combat a bacterium that can cause chronic lung infection in hospitalised patients, immunocompromised individuals and people with cystic fibrosis. The multidrug-resistant bacteria Pseudomonas aeruginosa infects the lung and promotes an accelerated decline of pulmonary function. It has been acknowledged as a serious threat by the Centres for Disease Control and Prevention and rated a critical priority by the World Health Organisation. The Fraunhofer International Consortium for Anti-Infective Research (iCAIR), led by Professor Mark von Itzstein AO at Australia-based Griffith University's Institute for Glycomics and Professor Dr Armin Braun at the Fraunhofer Institute for Experimental Medicine (ITEM) in Hannover, Germany, in collaboration with researchers at the Hannover Medical School, established a joint research programme that tackled antibiotic resistance development of Pseudomonas aeruginosa.

What's APAC's Recipe of Success in CLINICAL TRIALS MARKET?

Asia-Pacific (APAC) is emerging as one of the most promising and resilient markets for clinical trials. According to a report by Clinical Trials Arena, between 2017 and 2022, the region posted growth in clinical trials of around 10 per cent, outstripping growth in other major regions including the US, Europe and the rest of the world (RoW). Asia's growth far exceeded the overall average figure of 5.3 per cent per year. As of 2023, the number of trials reached 14,346 in APAC. Let's delve into the thriving clinical research landscape in the region and explore the trends driving its growth.

The APAC region continues to rule the roost in clinical trials, experiencing dramatic growth rates surpassing those in the US and Europe. Various reports highlight APAC's emergence as a pivotal hub for clinical trials, with almost half of the world's trials now conducted in the region.

"The number of clinical trials conducted in the APAC region has shown consistent growth over the past five years, with a significant increase from 11,571 trials in 2019 to 14,346 trials in 2023. China leads in the number of clinical trials conducted, followed by India and South Korea," said Gowri Prasad Gutti, Director of Pharma Intelligence at GlobalData.

Earlier considered the hotbed for late-stage multinational trials, early-stage trials are picking up. Between 2013 and 2022, the APAC region emerged as the fastest-growing area for early-stage clinical trials, with a combined annual growth rate 12 times higher than that of the United States and four times higher than Europe. By 2022, APAC accounted for 58 per cent of all global phase I clinical trials, according to a recent report from GlobalData and Novotech. This indicates higher levels of innovation within the region, focusing on the development of novel therapies.

"The transformation of the APAC region in the past decade is remarkable. Traditionally known for later-phase studies due to regulatory advantages and patient availability, we've witnessed a significant shift towards conducting early-phase work in countries like South Korea, Japan, and China. This transition is fuelled by regulatory reforms facilitating faster approvals, the expertise of local sites, and the burgeoning presence of APAC-based biotech companies eager to conduct trials in their home region. This evolving landscape not only underscores

the region's growing importance in global clinical research but also highlights the collaborative efforts driving innovation across borders," said Megan Morrison, Vice President, Commercial Strategy Lead APAC at Worldwide Clinical Trials. US-based Worldwide Clinical Trials is a leading full-service global contract research organisation (CRO).

China has stood out in the APAC region due to its significant growth in clinical research over the past decade. Unlike its counterparts, China predominantly conducts domestically sponsored trials, with over three-quarters of trials being initiated by local companies. In contrast, Japan, South Korea, and India see between 56 and 67 per cent of trials initiated by foreign sponsors. Australia presents a stark difference, with 95 per cent of trials being initiated by foreign companies. Australia also leads the APAC region in the number of first-in-human (FIH) trials, constituting 7 per cent of its total, according to a recent report from Citeline.

"There has been tremendous growth in the mainland China market with biotechs developing novel therapies. The large domestic market also serves as low-hanging fruit for these biotechs. South Korea and Taiwan have also consistently produced good quality biotechs with regional and global ambitions. As a result, you see rapid growth of early phase trials in APAC. This has also led to the development of a large number of sites in the region with strong phase 1 capability and experience. While most of the global pharma companies automatically involve China for their late phase global trials in recent years, more and more global pharma companies are involving China for their early-stage studies for global simultaneous development," said Suhail Ali, Vice President & Head, Clinical Delivery APAC, ICON. Headquartered in Ireland, ICON plc is a world-leading healthcare intelligence and CRO.

South Korea is also emerging as an important country for clinical trials and has ramped up its clinical infrastructure. The country has positioned life sciences and biotechnology as key focus areas, experiencing rapid growth thanks to continuous investment and government support through funding programmes to foster research and development activities.

"Apart from the strong contributions to multinational clinical trials funded by foreign companies, a notable trend in the South Korean pharmaceutical industry is the growth potential for domestic pharmaceutical companies including biosimilar development. The focus of the Korean clinical trial community and the Korean government in clinical trials has been shifting to support drug development by Korean companies evidenced by the fast-increasing number of phase 1 FIH trials approved by the Ministry of Food and Drug Safety (MFDS)," said Suhail Ali.

"The evolving regulatory landscape in the region is poised to significantly influence the efficiency and conduct of clinical trials for pharmaceutical and biotech companies. Key trends include the harmonisation of regulatory frameworks, which simplifies the multi-country trial process by reducing variability in requirements across different countries."

- Ding Ming,
Senior Vice President & General Manager, China Operations, Clinical Research Group (CRG), Thermo Fisher Scientific, USA

Beyond China, there remains significant interest in clinical trial activity throughout the region. India, for instance, ranked third globally in new trials, following China and the US, and experienced a 5 per cent compound annual growth rate (CAGR). Additionally, the proportion of planned trials in India

"The clinical research networks provide a key platform for clinician scientists and researchers to connect with other principal investigators beyond their countries to share best practices and stay updated on the latest developments as well as how effective certain therapeutics have been among their patient cohorts."

- Asst Prof. Danny Soon,
CEO, Consortium for Clinical Research and Innovation, Singapore (CRIS) and Executive Director, Singapore Clinical Research Institute (SCRI), Singapore

"The proactive measures taken by APAC regulatory authorities to support the local CROs to undertake global clinical trials is an ideal situation for global pharma companies to launch their products in APAC markets for wider reach and access to medical therapies to a large patient population."

- Dr Mahesh Bhalgat,
Group CEO, Veeda Clinical Research Limited, India

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- Suhail Ali,
Vice President & Head, Clinical Delivery APAC, ICON, Singapore

was three times higher than in the US, as reported by GlobalData.

"Indonesia, Malaysia, and other countries that have large populations and historically have had less exposure to clinical research are looking to improve their capabilities and attractiveness to the life sciences industry. More mature markets, such as South Korea and Australia, continue to attract clinical research through their cutting-edge healthcare facilities, domain expertise, and overall regulatory attractiveness," said Bryan Spielman, Chief Growth Officer at Advarra. US-based Advarra is the market leader in regulatory review solutions and clinical research technology for sites and sponsors.

Area of focus

Oncology remains the dominant therapeutic area in the APAC region, followed by Central Nervous System (CNS) disorders and Infectious Diseases. Notably, COVID-19-related trials have been prominent in Infectious Diseases in the past few years.

"Oncology clinical trials dominate the pipelines for Japanese and Chinese pharma companies; while India, with a younger population, has a greater variety of indications dominating their pipeline including metabolic, autoimmune, and infectious disease targets," said Spielman.

In terms of indications, gastrointestinal tract cancer, blood cancer, post-operative pain, and lung cancer are among the top indications for clinical trials in the APAC region.

Various Asian countries provide favourable regulatory landscapes for rare diseases and regenerative medicine. Japan, China, Singapore, and South Korea lead in stem cell therapy, benefiting from supportive government regulations and funding.

"The proactive measures taken by APAC regulatory authorities to support the local CROs to undertake global clinical trials is an ideal situation for global pharma companies to launch their products in APAC markets for wider reach and access to medical therapies to a large patient population," said Dr Mahesh Bhalgat, Group CEO, Veeda Clinical Research Limited. Veeda Clinical Research is an Indian CRO and offers a comprehensive portfolio of clinical, preclinical and bio/analytical services

Trends shaping clinical trials landscape

In addition to the region's appeal for global clinical trials - attributed to its diverse patient population, skilled professionals, and cost-effectiveness - it is positioning itself as a hub for complex clinical research. Recent years have seen several significant trends, accelerated by COVID-19.

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- Bryan Spielman,
Chief Growth Officer, Advarra, USA

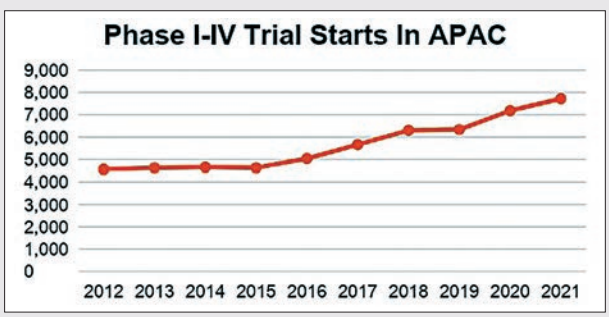
How APAC Has Turned into Clinical Trial Behemoth

« **Mohammad Imran,**
Global Head,
Business Development & Operation,
3H Medi Solution,
Japan

From being a consistent participant in clinical trial conduct worldwide, the APAC has emerged as a major power. A number of causes, including the region's thriving drug development innovation and the ongoing presence of international pharmaceutical corporations conducting multi-regional studies, are driving this growth.

Over the past decade, the Asia-Pacific (APAC) region has emerged as a global leader in clinical trial conduct. In 2021, nearly half of all new clinical trials conducted globally were in the APAC region. This surge is evident in the significant rise in clinical trial-related activities in this region. From 2012 to 2021, the number of trials initiated in the APAC region (Phases I-IV) has nearly doubled, from 4,562 to 7,718, with an average annual increase of 5.4 per cent.

No Clinical Trials conducted from 2012 to 2021



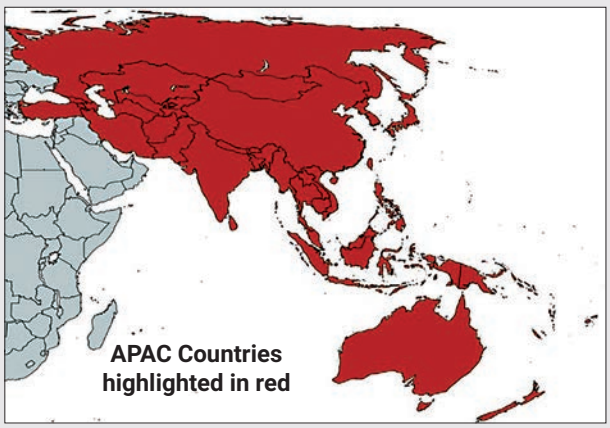
Notably, this growth has accelerated in recent years, with double-digit increases in new trial starts since 2016. In contrast, clinical trials outside of APAC have declined slightly over the same period, with an annual decrease of 0.4 per cent. This trend suggests that APAC could become the dominant region for clinical trials soon. This is a remarkable shift for a region that traditionally lagged behind the US and Europe, and it highlights APAC's position at the forefront of clinical research.

Why's APAC Leading?

The rise of Phase I trials especially in the Philippines, Australia and Malaysia (Study sites at Penang Island) indicates that researchers in the APAC region are developing entirely new drugs rather than simply testing established drugs for global markets (Phase III) or monitoring their long-term effects (Phase IV). This suggests a growing number of drug discoveries by APAC companies, with China leading the way as the second-biggest R&D location globally. Other countries like South Korea, Japan, and Australia are also making significant contributions and advances in the field of research. Research shows that APAC holds 60 per cent of the global cardiometabolic disease burden and holds a lot of potential for clinical research.

Japan as a clinical trial hub

Major multinational drug companies favour Japan for their clinical trials in APAC. Nearly half of all trials conducted by the top revenue-generating pharmaceutical companies in the region have included Japan as a site in the past decade. Japan's long history of positive reputation in clinical trials as well as Ivy League Japanese universities making their infrastructure compatible with high technology such as Decentralised Clinical Trials (DCT) in oncology, gene and cell therapy research environment are likely reasons behind this. Additionally, Japan holds a unique position as the only APAC member to be a founding member of both the regulatory (Ministry of Health, Labour and Welfare (MHLW) / Pharmaceuticals and Medical Devices Agency (PMDA) and industry the Japan Pharmaceutical Manufacturers Association (JPMA) sides of the International Conference on Harmonisation (ICH). Good regulatory guidance has helped Japan's global position in clinical trials as well as ethnic sensitivity assessment.



(Source: United Nations Economic and Social Commission for Asia and the Pacific (ESCAP))

Role of APAC's huge population

With a massive population of nearly 60 per cent of the world, APAC is a goldmine for pharmaceutical and biotech companies seeking new clinical trial locations. The region has many ethnicities offering a unique chance to run clinical trials on a wide range of patients. This variety makes the results of these trials more applicable to a wider population and speeds up the process of finding study participants. The region offers several other advantages, including lower costs, simpler regulations, and also as government or insurance reimbursement for medical care is limited in many APAC countries, clinical trials provide patients with access to cutting-edge treatments that they wouldn't otherwise be able to get.

Apart from the large population in the APAC region, strict data standards and the availability of local data from research also drives clinical trial conduct in the region. Certain APAC countries, like Japan, Korea, and China, require local data for drug approval. Running trials in these countries allow companies to get approval and market in these countries while also potentially using the data for US and European approvals. China generally demands local data for phase 1 trials but might accept data from ethnically Chinese patients elsewhere. In addition, streamlined systems and efficient application processes with fast approval have given a boost to clinical trial conduct in the APAC region.

The APAC has transformed from a steady contributor to a dominant force in global clinical trial conduct. This surge is fuelled by a combination of factors, namely, the region's flourishing innovation in drug discovery and the continued presence of multinational pharmaceutical companies running multi-regional trials. China is poised to become an even bigger player, while other major APAC countries each offer unique advantages that make them attractive destinations for clinical trials. BS

China's dominance: It wouldn't be outlandish to say China has single-handedly driven the clinical trials landscape in APAC. The mainland China market is emerging as a strong driver of growth and innovation in the pharma and biotech space. There is a strong interest and increased appetite for newer therapy trials like cell and gene therapies, antibody-drug conjugates and devices. China is already running the largest number of cell therapy trials in the world. There are commercially approved home-grown cell therapies available in China, thereby greatly increasing the exposure of sites to these kinds of newer therapies.

"More and more global biotechs are looking at the co-development model whereby their China partner co-funds the clinical trial and sometimes also independently runs the 'Greater China' (mainland China, Hong Kong and Taiwan) component of the trial directly or through their preferred CRO partner. Often this comes with marketing rights for Greater China for the China partner. This further exposes the market to more innovation from global biotechs simultaneously giving more growth opportunities to Asian biotechs. In China, the number of clinical trials has risen year on year. In 2022 there were 3,318 trials on the clinical trial registry, increasing to 4205 in 2023. More hospitals in China are embracing the opportunities to participate in clinical trials," said Suhail Ali.

Increased R&D efforts: Several companies in the region are actively developing newer therapies such as CAR-T, mRNA, and ADCs, reshaping the clinical trial landscape. Big pharma companies are announcing partnerships in the region practically every day, significantly enhancing clinical research capabilities.

Interest in newer geographies like Malaysia and Vietnam: "The last few years have seen significant improvement in the clinical trial landscape in newer geographies like Malaysia. Strong industry-friendly measures and improvements in the regulatory landscape have led to the placement of more and more trials in Malaysia. Malaysia also has two government-approved phase 1 trial centres. Vietnam's large population with less exposure to clinical trials is attracting strong interest from the pharma world. Many pharma and CROs have established clinical teams in Vietnam, setting the stage for future growth there", noted Suhail Ali.

Clinical research networks: Clinical

What Are the Main Challenges of Modern Clinical Trials?

« **Mark Weadon,**
Global Analytics Product Marketing Manager, Revvity Signals

With a cumulative total of almost 478,000 globally registered trials from the year 2000 to 2023, and growing at around 10 per cent a year in the last five years, the pharmaceutical industry continues to invest in clinical trials as the gold-standard test of therapeutic safety and efficacy. In addition, as the world's economies and populations move in new directions, the share of non-US trials has reached 54 per cent, a trend that is likely to continue, driven by demographics and epidemiology. As the pace accelerates, trial managers and clinicians face a significant challenge: the explosive growth of data volumes. To succeed in the future, clinical trials need to increase efficiency and better utilise clinical trial data to support informed clinical and operational decision-making.

While the increasing volume of clinical data is welcome in many respects, clinicians and trial managers often struggle with timely access to data held in multiple repositories, and face issues around quality, complexity, and format. To address the problem, the biopharmaceutical sector has invested large sums in data warehouses and data lakes, but timely access to analytics-ready data remains a serious challenge for non-specialists.

Some of the difficulties themselves stem from prior approaches. Manual solutions for data extraction, such as custom programs or scripts, can be costly to develop, deploy and maintain. A network of point-to-point data exchange services soon becomes inordinately complex as new sources are added, and the lack of centralised management can hinder or prevent team collaboration and efficiency.

For example, a cross-study analytics project to review drug safety information across a portfolio of oncology products would naturally need access to clinical data from multiple trials. The combination of different protocols, cohorts, data gathering, and formats soon leads to ballooning complexity as each trial is added to the project.

Solving or reducing data management challenges would immediately release time for better and deeper analytics, supporting the true purpose of a clinical trial, to discover the efficacy and efficiency of new therapies. Ultimately, the less time spent on wrangling data and the more time spent on investigation, the better.

Closing clinical trials data prep gap

To reduce the time preparing clinical data for analytics means removing manual processes and automating data management wherever possible. The key is to enable a centralised clinical data science information hub, acting as a single, unified resource. This change of architecture removes the complexity and tedium of manual point-to-point connections and embeds a simple structure that provides self-service access to robust, reliable data that is ready for analysis.

This information architecture is designed to connect input sources from almost any data type, including flat files, online databases, and a wide range of industry-standard electronic data-capture solutions. The majority of modern software solutions, usually based on open standards, offer application programming interfaces (APIs) that enable easy and reliable data integration. The beauty of the centralisation approach is that connections, even hard-coded links to legacy systems, are built only once. Subsequent data interrogation uses the new unified resource as the classic 'single source of truth.'

Creating true understanding by extending trial data

Good clinical trials will raise at least as many questions as answers. If a trial shows therapeutic advantage, the natural response will be to drill down into the data to discover the root cause. In some cases, extending the analysis factors – such as income group, ethnicity, gender and more – can prove invaluable.

Health analysts are very aware of the potential for bias in clinical trials: a 2021 review showed that, globally, 62 per cent of trial participants were white

(rising to 84 per cent in the US). For clinicians without a data science background, locating and integrating relevant data for analysis can prove to be highly complex, requiring significant effort.

Again, the essential point is that creating a unified resource allows data to be harmonised and standardised, to which clinicians can then apply their preferred analysis tools. Humans, and increasingly AI solutions, are exceptionally good at identifying patterns and exceptions, particularly from visualisations. Rapid visual presentation of trial data, complete with interactive drill-down, enables clinicians to follow their instincts, explore anomalies and test new ideas quickly – all helping to bring new therapies to market more rapidly than ever.

The right clinical data and analytics solution

Naturally, there are multiple clinical trial data management and analytics solutions available with various capabilities, including Revvity Signals Solutions. The possibilities are plenty, but the key decision factors when reviewing the market are likely to centre around near real-time, self-service access to clinical trial data and cloud-native design, with software that is almost invisible to the user.

In a connected world, where clinical development programs are conducted across geographies and completed by teams assembled from partner organisations, self-service access to timely data is essential so clinicians can apply advanced analytics to get a complete picture of patient safety, treatment efficacy, and trial progress. Costly, closed, proprietary systems are likely to lead to another data warehouse dead-end in a world where collaboration is key.

Similarly, cloud-native means finding a solution that takes advantage of connectivity, scalability, and security from first design principles. A pure-cloud solution eliminates the challenges associated with building and maintaining an on-premises data store and provides immediate access to high-performance, highly visual clinical trial analytics. BS

research networks have emerged as an increasingly important platform for advancing clinical trials and research in the APAC region by providing engagement opportunities, especially for research into diseases of Asian significance. To leverage this growth, the Singapore Clinical Research Institute (SCRI), Singapore's national coordinating body to implement the national clinical trial strategy and enhance Singapore's clinical trial ecosystem, coordinates and supports 11 of such networks across the region.

"These clinical research networks provide a key platform for clinician scientists and researchers to connect with other principal investigators beyond their countries to share best practices and stay updated on the latest developments as well as how effective certain therapeutics have been among their patient cohorts," said A/Prof. Danny Soon, the inaugural Chief Executive Officer at the Consortium for Clinical Research and Innovation, Singapore (CRIS) and Executive Director, Singapore Clinical Research Institute (SCRI).

For instance, the Asian Myeloma Network (AMN), established in 2011 and the first of its kind in the region, comprises myeloma experts from China, Hong Kong, Malaysia, Taiwan, Japan, South Korea, Singapore and Thailand. Another example is ADVANcing Clinical Evidence in Infectious Diseases (ADVANCE-ID) which involves more than 30 hospitals across Asia collaborating in the conduct of clinical research in infectious diseases.

"With this network, healthcare institutions in the region can come together and study how to change the way we prevent, diagnose and treat infections, which would not have been possible with single sites. This is a critically important and relevant area of prevention and management of infectious diseases," said A/Prof. Soon.

Multi-site expansion: In a Novotech survey, one of the challenges identified was patient recruitment in clinical trials, particularly focusing on patient retention and addressing the diversity of the patient population (55 per cent of respondents). Historically, clinical trial populations were predominantly white, male participants, exacerbating gaps in knowledge regarding diseases, conditions, preventive factors, and treatment effectiveness. This is especially crucial for complex oncology trials involving newer and sophisticated therapies.

Regulatory framework

The rise of new regulatory challenges, particularly amidst the COVID-19 pandemic, is fueling the development of flexible regulatory frameworks. Countries across the APAC region, such as China, Korea, Thailand, Malaysia and Singapore, have introduced streamlined regulatory review pathways to accelerate the approval process. These initiatives are designed to reduce review times and improve overall regulatory efficiency.

"In South Korea, the Clinical Trial Authorisation (CTA) process was put in place to foster faster study startup times, with the goal being to get trials approved 30 days from the date of submission. The MFDS then either approves the trial or issues a request for additional information. The procedure allows sponsors to simultaneously submit trial requests to IRBs (Institutional Review Boards), ethics committees, and the MFDS, thereby reducing the time needed to get approval. Study startup is one of the most costly and time-consuming phases of clinical research. South Korea's efforts have reduced this significantly," said Suhail Ali.

Similarly, China's National Medical Products Administration (NMPA) has implemented fast-track pathways for innovative drugs, significantly reducing review times.

"Additionally, governments are promoting innovation and R&D through policies that offer incentives for local and foreign investment. This is fostering an environment that is more conducive to clinical trials and enhancing the region's clinical research capacity," said Ding Ming, Senior Vice President & General Manager, China Operations, Clinical Research Group (CRG), Thermo Fisher Scientific.

Australia offers a Research and Development Tax Incentive (R&DTI) scheme which encourages innovation and growth. Similarly Taiwan offers incentives to those who wish to invest in Taiwan's healthcare industry.

"Health authority provides incentives to attract global clinical trials to Taiwan. If a company runs a global clinical trial in the country, the Taiwan Health Authority offers two extra years of market exclusivity and potentially a 10 per cent higher reimbursement rate for the drug," highlighted Dr Bhalgat.

Regulatory bodies acknowledge the role of technology in clinical trials and have taken proactive measures in response. Governments have introduced various initiatives to encourage the utilisation of electronic health records (EHRs), telemedicine, and other digital health tools.

"Throughout the region, regulatory bodies

are looking at how real-world data complements traditional development approaches, leveraging technology solutions to enable decentralised gathering of participant data, where appropriate, and what role patient advocacy should have in clinical trial design. Singapore is at the vanguard of regulatory innovation in the Asia-Pacific region, and the country is always looking to ensure that they are competitively positioned with the rest of the region and world. To that end, streamlining the ethics review process is one of the areas they are exploring," said Spielman.

Countries are actively exploring the use of Decentralised Clinical Trials (DCTs) and digital health technologies in clinical research. Australia, Singapore, and China have all released frameworks for DCTs.

Lastly, with the increasingly global nature of clinical trials, robust data protection and sharing regulations are being prioritised to ensure privacy and security while facilitating cross-border collaboration.

"The evolving regulatory landscape in the region is poised to significantly influence the efficiency and conduct of clinical trials for pharmaceutical and biotech companies. Key trends include the harmonisation of regulatory frameworks, which simplifies the multi-country trial process by reducing variability in requirements across different countries. Streamlined approval processes, as seen in countries

Data analytics coupled with Artificial Intelligence (AI) will play a big role in shaping the clinical trials of the future. Already analytics and AI are used for site selection, patient recruitment projections, translation services and interpretation of diagnostics data like ECG, scans etc. Predictive analytics are also projected to grow at a faster rate making clinical trials more predictable in terms of timelines and cost. As with all things technology, the implementation of robust data governance strategies is crucial. While data is a key driver of research insights, there have been rising concerns regarding access, security, and ethical use, which must be addressed.

such as Singapore and Australia, are expected to accelerate the clinical trial timeline, making the region more attractive for trial conduct. Moreover, the adoption of international standards is enhancing the quality and reliability of clinical trial data, boosting global confidence in the region's research capabilities," said Ding Ming.

The Tech Thrust

Moving forward, technology will play a crucial role in advancing clinical research. According to a recent IQVIA survey, 89 per cent of participants from West China Hospital embrace decentralised trials as a viable research option. Additionally, 98 per cent approve the integration of electronic diaries, 96 per cent endorse digital devices, and 90 per cent support telehealth visits in clinical trials.

Digital technologies offer immense opportunities for trial efficiency and access. The adoption of digitalisation has not only enabled trials to be conducted remotely but has also empowered participants through the use of wearable devices, which can provide real-time updates to both researchers and participants alike.

"This advancement not only enhances convenience by reducing the need for frequent site visits but also broadens the reach of trials, to be able to recruit from a more diverse participant pool across APAC, including those with limited trial infrastructure," said A/Prof. Soon.

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As with all things technology, the implementation of robust data governance strategies is crucial. While data is a key driver of research insights, there have been rising concerns regarding access, security, and ethical use, which must be addressed.

"As the region continues to develop its health care infrastructure, the integration of these technologies will be crucial in expanding access to clinical trials and improving health care services, especially in underserved areas. In conclusion, digital health technologies are set to play a pivotal role in the future of clinical trials in the Asia-Pacific region, driving progress toward more efficient, patient-centric and data-driven research processes," said Ding Ming.

The Asian clinical research market has grown by leaps and bounds and is projected to be worth $7.47 billion by 2029 from $4.88 billion in 2024. As demand for new therapies rises globally, the region offers lucrative opportunities for all stakeholders to innovate and grow. BS

Ayesha Siddiqui

"Regulatory encouragement of advanced tech, including AI will accelerate clinical trials in APAC"

« **Rohit Nambisan,** CEO and Co-Founder of Lokavant, USA

Lokavant Holdings, a US-based clinical trial intelligence technology company provides clinical trial intelligence that enables study teams to make data-driven decisions, as well as risk-based quality management and monitoring services to pharmaceutical companies and contract research organisations (CROs). Recently, the firm received $8 million in funding from Japanese behemoth Mitsui & Co. to bring its technology to APAC. Rohit Nambisan, CEO and Co-Founder of Lokavant, shares his perspectives with BioSpectrum Asia on the evolving clinical trial landscape in the region and the importance of digital health technologies for clinical trials. ***Edited excerpts:***

Could you elaborate on the most prominent trends shaping the APAC clinical trials landscape?

One of Lokavant's earliest customers, CMIC Group – the largest CRO in Japan – taught us a lot about this unique part of the world. Since then, we have received an $8 million strategic investment from Mitsui & Co. Ltd. to expand our AI-optimised platform across the Asia-Pacific (APAC) region. Today, three trends stand out:

The first is better regulatory alignment with international standards. Several APAC countries are reforming their regulatory processes to attract more trials to the region, which can lead to more competitive timelines for trial approvals and clearer regulatory guidelines. Korea, Singapore, and Australia standout here, with Japan also seeing similar regulatory shifts.

Multinational trial expansion is the second notable trend. Participant enrollment has become more difficult as clinical trials have evolved to focus more on specialised indications and sub-indications. Given their genetic diversity and substantial populations, APAC countries can support the acceleration of multinational trials. Lastly, there's a growing focus on oncology and rare disease in APAC countries – Japan in particular – and this aligns with global research trends. These countries often have incentives for orphan drug development which is attracting more rare disease trials.

Will the evolving regulatory landscape in key APAC countries impact clinical trials for biopharma companies?

The region's increasing alignment with international guidelines will simplify the processes required to conduct multinational trials and achieve regulatory approvals in APAC countries. This will greatly benefit local sponsors who are planning niche-indication trials that depend on the recruitment of participants from various countries to meet their enrollment targets.

Additionally, streamlined regulatory processes may lead to faster approval times for clinical trial applications. This efficiency can attract more international clinical studies, and encourage local companies to invest in research and development, thus promoting business in local pharmaceutical and biotech firms.

How do you see the adoption of digital health technologies influencing the future of clinical trials in the region?

Regulatory bodies in several APAC countries are encouraging the use of eClinical data systems, remote monitoring tools, and virtual patient visits. These enhancements should improve patient access, participant retention and trial adherence, which can drive a greater consistency in study conduct for global trials. Regulatory encouragement of such advanced technologies, including artificial intelligence (AI) and real-world data, will all help to accelerate clinical trials in APAC countries. We should see an increase in trial efficiency and a reduction in overall costs – including but not limited to applications in patient and investigator identification, automation in data quality, and dynamic and real-time reporting. BS

Ayesha Siddiqui

"Australia offers a simple, supportive and robust regulatory process to initiate human trials efficiently"

US-based Uvax Bio, LLC, a spin-off vaccine company from Scripps Research, employs proprietary 1c-SApNP platform technology invented by Dr Jiang Zhu of Scripps Research to develop and commercialise prophylactic vaccines for challenging infectious diseases. The firm is currently conducting phase 1 trials of its HIV vaccine in Australia. Dr Pedro Garbes, Vice President and Global Medical Lead, Uvax Bio elucidates why the firm has chosen Australia for its phase 1 trial. ***Edited excerpts:***

« **Dr Pedro Garbes,** Vice President and Global Medical Lead, Uvax Bio, USA

What makes Uvax Bio's technology different from other vaccine technologies?

Recombinant protein vaccines are well-known and have delivered some of the most safe and successful vaccines, such as Hepatitis B (HBV) vaccines and the Human Papilloma Virus (HPV) vaccines. But the goal of our technology is to present a protein-based nanoparticle that closely resembles the target virus in size, and shape and with multiple copies of the antigen presented in a stabilised pre-fusion configuration. Our scientists use computational tools to analyse viral structures and rationally design our vaccine antigens. They have also designed a stable, multilayered, protein particle scaffold that can display and deliver 20-60 antigens. Other vaccine technologies utilise the spike antigens alone that may not be in a stable prefusion state. This innovative approach has clear applications in several different disease areas, such as respiratory viruses (Influenza, SARS-CoV-2, RSV, etc.), pandemic preparedness (Lassa, Marburg, Dengue, Zika, etc.), Malaria, Tuberculosis and Hepatitis C. The Uvax Bio 1c-SApNP protein platform can be utilised for most if not all 'enveloped' viruses which do not have protein core like HPV and HBV.

How are UVAX-1197 and UVAX-1107 different from HIV prevention vaccines that have failed in clinical trials, such as those studied in the PrEPVacc trial?

There are three key differences in the Uvax Bio HIV-1 vaccines that have been shown to dramatically increase the vaccine responder rates and produce robust and broad neutralising antibodies in preclinical models:

i. A novel 'uncleaved prefusion-optimised (UFO)' HIV-1 trimer with stable, native-like structures.

ii. The Uvax HIV-1 vaccines deliver 20 perfusion trimers on each stable, 'multilayered' protein nanoparticle with a built-in T-cell activator.

iii. Introduction of glycan trimming to remove part of the HIV-1 Env spike's glycan shield thereby making conserved, neutralising epitopes on the virus surface more accessible to the immune system.

Why is the clinical trial being conducted in Australia?

Australia offers a simple, supportive and robust regulatory process that enables small biotech companies to initiate human trials efficiently. Australia also has a strong reputation for the quality of its scientific and medical research. Australia is internationally recognised for its highly trained clinical workforce, and the high-quality data produced by its experienced, trained (and accredited) research teams and regulatory agencies.

What is the global and APAC HIV data? Why is this particularly significant for the APAC region?

UNAIDS estimates that 38.4 million people worldwide are currently living with HIV, and 1.5 million people became newly infected with HIV in 2021 alone. Asia is second only to sub-Saharan Africa as the region with the greatest number of people with HIV. Although HIV prevalence is low, the absolute number of people living with HIV was high at more than 2.2 million in reporting countries and territories in 2021, because of APAC's large population. Over the past years, many countries in APAC responded to HIV/AIDS successfully and incidence rates have declined. However, certain countries have experienced increases in infections. According to UNAIDS, the Philippines more than tripled the number of new cases of HIV infection between 2000 and 2018. BS

Ayesha Siddiqui

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Australia's quest for ethical Artificial Intelligence

Australia is at the forefront of Artificial Intelligence (AI) innovation in healthcare and recognises evolving risks associated with its use. With a series of initiatives, the country is spearheading efforts to ensure the safe and ethical implementation of AI in healthcare practices.

Australia, with its ageing population and advanced healthcare systems, has embraced AI technologies to enhance patient care and improve overall health outcomes. Patients are also eager and receptive to personalised medicine and digital health technologies.

According to recent government-commissioned survey findings, Australians are increasingly seeking personalised healthcare services that offer more choices. Approximately seven in 10 consumer respondents stated that technology provides them with 'more control over their daily lives. Meanwhile, healthcare professionals expect digital health solutions to streamline health information access, enhance care delivery, and align with their workflows, with about eight in 10 considering these technologies imperative for healthcare providers.

In response to the growing demand and recognising the transformative potential of AI in healthcare, Australia has launched several initiatives aimed at accelerating AI adoption.

The Australian government earmarked over $1 billion in the May 2023 Federal Budget for various digital health initiatives, including modernising My Health Record, renewing the Intergovernmental Agreement on National Digital Health, and enhancing electronic prescribing capabilities.

Moreover, Australia has unveiled comprehensive strategies to drive digital health transformation. This includes Australia's Digital Health Blueprint and Action Plan 2023-2033, and the National Digital Health Strategy 2023-2028, accompanied by a Strategy Delivery Roadmap. These strategic documents outline the Australian Government's vision for digital health over the next decade, emphasising the importance of safe patient information sharing, accurate diagnosis, and empowering patients to manage their health effectively.

As part of the National Digital Health Capability Action Plan (CAP), the Australian Digital Health Agency partnered with AIDH (Australasian Institute of Digital Health) to establish an online hub. This hub, which went live in December 2023, is designed to support both clinical and non-clinical professionals in developing their career pathways and enhancing digital health capabilities, including proficiency in AI technologies.

In addition, recognising the potential of AI in the public health system, Australia has established a new task force dedicated to guiding its use.

Ethical considerations

AI is utilised across healthcare pathways, spanning from screening to diagnosis, treatments, and personalised therapeutics, and has greatly benefitted the health system. But there are legitimate concerns around data governance, safety, and ethical use.

In an article in the Medical Journal of Australia, experts offer solutions to address gaps in Australia's capacity to fully leverage the benefits of AI and manage evolving risks associated with the technology. "Our health system is unprepared to take advantage of AI's benefits nor face the rapidly evolving risks," according to experts calling for a national strategy on AI in healthcare.

Similarly, in a submission to a Department of Industry, Science and Resources discussion paper, Supporting responsible AI, the Australian Medical Association (AMA) said the key challenge with AI in Australia is it remains largely unregulated with a lack of transparency on the ethical principles of AI developers and no real governance arrangements in place. Last August, the AMA published its first position statement on AI, outlining the need for regulation to be put in place before the widespread use of the technology in healthcare.

To address these challenges, the country has launched a National Policy Roadmap for

AI in Healthcare that identifies current gaps in Australia's capability to translate AI into effective and safe clinical services. The vision of the roadmap is for an AI-enabled healthcare system delivering personalised and effective healthcare safely, ethically, and sustainably. Its mission is to achieve a fully funded national plan by 2025, designed to create an AI-enabled Australian healthcare system capable of delivering personalised healthcare safely, ethically, and sustainably.

Prof. Karin Verspoor, Dean of the School of Computing Technologies at RMIT University, who was also on the committee of this roadmap explained this in detail. She said, "Under the leadership of the Australian Alliance for Artificial Intelligence in Healthcare, led by Prof. Enrico Coiera (Macquarie University), Dr David Hansen (Australian e-Health Research Centre at CSIRO), and me, and in consultation with representatives from stakeholders across the health sector, we developed the National Policy Roadmap for AI in Healthcare. The roadmap provides recommendations that specifically address safe and ethical use of AI in healthcare. These recommendations include the establishment of a National AI in Healthcare Council, and direct collaboration with the broader national initiatives from the Department of Industry, Science, and Resources to establish a national AI ethical framework."

She added, "The aim is to ensure that a risk-based safety framework, and practice standards relating to the use of AI in healthcare services are put in place. Furthermore, through Standards Australia, a subcommittee of the general Health Informatics standards committee has been established to address AI in Healthcare (technical subcommittee IT-014-21), to provide guidance on best practices for the clinical use of AI. There is significant innovation already underway, and active conversations throughout the health sector as well as community groups about opportunities and use cases for AI to improve patient care, outcomes, and experiences. These initiatives seek to help ensure that this innovation truly results in positive benefits for Australians through evidence-based and safe use of these powerful technologies."

In January 2024, the Australian government published its interim response to community feedback on its safe and responsible AI in Australia discussion paper.

"In the government's January 2024 'Safe and Responsible AI in Australia' interim response, the government noted the potential of AI to 'uplift' healthcare, but also the technical risks it posed. The government further observed that healthcare is an industry where existing laws may need to be updated to manage risks," said ***Sidney Kung, a senior associate in Baker McKenzie's IP and Healthcare and Life Sciences Practice in Sydney.***

His colleague ***Toby Patten, a partner in Baker McKenzie's Data & Technology and Healthcare and Life Sciences Practice in Melbourne*** echoes the same sentiments, "Ultimately, the Australian government has indicated it will take a 'risk based' approach to regulating AI. This is likely to mean that measures taken will be reflective of the risks posed by AI use, rather than a top-down imposition of mandatory rules for AI generally. In this way, Australia can be seen as forging a course between the highly prescriptive and centralised regulatory approach of the EU and the more relaxed, sectoral approach of the UK."

The University of Wollongong (UOW) has also launched a project that seeks to establish a new interdisciplinary research programme at UOW that addresses the ethical, legal and social implications (ELSI) of using AI in health and social care.

"As the government continues to formulate its position on the regulation of AI some of the specific risks they will need to consider in a healthcare setting are the risk for patient harm due to inaccurate diagnoses, recommendations and provision of erroneous results, biassed algorithms due to reliance on non-representative datasets which do not reflect the Australian population or healthcare system, and data breaches during collection, storage, or transmission of patient data and use of data without patient approval," said Sidney.

There's no denying that AI presents tremendous opportunities for revolutionising healthcare. However, as with any technological advancement, the implementation of robust strategies is paramount for safeguarding patient privacy, maintaining data integrity, and upholding ethical standards in AI-driven healthcare initiatives. Australia has taken a step in the right direction in this regard. BS

Ayesha Siddiqui

The Lure of USA for BioStartups

Asian biotech startups are increasingly expanding their global footprint and making a mark in the global healthcare industry. We examine the challenges they faced while doing so and strategies for successful international expansion.

Global expansion is a natural trajectory for any startup. Asian biotech startups, even those with large domestic markets, need to expand globally at some point to fuel their growth.

Depending on the stage of a biotech startup and where it hails from in Asia, there are several considerations for their expansion internationally – to tap on global resources such as financing, talent, experienced contract development and manufacturing organisations (CDMOs), and to access the wider market.

Expansion to other markets also reap financial benefits. Approximately two-thirds of US (United States) biotech launches are followed by launches in other countries, generating around 35 per cent of total revenues from drugs launched internationally. It's clear that the global reach of biotech startups contributes to their success and impact on global health, a report by McKinsey highlights.

Recognising this, several Asian biotech companies are expanding globally, with the US and EU being top destinations due to advanced healthcare systems, innovative ecosystems, talent availability, and broader markets.

Several Asian startups have also shifted their base overseas. One such example is Biofourmis, which originated in Singapore but is now headquartered in Boston, USA. They offer care-at-home solutions utilising FDA-cleared AI-guided algorithms, clinical-grade wearable devices, in-home services orchestration technology, and nursing services. Another example is BeiGene, a global oncology firm that originated in China and now has a major presence in the US and Europe.

Startups going global

Here are a list of the few startups who have expanded to the international space in the recent times:

Founded in Singapore, Lucence is a precision oncology company that has developed ultra-sensitive liquid biopsy tests. These tests make it possible to profile cancer accurately, rapidly, and affordably with a single blood draw. In early 2023, Lucence secured coveted Medicare approval for its cancer tests, granting access to millions of patients in the US under the reimbursement scheme. This approval establishes Lucence as the first and only Asian-headquartered healthcare services company to secure United States national insurance coverage.

Lunit, a South Korean medical AI company, develops AI-powered tools for accurate cancer screening, diagnosis, and personalised treatment guidance, with the aim of improving patient outcomes. The firm is aggressively pursuing global expansion and has announced several deals in Europe and the Middle East. It has now set its sights on the US market and sealed a deal to acquire a breast and lung imaging AI software firm Volpara Health Technologies for approximately $193 million. This acquisition positions Lunit as a leading force in the American market, leveraging Volpara's mammography solutions operational in over 2,000 US medical sites.

Telix, an Australian-headquartered commercial-stage radiopharmaceutical company, pioneers targeted radiation imaging and therapy technologies with the potential to revolutionise cancer management and address critical rare diseases globally. In 2022, Telix launched its first commercial product, Illuccix, for prostate cancer imaging in Australia and the United States. Further expanding its presence, Telix acquired Iso Therapeutics in 2024 to bolster its US development and manufacturing infrastructure.

Toku Eyes, a New Zealand-based startup develops tools using AI and retinal photography to enable accessible healthcare for early and accurate diagnosis of health conditions. In 2022, Toku Eyes made its mark in the US market with the launch of ORAiCLE, an AI platform that assesses heart risk through a retinal scan.

FELIQS is a Japanese startup company funded with a seed round of $2.5 million to develop a portfolio of two patent-protected drug product candidates targeting two attractive multi-billion-dollar markets

in ophthalmology and neonatology: Retinopathy of prematurity (ROP) – FLQ-101, a lipid peroxidation inhibitor repurposed to prevent ROP. FLQ-101 will be in Phase I/II dosing planned in the US for 2024. Age-related macular degeneration (AMD) – FLQ-104, proprietary lipid peroxidation and ferroptosis inhibitor for earlier intervention to treat AMD. FLQ-104 is currently in the discovery stage in the US. Each of these developmental candidates is identified through FELIQS's proprietary screening platform targeting lipid peroxidation/ ferroptosis with proven efficacy from past prospective clinical trials. In 2023, FELIQS opened the US office in JLABS@NYC.

The path to global leadership

Expanding into international markets is not easy; biotech startups face numerous challenges worldwide, including policy, regulatory, talent, technology, and cash flow obstacles.

"Asian biotech startups face valuable growth opportunities when expanding internationally, especially into US and European markets such as complex regulatory environments, establishing secondary operational bases, securing funding, and understanding local ecosystems. Additionally, recruiting suitable talent and managing dispersed organisations are significant areas for strategic development," said Dr Grace Lau, Head of the Institute for Translational Research at Hong Kong Science and Technology Park (HKSTP).

With a vibrant community of over 250 biotech companies, HKSTP has developed an extensive network of world-leading scientists and industry and academic partnerships to support the translation of biotech breakthroughs for global impact. In particular, HKSTP provides a prime ecosystem to leverage Hong Kong's status as a gateway between Asian and global markets.

Healthcare is a highly regulated space worldwide. To access market opportunities, biotech startups need to understand and adhere to rigorous clinical trial standards and secure regulatory approvals. However, that just does not end there.

"Beyond having to navigate regulatory hurdles, biotech startups with approved therapeutics will still need to secure reimbursement from payors and insurers for scaled adoption of their therapeutic solutions," said Dr Clarice Chen, Director, Healthcare & Biomedical, Enterprise Singapore (EnterpriseSG). EnterpriseSG is cognisant of these challenges and has put in place partnerships and programmes that will enable these startups to overcome them.

To navigate regulatory hurdles, one important strategy is forming partnerships. Partnerships with

"Investing in human resources is crucial. If you want to effectively navigate the intricacies of the new market, it requires to build a team of local experts who possess a profound understanding of the cultural landscape, consumer preferences, and business dynamics that shape the market environment and are beneficial to the company moves."

- Steven Truong,
Founder and CEO, VinBrain, Vietnam

"With a significant increase in licensing deals between Asian biotech companies and US/ European biopharmaceutical companies, Asia is playing an important role in global innovation, especially in licence-out deals. Global CDMOs can help biotech companies go to market from the pre-clinical to commercial manufacturing stages, leading to a win-win situation, which will be a major trend in the next decade."

- Michelle Pan,
Head of Marketing, Chime Biologics, China

"Asian biotech startups face valuable growth opportunities when expanding internationally, especially into US and European markets such as complex regulatory environments, establishing secondary operational bases, securing funding, and understanding local ecosystems. Additionally, recruiting suitable talent and managing dispersed organisations are significant areas for strategic development."

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- Dr Clarice Chen,
Director, Healthcare & Biomedical,
Enterprise Singapore (EnterpriseSG), Singapore

"By prioritising flexibility, innovation, and collaboration, startups can overcome obstacles and establish a strong foothold in global markets, showcasing the potential of Asian biotech innovation."

- Vishal Doshi,
CEO, AUM, Singapore

large pharmaceutical companies are valuable as they have the necessary experience and expertise to bring potential treatments through validation and into clinics around the world.

"By prioritising flexibility, innovation, and collaboration, startups can overcome obstacles and establish a strong foothold in global markets, showcasing the potential of Asian biotech innovation," said Vishal Doshi, CEO of AUM. AUM, a Singapore biotech company, focuses on developing cancer therapies. To navigate potential regulatory hurdles, AUM forms strategic partnerships with local pharmaceutical companies, such as Newsoara in China, to leverage their expertise to gain market access.

Licensing is another strategy that startups can utilise to springboard into the international markets. "With a significant increase in licensing deals between Asian biotech companies and US/European biopharmaceutical companies, Asia is playing an important role in global innovation, especially in licence-out deals. Global CDMOs can help biotech companies go to market from the pre-clinical to commercial manufacturing stages, leading to a win-win situation, which will be a major trend in the next decade," said Michelle Pan, Head of Marketing, Chime Biologics, China. Chime received $190 million in Series A+ financing in 2021 and built the world's first GE Kubio modular bio-manufacturing facility in China's Wuhan Bio-Lake Biotech Industry Development Zone (China Optics Valley).

And of course building local expertise is crucial for successful international expansion, as it enables startups to navigate cultural nuances and regulatory environments effectively.

"Investing in human resources is crucial. If you want to effectively navigate the intricacies of the new market, it requires to build a team of local experts who possess a profound understanding of the cultural landscape, consumer preferences, and business dynamics that shape the market environment and are beneficial to the company moves," said Steven Truong – Founder and CEO VinBrain, Vietnam. VinBrain which has successfully expanded to the US, is developing AI solutions for healthcare and has developed more than 300 AI models specifically designed for processing medical images.

Countries in the region are implementing various programmes to assist startups in establishing international expansion. Singapore launched the Global Innovation Alliance (GIA) acceleration programme in San Francisco, specifically aimed at helping Singaporean small and medium-sized enterprises (SMEs) and startups seize opportunities in the US market. Over 60 Singaporean tech SMEs and startups have participated in the programme to date.

CSSi LifeSciences, a prominent international provider of regulatory affairs and access to the US healthcare market, has entered into partnerships with the governments of New South Wales, Queensland, and Victoria, three key Australian states. This strategic collaboration is designed to provide support to Australian life science enterprises aiming to penetrate the US healthcare market.

Japan has also taken initiatives in this regard. The government launched the Beyond JAPAN programme. Launched by the Japanese government's Ministry of Economy, Trade and Industry (METI) and the Japan External Trade Organization (JETRO), this five-year endeavour aims to cultivate entrepreneurial talent capable of driving the expansion of global businesses. As part of this initiative, 1,000 participants are slated to participate in overseas training programmes over the duration of five years.

For biotech companies, scaling up is essential to fulfil their commitment of delivering innovative medicines to patients. By cultivating local expertise and navigating regulatory landscapes adeptly, these companies can effectively address unmet medical needs and make significant contributions to healthcare globally. BS

Ayesha Siddiqui

"We are exploring opportunities to collaborate with startups and incubators"

Agilent Technologies, a global leader in analytical and clinical laboratory technologies, has named Padraig McDonnell CEO-elect and Chief Operating Officer (COO), succeeding current President and CEO Mike McMullen. Upon joining Agilent's Board of Directors on May 1, 2024, McDonnell will become company's President and CEO. In an exclusive interaction with BioSpectrum Asia, both outgoing and incoming CEOs shared their vision for strengthening the life-science potential during their recent visit to the Asia Pacific hub in Singapore. ***Edited excerpts:***

« **Padraig McDonnell,** CEO-elect and Chief Operating Officer (COO), Agilent Technologies

How is Agilent advancing cell and gene therapy modalities to enable next-gen therapeutics and applications? What are Agilent's strategies for further stabilising its footprint in APAC?

Mike McMullen: Agilent has always been ahead of the curve and aligned with the latest trends in the bioscience industry. The company has achieved a global footprint in life sciences, diagnostics, and applied markets with sales offices, logistics centres, and manufacturing facilities in three major regions. In 2015, Agilent spun off key parts of its operation to become a purely biotechnology company. After acquiring Seahorse Bioscience for $235 million in 2015, Agilent then acquired BioTek Instruments in 2019, & subsequently integrated with Seahorse Bioscience. Together, these three interdisciplinary portfolios give us a very complementary suite of technologies for analysis of cell metabolism & functions. These technologies are likely to be in high demand. Ultimately, Agilent Singapore remains a key operational zone with important investments, especially in the development of new modalities, such as CAR-T cells. Furthermore, in September 2023, Agilent Technologies signed a Memorandum of Understanding (MOU) with the Advanced Cell Therapy and Research Institute, Singapore (ACTRIS), to develop cell-based therapy advancement. The collaboration aims to boost the nation's role as a leading cell & gene-therapy manufacturer & clinical services enabling translational research & development.

These emerging modalities will be crucial in the future for patient care, and they will be a vital part of our innovation strategy. Our collaboration with organisations like ACTRIS is crucial for advancing alternative therapies so that more patients can receive treatment tailored to their immune system.

Cell and gene-therapy is expected to gain increasing traction in the coming years, so we have built a compelling cell-analysis business with innovative approaches. Using the Seahorse platform, for example, we can perform metabolomic analysis on live cells, which allow us to see how live cells respond to different therapeutics, making sure what we propose is safe for patients. We are providing core technologies to the R&D workflow to advance this domain and these efforts will further contribute toward reducing the cost of treatment in the near future. Also, the Companion-Diagnostics (CDx) business leads the cell-analysis workflows, and we are already working on next-gen biomarkers for therapeutics and personalised medicine. Our Nucleic Acid Solutions Division (NASD) as well as cGMP-grade CRISPR platform for gene editing serve as backbones for molecular technologies by generating cGMP-grade oligonucleotides which are vital for next-gen therapeutics. So, we are investing heavily in biopharma across both instrumentation and modalities enabling customers to seamlessly execute their workflows.

Agilent's market capitalisation was estimated at $7 billion in fiscal 2023. How is Agilent positioning its diversified business across manufacturing, operations & logistical hubs?

Mike McMullen: Across Asia and globally, biopharma is an important market, and we are able to assist customers with these modalities with suitable workflows. A substantial part of our revenue

comes from the pharma/ biopharmaceutical space, where we have been strategically investing for nearly a decade and built a sizeable biopharma business.

Focusing mostly on the CRISPR technology & oligonucleotides potentials in therapeutics, we have invested nearly $500 million to date, with another $750 million investment planned for the upcoming initiatives globally. Approximately Agilent's direct investment in biopharma is close to $1 billion. Agilent also acquired roughly $2 billion' worth of assets through M&A deals. In addition, we continue to bring more workflow tools and technologies, & ongoing acquisitions will supplement further augmentation. We will continue to invest in our consumable space to expand our instrumentation & technology workflow portfolios.

Amidst the upward trend of laboratory management costs across the R&D value chain, how do Agilent's transformative workflows make a difference?

Mike McMullen: Since the biopharma industry is very dynamic, Agilent's suite of tools continues to grow to provide a more productive workflow for laboratories. Our enhanced capabilities provide uptime and biopharma services.

Further, Agilent has an application programming interface (API) which enables customers to seamlessly integrate outside applications with iLab's billing and reporting modules to support numerous workflows. We are strategically partnering across the entire value chain of biopharmaceuticals. Besides research tools, we implement analytical technologies for bioprocessing, quality control, and QA/ QC workflows - in addition to R&D tools to advance discovery, and development activities in biopharma.

What are the initiatives you've implemented to achieve your goal of net-zero greenhouse gas emissions by 2050?

Padraig McDonnell: Agilent implements an ESG programme with defined operational plans and goals. With industry digitalisation, the transformation of workforces and sustainability is paramount for our business in the future. In other words, we believe that by automating the production process, we can actually reduce our footprint of consumption, as well as consumption during manufacturing. The four infrared technologies, for example, allowed us to monitor every single litre of gas we use, the temperature of every single instrumentation we use, and control electricity consumption at the facility.

Plus, we diligently monitor Environmental Impact Factor (EIF) criteria for all our manufacturing operations by adhering to the ACT Environmental Impact Factor Label which emphasises Accountability, Consistency, & Transparency (ACT) around manufacturing, energy, and water use and packaging. Agilent has achieved the My Green Lab Certification by further reducing power consumption, & minimising the use of hazardous solvents & glasses.

In your new role, how do you envision business-transformation potential to drive innovation and profitability in the evolving market landscape?

Padraig McDonnell Over the past 10 years of accelerated growth in Agilent, Mike McMullen has played a crucial role at this Singapore-based regional centre. In the short term, my primary focus will be on transitioning into my new role and building my leadership team so we can execute on our strategy. One of our key focus areas is increasing customer centricity, as well as expanding our global capabilities to help serve our customers around the world. We will continue to invest in our digital capabilities and the APAC region represents a great potential driver for us.

We will continue to support our research-and-innovation academic initiatives through Agilent University; and continue to sponsor similar activities and advance the technology frontier together with Singapore. The biopharma market is diversified. So, we're looking at how we can invest and differentiate in certain areas, as well as how we can bring together capabilities to create new modalities to add value for our customers. We are also investing in our digital efforts to accelerate all aspects of our business as we help our customers bring great science to life. Moreover, we are exploring opportunities to collaborate with startups and incubators. Our intent is to remain nimble and agile so we can quickly pivot to changing market dynamics. BS

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"Biotech startups still need support in terms of talent, and resources to bring their innovations to market"

Raymond Chow has recently stepped in as the Vice President, Asia Pacific at US-headquartered Cytiva, a global provider of technologies and services for biological therapies, formerly known as GE Healthcare Life Sciences. Chow brings with him more than 30 years' experience in the life sciences industry, working with renowned companies such as Philips Healthcare, Boston Scientific, GE Healthcare, BD. In conversation with BioSpectrum Asia, Raymond Chow, Vice President- Asia Pacific, Cytiva shares details about his vision to take the brand to the next level. ***Edited excerpts:***

« **Raymond Chow,** Vice President, Asia Pacific, Cytiva

What are the key drivers for you to join Cytiva? What "new air" do you hope to bring to Cytiva?

One of the major factors in my decision to join Cytiva was the allure of the biotech/biopharma sector, where so many technologies are being developed to address the need for new therapeutics that can serve the community at large. The merger of Pall Life Sciences and Cytiva forming the "new Cytiva" also possesses the portfolio and technical expertise that can address the needs of the industry to bring these therapeutics from bench to bedside. This is what excites me. As an experienced business veteran, I am also curious to apply the Danaher Business System (DBS) to create an environment where our people can bring their best to work, and help our customers bring life-changing therapeutics to the wider community in the shortest time possible.

After the integration of Cytiva and Pall Life Sciences, what are the key strengths and challenges for the "new" company?

Both Pall and Cytiva are distinguished brands. By coming together, our customers benefit by tapping our combined expertise. For example, in upstream bioprocessing, Cytiva's single-use technology for fluid management complements Pall's bioreactor system, which is well known in the market. Cytiva also benefits by bringing Pall's incredible expertise in filtration to the fold, and this was formerly a missing puzzle in Cytiva's portfolio.

As we celebrate our fourth anniversary, we're excited to continue being that strong partner to our customers by focusing on innovation and digitalisation, especially in data management.

In terms of challenges, I can see that the industry is still adjusting to a post-COVID reset. Amid that, our industry continues to face the perennial challenge of securing talent and funding, especially for startups.

While biotech advances continue to create surges in demand for highly-qualified staff, startups are struggling to compete for mature talent, and to train the fresh hands, compared to well-established institutions and big biopharma companies. Data from the 2023 Global Biopharma Resilience Index shows that nearly 25 per cent of pharma executives globally report that it's a substantial challenge to find and retain manufacturing talent. Biopharma leaders say that manufacturing talent for GMP-certified or equivalent facilities, R&D talent, and digital/technology talent are the hardest to attract, find and retain.

In addition, during the pandemic, when mRNA vaccines saved lives around the world, the biotechnology industry and its investors have been searching eagerly for 'the next BioNTech.' However, the inflow of capital to startups has declined since 2022. Despite the successful collaborations that brought the world COVID-19 vaccines, Cytiva's Biopharma Resilience Index shows that the global R&D ecosystem has weakened since 2021. Biotech

startups still need support in terms of talent, and resources to scale up production and bring their innovations to market.

What's the role of the Asia-Pacific to Cytiva? Does Cytiva have new investment plans in the region?

Asia Pacific is a region where Cytiva can make a positive impact. For example, we have an opportunity to address the need for training and education and in turn, improve the industry's resilience in the talent pillar across Asia Pacific.

This is done in part through our Fast Trak Education and Training Program, which is available at six centers globally – three of which are in APAC (Korea, China, and India). For example, the India center collaborates with Bangalore BioInnovation Centre (BBC) to set up a world class incubation center and provide bioprocessing training programs to support the startup ecosystem. In September 2023, we expanded our Fast Trak center in Shanghai. Now, the 11000 square metre facility can train 2000 people every year, up from 300 per year, covering the whole biopharma process from process development to commercialisation.

To bridge the talent gap between industry and academia in Southeast Asia, we offer trainings at the Cytiva Experience Learning Lab (CELL), and our center of excellence in Nanyang Polytechnic. Altogether, we've conducted more than 100 trainings with academic and research institutes on the latest bioprocessing and production techniques. We'll continue to do our part to nurture talent in Southeast Asia. In addition to the Fast Trak center in Shanghai, we recently invested in our capabilities within APAC by establishing a manufacturing facility and customer experience center in Pune, India. The facility is set to double Cytiva's manufacturing capacity in India for tangential flow, virus filtration, and inactivation systems. Our Cytiva Experience Center also provides the ongoing learning and development needed to accelerate the development of novel therapeutics and help India deliver on its mission to become a global biomanufacturing hub.

We'll continue to nurture innovation and the R&D ecosystem by rolling out our BioChallenge competition across Asia Pacific. Since 2018, Cytiva's BioChallenge competition has helped address challenges that many biotechs face – access to funding and talent, scaling up and getting to market faster. Cytiva in China, South Korea, Australia, and New Zealand have hosted their own iterations of it.

With BioChallenge, biotech startups can present their methodologies and how they plan to address patients' needs. In turn, Cytiva supports the best ideas by assisting with scale up, process development and optimisation, as well as training programs to attract and develop talent.

After COVID-19, the biopharma industry has entered a new era. What's Cytiva's game changer to embrace the latest trends in the industry?

As a technology-oriented company, innovation to support new modalities, such as cell and gene therapies and mRNA, will enhance the efficiency and accelerate the speed to support patients.

mRNA is a high-potential technology to address virus-related cancers, which account for 20 per cent of cancers as well as infectious diseases such as dengue and malaria. However, mRNA molecules need to be more stable. They have logistics and storage challenges. They can require down to -20^0C or even -70^0C storage conditions. mRNA also rapidly degrades inside the body, which is an advantage for vaccines, but creates some challenges for many therapeutics that require long-term exposure for effect. Cytiva supports drug developers working on mRNA vaccines and therapeutics from discovery to delivery with our FlexFactory and KUBio solutions, as well as our robotic aseptic filling solutions.

Cell therapies have proven to be effective for patients with blood cancers and are set to bring major improvements to many other cancer treatments over the next decade. However, the development of cell and gene therapy products is still fraught with complex supply chains, and high risks of failure. They also need to be produced close to the patient, making them highly complex to manufacture. Risk reduction and time to market are critical parameters for success to roll out cell and gene therapies.

As Cytiva was involved in the first successful paediatric trial of CAR-T therapy in 2012, we foresaw challenges and the need for simplification and automation. Manufacturing technologies have since matured to allow for the reproducible manufacturing of cell therapies and I'm proud to share that our current range of flexible solutions and expertise positions us well to support customers as they roll out this next generation of medicines. BS

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From Haematologic to Autoimmune Disease– The CAR-T Therapy Second Revolution

« **Dr Davide Garrisi,** Vice President, PPD Cell and Gene Therapy Institute

« **Dr Kim Watanabe,** Executive Director, Cell and Gene Therapy, PPD Cell and Gene Therapy Institute

Cell and gene therapies have revolutionised the field of medicine, offering new treatment options for patients with various diseases that, by type of disease or severity, were considered untreatable until a few years ago. Rapid technological advancements in genetic and biological engineering and improvements in the quality and standardisation of the manufacturing process are fostering a marked increase in clinical development of these advanced therapies, generally named cell and gene therapies (CGT), and they are expected to receive more approvals in the near future.

The Alliance for Regenerative Medicine reported in its January 2024 meeting that, up to 17 regulatory approvals in the U.S. and Europe are anticipated for the coming year in cell & gene therapies, compared to eight approvals in 2023. This is despite the impact & changes in priorities caused by COVID-19. In the CGT field, chimeric antigen receptor-directed (CAR-T) cell therapies have emerged as a groundbreaking approach for treating patients with cancers that previously had proved to be resistant to available conventional therapies. Specifically, CAR-T cell therapies targeted against antigens expressed on B cells (CD19 and BCMA) have been successful in treating blood-related cancers. Now we are seeing early promising results in expanding CAR-T application to autoimmune diseases, providing new hope for patients suffering from these debilitating conditions.

Evolution and Medications Approved to Date

CAR-T therapy has come a long way since its inception, with significant advancements in design, manufacturing and clinical applications. The first CAR-T therapy approved by the U.S. Food and Drug Administration (FDA) in 2017, Novartis's Kymriah, targeted CD19-positive B cell malignancies, such as acute lymphoblastic leukemia and non-Hodgkin lymphoma. Since then, five more CAR-T therapies targeting CD19 and BCMA antigens (Tecartus, Abecma, Yescarta, Breyanzi and Carvykti) have been approved. To date, across all six FDA-approved CAR-T therapies, drugmakers have reported treating about 34,400 patients worldwide, and these therapies have demonstrated remarkable efficacy, with durable remissions in patients who have exhausted other treatment options. The success of CAR-T therapy in hematologic diseases has sparked interest in exploring its potential in treating other indications.

Autoimmune and Other Diseases Responsive to CAR-Ts

In recent years, research has yielded promising results in using CAR-T therapy for treatment of autoimmune diseases, particularly in clinical data from Müller et al. Notably, patients with systemic lupus erythematosus (SLE), idiopathic inflammatory myositis and systemic sclerosis have shown varying stages of responsiveness to CAR-T therapy. Several studies have demonstrated the potential of CAR-T cells targeting specific immune cells or autoantigens for improved disease control, reduction in autoantibody levels and amelioration of symptoms in these diseases.

In 2021, a team of researchers from the University Hospital Erlangen in Germany began the first study of CAR-T therapy in patients with autoimmune diseases. In late 2023, the team reported that all of the first 15 autoimmune disease patients who received CAR-T therapy saw the debilitating symptoms of their diseases, including lupus and myositis, substantially improve or go away entirely. Data from this trial showed that CD19 CAR-T cell treatment not only

effectively depleted the B cell surface antigens in patients with SLE, but also led to drug-free remission of this systemic autoimmune disease.

Encouraged by the promising results of CAR-T therapy in autoimmune diseases, a number of biopharma & biotech companies such as Novartis, Bristol-Myers Squibb, Cabaletta Bio, Nkarta & Kyverna have started & are at different stages of clinical programmes with CAR-T therapies directed against CD19, BCMA & target antigens. This research is attempting to validate & assess the safety & efficacy of CAR-T in treating a vast array of diseases, including the already-mentioned SLE & lupus nephritis, but also primary membranous nephropathy, pemphigus vulgaris, myasthenia gravis & ulcerative colitis.

Challenges in the Field

Despite the potential of CAR-T therapy, several challenges need to be addressed; for example, the FDA's recent concerns regarding the potential development of T-cell malignancies in patients receiving such therapy. Companies with CAR-T therapies in autoimmune indications have been particularly sensitive to the news, as the risk of cancer might not be as acceptable to the overall benefit/risk ratio for chronic diseases as it might be in oncology. Additional analysis of safety data is currently ongoing by CAR-T drugmakers, but these safety concerns emphasise the need for better understanding of patient medical history, rigorous monitoring and follow-up of patients to collect long-term data after exposure to therapy. (The latter will probably be a lifelong requirement as recently proposed by the FDA, instead of the previous mandate of 15 years.)

Another aspect to be considered, and likely to be impactful for future clinical development, is the availability of qualified investigational sites and physicians to support the rapid expansion in the number of CAR-T clinical trials, and their capacity to treat the increasing volume of patients to be administered with these therapies in the coming years. Currently, many experienced cell therapy clinical sites are located at major hospitals or academic research institutions, which may not necessarily align with where patients are located. Combined with increasing regulatory requirements for patient diversity data, especially when targeting chronic diseases, there is an overall industry need for innovative ways to drive patient enrollment.

Conducting studies in CAR-T therapies requires certain specific features of sites; for example, experience in and dedicated spaces for apheresis procedures and infusions. In addition, there will be a need for additional training of medical staff not yet familiar with CAR-T therapies' associated reversible toxicities, such as cytokine release syndrome (CRS) or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), even if fewer and milder cases have been reported to date in CAR-T therapies specifically used in autoimmune diseases.

Future Opportunities

The future of CAR-T therapy in treating autoimmune diseases holds immense promise. One opportunity lies in the development of more targeted CAR-T therapies for different autoimmune indications. By identifying specific antigens and designing CAR-T cells to target them, researchers can enhance the efficacy and safety of these therapies for a broader spectrum of diseases. Furthermore, advancements in manufacturing techniques, such as the mass production of CAR-T cells, can potentially reduce costs and increase accessibility.

One approach to decrease CAR-T treatment cost is to transiently modify T cells in vivo using mRNA without the need for ex vivo cell processing. This novel technology allows for the modification of gene expression within the patient's own cells, providing a more precise and adaptable approach to CAR-T therapy. By leveraging mRNA to transiently engineer T cells, researchers can enhance the durability and controllability of CAR-T therapy, potentially reducing the need for repeated treatments. Companies such as Moderna are exploring this option. However, the main challenge for any in vivo gene therapy remains the delivery mechanism of such therapies to minimise off-target effects and more on-target tissue delivery.

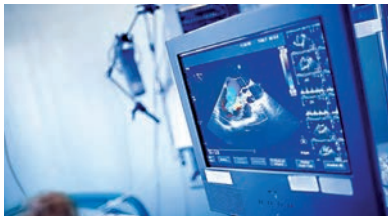
Another strategy to reduce autologous CAR-T manufacturing complexities, while potentially providing patients with quicker access to treatment, is to bypass the T cell expansion phase after the T cell engineering process and allow patients' T cells to expand in vivo. This shortened manufacturing process and approach is referred to as "next day manufacturing" and has generated market excitement when AstraZeneca acquired Gracell Biotechnologies, a leader in next-day CAR-T manufacturing, in a $1.2 billion transaction in late Q4 2023.

Creating Positive Impact

CAR-T therapy has entered a new era with its potential application in autoimmune, metabolic and other chronic conditions. With ongoing efforts to address safety concerns, expand research sites and embrace emerging approaches such as mRNA in vivo modifications, CAR-T therapy is poised to make a significant impact on the lives of more patients with improved treatment options. BS

New Zealand launches first training programme for cardiac ultrasound

A training programme in specialist heart imaging, crucial for diagnosing, treating and researching heart disease, has started for the first time in New Zealand (NZ). The Ministry of Health in NZ has provided seed funding towards a new training programme in cardiac ultrasound use, which has just got under way at the University of Auckland. The development of this programme is a partnership between the health and education sectors. As part of the Health Workforce Plan, Health Ministry



is seeking to increase training numbers in these professions, which include cardiac ultrasound. To achieve this, the Ministry would seed-fund and invest in new training programmes and pathways. The two-year programme was developed by, and will be delivered through, the Department of Anatomy and Medical Imaging located within the University's School of Medical Sciences. The first cohort of students attended an in-person introductory course covering the basics of cardiac ultrasound at the University's Grafton campus in February. The rest of the course will be taught online to allow students from across the motu to apply for training. All students in the first cohort are fully employed by the Health Ministry as they undertake their training.

Singapore and Indonesia deepen cooperation in education with two new postgraduate scholarships

Nanyang Technological University (NTU), Singapore and the Indonesia Endowment Fund for Education Agency (LPDP), a public service agency under Indonesia's Ministry of Finance, are launching two new postgraduate scholarships to foster greater collaboration between Singapore and Indonesia in the area of higher education. Indonesian students who are keen to pursue postgraduate research at NTU can apply for the LPDP-NTU Graduate Scholarship, which will fund eligible Indonesian students to do a PhD programme in social science, humanities, science, technology, engineering, and medicine at NTU Singapore. The LPDP-NTU Fellows MBA Scholarship will financially support eligible Indonesian students for the Nanyang Fellows MBA (Master of Business Administration) programme, a one-year executive education programme offered by the Nanyang Business School at NTU and is designed for senior public sector executives.

AICTE inks MoU with C-CAMP to strengthen collaboration between engineering and medical domain

The All India Council for Technical Education (AICTE) has signed a Memorandum of Understanding (MoU) with Bengaluru-based Centre for Cellular and Molecular Platforms (C-CAMP) and launched AICTE-Inter-Institutional Biomedical Innovations Programme (IBIP) to catalyse interdisciplinary education, research and innovations between medical and engineering institutions. AICTE Chairman Prof. TG Sitharam launched the AICTE-Inter-Institutional Biomedical Innovations Programme (IBIP), to promote education, research and innovations through facilitated, forged and focused interaction between medical and engineering institutions. The AICTE-IBIP programme is the collective endeavour of AICTE and C-CAMP to promote accessible, affordable and quality healthcare to all, making health and lives better. The objective of the programme is to facilitate engineering and medical graduates, post graduates and faculty members to jointly work on the challenges from the medical domain.

Aculys Pharma appoints Hidemasa Tanigaki as new CEO

Aculys Pharma, Inc., a Japan-based clinical-stage biopharmaceutical company focused on commercialising innovative treatments for neurological conditions, has announced the appointment of Hidemasa Tanigaki as Chief Executive Officer (CEO) and Representative Director. Tanigaki has an outstanding track record and has been a leader in the pharmaceutical sector for over the last 30 years. Hidemasa began his journey with Takeda Pharmaceutical Company in 1992 and held numerous key positions throughout his tenure with the company. After starting his career as a medical representative, he was later involved in the successful launch of multiple products. From 2015, he was global lead in Boston for the oncology business strategy. Upon his return to Japan, he served as Sales Director for Specialty Pharma and the Head of Rare Haematology, before assuming the role of President and Representative Director of Nihon Pharmaceutical in 2021. He then led the Gastrointestinal Disease Business Unit at Takeda.

Nuevocor names Dr John Lee as Chief Medical Officer

Nuevocor, a Singapore-based pre-clinical stage biotechnology company dedicated to developing novel medicines to treat cardiomyopathies with aberrant mechanobiology, has announced the appointment of Dr John Lee, as its Chief Medical Officer. Dr Lee is a life science executive with experience spanning from early drug discovery to late-stage clinical development. Dr Lee is a board-certified cardiologist who brings over 15 years of clinical development and regulatory expertise to Nuevocor. He was most recently the Chief Medical Officer of PhaseBio Pharmaceuticals, a publicly listed biotech, where he led Phase I-III development of its clinical programmes. Prior to PhaseBio, Dr Lee was the Vice President, Global Head, Cardiovascular Centre of Excellence at Quintiles, where he was responsible for developing and implementing the cardiovascular therapeutic area business growth strategy and also represented their cardiovascular therapeutic expertise across the broader enterprise and in the global marketplace. Dr Lee also served as Executive Director, Discovery Medicine at Bristol-Myers Squibb, where he was responsible for leading the team that provided medical, clinical, scientific, regulatory and R&D advisory expertise in cardiovascular drug development across BMS.

Dhananjay Singh steps in as MD of Merck Life Science in India

Merck, a leading science and technology company, has recently announced the appointment of Dhananjay Singh as the Managing Director of Merck Life Science in India, in addition to his current position as Head of Science & Lab Solutions Commercial, India. Effective April 1, 2024, Dhananjay Singh took over from Sreenath NS, who retired after 36 years of illustrious service with Merck in India. In his role as the Managing Director, Singh will be responsible for driving the Life Science strategy in India, ensuring governance and compliance alongside other leaders from Merck's businesses in India. Singh joined Sigma-Aldrich in 1997. Over the years he took on several leadership roles in Commercial Organisation before his appointment as Head of Science & Lab Solutions Commercial for India, a position he held since 2022. As an expert with 26 years with Merck, Singh has been instrumental in shaping the Science and Lab Solutions Commercial business in India and is exemplary in his commitment to advancing scientific progress in partnership with the customers. His expertise in market dynamics and multi-stakeholder relationship management will further strengthen Merck Life Science's position in the Indian market.

ABLE re-elects G S Krishnan as President for 2024-26

G S Krishnan, President of the Association of Biotechnology Led Enterprises (ABLE) in India, has been re-elected for another two-year term from April 2024 - 2026, as the head of India's leading biotech industry organisation. Krishnan, with three decades of experience in the Bio Industrial sector, currently - Director, external stakeholder relations at Danish biotech company, Novonesis and Independent Consultant/Advisor to various biotech companies, assumed ABLE president's role in April 2021. Krishnan will head a 14-member governing body that is elected for a two -year term, during the recently held elections. The other office bearers will be: Vice President- Dr Deepanwita Chattopadhyay, Chairperson of IKP, Hyderabad; General Secretary- Dr Ezhil Subbian, co-founder and CEO, String Bio, Bengaluru and Treasurer- Ravi Bhola, senior Partner, K&S Partners, Bengaluru. Dr Kiran Mazumdar-Shaw, will continue as the association's honorary non-executive chairperson.

CSIRO appoints Dr Debbie Eagle as Director of Australian Centre for Disease Preparedness

Australia's national science agency, Commonwealth Scientific and Industrial Research Organisation (CSIRO), has announced Dr Debbie Eagles' appointment to Director of the Australian Centre for Disease Preparedness (ACDP), after an extensive international search and recruitment process.

Dr Debbie will lead CSIRO's high-containment facility in Geelong, Victoria, which helps protect Australia's multi-billion-dollar livestock and aquaculture industries as well as community from emerging infectious disease threats. Prior to this, she was ACDP's Deputy Director, and played a pivotal role in CSIRO's response to the COVID-19 pandemic. Dr Debbie has held science leadership roles in CSIRO for many years, and has already helped guide and shape the future direction of ACDP. She has an impressive track record and is well placed to continue to lead the work required to elevate ACDP further and keep supporting Australia well into the future.

Qosina on-boards David Oh as new representative in Korea

US-based Qosina, a global supplier of OEM single-use components to the medical and pharmaceutical industries, has announced the addition of David Oh as the new representative for the Korean market. Oh brings over two decades of invaluable experience to his new role, having been actively involved in the medical device industry since graduating from Penn State University in 2000. With a solid foundation in market analysis and sales forecasting, he has a proven track record of driving business growth and implementing effective sales strategies. Additionally, Oh has a keen eye for monitoring service quality, guaranteeing that Qosina's customers in Korea receive nothing short of excellence in all their interactions. One of his notable strengths lies in his ability to navigate regulatory matters, particularly with the Ministry of Food and Drug Safety (MFDS).

His experience in developing policies to handle regulatory affairs will help the Qosina customer move towards compliance with standards and regulations. Oh is also well-versed in developing quality control strategies essential for maintaining MFDS approvals and advising customers on the requirements set forth by the Korea Medical Device Industry Association (KMDIA).

New Zealand announces new trial for treatment-resistant depression

Researchers at the University of Otago in New Zealand are recruiting for a novel trial, combining use of the drug ketamine with a proven form of psychotherapy, in the hope that people with treatment-resistant depression can stay well for longer. The study is seeking 60 patient recruits from Christchurch and Dunedin for whom regular antidepressant therapy has repeatedly failed, so-called 'treatment-resistant depression'.

Half the participants will receive an eight-week course of ketamine alone; the other group will receive ketamine in conjunction with Behavioural Activation Therapy (BAT). Study investigator Dr Ben Beaglehole, a Senior Lecturer in the Christchurch campus's Department of Psychological Medicine, says while injectable ketamine has a lot of promise as an antidepressant, the drug's positive effects are, unfortunately, only short-term. The ketamine in this trial will be given in a tightly controlled setting to minimise concerns about its abuse potential, alongside concerns it can lead to bladder issues and possible memory side effects.

Singapore pilots personalised transcranial magnetic stimulation for treatment-resistant depression

The Institute of Mental Health (IMH), in collaboration with the Yong Loo Lin School of Medicine at the National University of Singapore (NUS Medicine), has embarked on two clinical pilots to study the efficacy of personalised Transcranial Magnetic Stimulation (TMS) in treating persons with treatment-resistant depression (TRD). The trials, named APIC-TMS (Asia Pacific Individual Connectomics – Transcranial Magnetic Stimulation) and SPARK-D (Singapore's Precision Approach for Relief from Depression), are catalysed by Temasek Foundation (TF) and the National Medical Research Council (NMRC) respectively, with a grant of S$1 million each. Both clinical trials will run concurrently from March 2024 to 2026. Both trials will only recruit individuals who have undergone conventional psychiatric treatment for Major Depressive Disorder and failed to achieve remission, and they will be screened for suitability. Singapore is the first country in Southeast Asia to conduct such clinical trials of personalised TMS, modelled after the Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT) protocol.

Hong Kong designs nanorobots for saving stroke patients from brain damage

A cross-disciplinary research team from The Chinese University of Hong Kong (CUHK) has developed magnetic tissue plasminogen activator (tPA)-anchored nanorobots (tPA-nbots) to treat ischemic stroke. The novel technology exhibits a thrombolysis rate 5 to 20 times faster than traditional treatment and capabilities in recanalising more distal and smaller branches. It demonstrates potential to benefit patients by reducing brain damage and minimising side effects. The team also succeeded in using laser speckle contrast imaging (LSCI) guidance for real-time tracking and delivery of nanorobots and instant monitoring the bloodstream, providing a novel approach for nanorobots-based endovascular intervention therapy. LSCI can monitor the changes in the bloodstream within the area of interest and assess reperfusion status after an ischemic stroke. It ensures delivery efficiency and biomedical safety in complex vascular environments, allowing monitoring and analysis of the thrombolysis process, including changes to the state of the blood clot.

Taiwan develops world's first AI-powered sepsis alert system

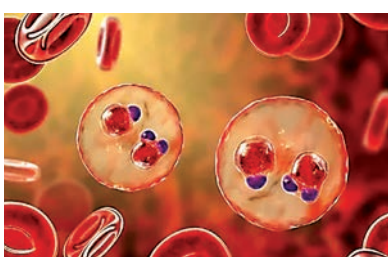
A team of researchers at China Medical University Hospital (CMUH) has developed the Intelligent Sepsis Early Prediction System (ISEPS), the world's first artificial intelligence (AI)-powered sepsis alarm system. The AI model of ISEPS takes only one minute for the early detection of sepsis and bacteremia to help clinicians identify patients at higher risk and provide early intervention with antibiotics to improve patient outcome and prevent it from progressing to sepsis. When compared to conventional blood cultures, it doesn't require additional blood collection or device operation, reducing the demands on healthcare labour while keeping the timeliness and quality of management. Bacteremia is a relatively common acute condition, occurring in about 30 per cent of UTI patients. Without prompt intervention, bacteremia can escalate to septic shock, resulting in a mortality rate exceeding 40 per cent. For each hour delayed for antibiotic administration, the mortality risk increases linearly by 7-9 per cent. With the ability to provide immediate bacteremia risk prediction, ISEPS provides the physicians timely and precisely assistance against infectious disease.

India makes low-cost AG Chitra Tuberculosis kit

Thiruvananthapuram-based Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) has developed a new low-cost AG Chitra Tuberculosis kit for the rapid detection of pulmonary tuberculosis at an early stage. The product was recently launched by Dr VK Saraswat, Member Science, NITI Aayog. The method is similar to current DNA-based diagnostic methods like CB-NAAT and can be used with any qPCR machine. With a large infrastructure of qPCR machines already available in the country after the COVID-19 pandemic, this facility can be converted for screening large populations for Tuberculosis. Up to 96 samples can be tested simultaneously, with the entire testing process taking approximately 1 hour from the sample DNA extraction to the final result. In comparison, commercially available GeneXpert and Truenat require around 3 hours and can only process 8 to 16 samples at a time. The cost per test is less than Rs 500, significantly lower than other tests in the market. This innovative technology has been licensed to Agappe Diagnostics, a Kochi-based company, and is a unique example of collaborative efforts of medical and engineering talents.

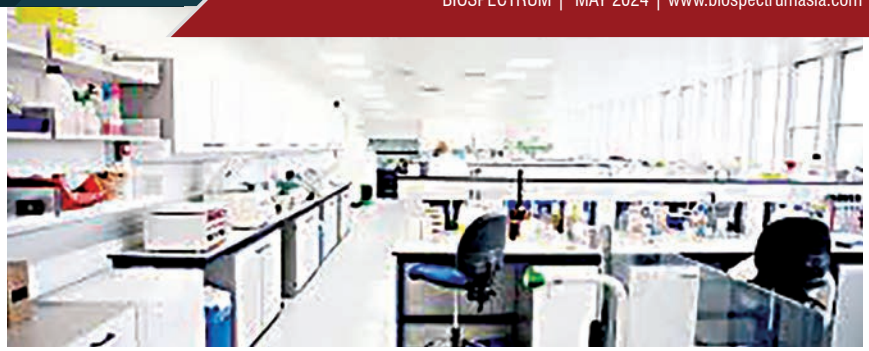
New discovery by Australia unravels malaria invasion mechanism

In a significant breakthrough, researchers from the Swiss Tropical and Public Health Institute (Swiss TPH) and Australia-based Griffith University's Institute for Glycomics have unveiled a crucial aspect of how the malaria parasite infiltrates human red blood cells. The study highlights the pivotal role of a sugar known as sialic acid in this invasive process, with far-reaching implications for malaria vaccine and drug development. While the invasion of human red blood cells by Plasmodium falciparum has long been recognised, the precise molecular targets exploited by the parasite remained elusive. Although the role of the malaria protein, cysteine-rich protective antigen (CyRPA), was acknowledged in this invasion process, its specific contribution remained unclear. The new study has delved into the binding dynamics of CyRPA.



BD increases access to cutting-edge image-enabled, spectral cell sorters

American firm BD (Becton, Dickinson and Company), a leading global medical technology company, has announced the global commercial release of new cell sorters that will enable more researchers in a broader range of fields, including cell biology, cancer research and immunology, to reveal insights that were previously invisible in traditional flow cytometry experiments. The new BD FACSDiscover S8 Cell Sorters feature BD CellView Image Technology, and BD SpectralFX Technology, bringing to market breakthrough innovations in real-time imaging and spectral flow cytometry. The three- and four-laser additions to the BD FACSDiscover S8 Cell Sorter family complement the five-laser instrument launched last year and provide scientists greater access, options, and flexibility to incorporate real-time imaging and spectral cell sorting technology in their labs.



Shimadzu opens R&D centre for scientific instruments in US

Shimadzu Scientific Instruments, Inc. (SSI), a Shimadzu Group company in the United States, has established an R&D centre to enhance its product development capabilities for analytical and measurement equipment. The R&D centre consists of three locations, with one laboratory located at SSI's headquarters in Maryland, an East Coast (near Boston, Massachusetts) laboratory, and a West Coast (near San Francisco, California) laboratory. The North American market is a region where investment in advanced technologies and products is strong. Through the R&D centre, Shimadzu will be able to accurately understand customer needs and accelerate product and technology development. At its headquarters in Maryland, the R&D centre will be used to evaluate prototypes and undertake agile development in cooperation with the Analytical and Measuring Instruments Division of Shimadzu Corporation. The Maryland headquarters will also include laboratories for the installation of prototypes and new products and for conducting joint research with customers. The Japan-headquartered Shimadzu Group plans to use its SSI base to expand its business to pharmaceutical companies, increasing sales in North America from 51 billion yen in fiscal 2022 to more than 70 billion yen in fiscal 2025.

Waters launches Alliance iS Bio HPLC System for biopharma QC labs

Waters Corporation has announced the launch of the Alliance iS Bio HPLC System with new capabilities that address the operational and analytical challenges of biopharma quality control (QC) laboratories. The new HPLC system combines advanced bio-separation technology and built-in instrument intelligence features. It is designed to help biopharma QC analysts boost efficiency and eliminate up to 40 per cent of common errors, saving time lost by investigating the source of failed runs and out-of-specification results. The bio-inert design of the instrument features Waters MaxPeak HPS Technology applied to key internal components including the system flow path to reduce unwanted interactions from metal-adsorbing analytes. The system pairs with Waters QuanRecovery Vials and Plates, as well as MaxPeak Premier HPLC Columns with eConnect Column Tag Technology, allowing for more confident platform methods that eliminate the need for lengthy column conditioning and method development. The Alliance iS Bio HPLC System also combines with Waters compliance-ready Empower Chromatography Software to help laboratories collect, manage, and report chromatography test results.

Thermo Fisher offers animal origin-free formulation to support scaling of cell therapy manufacturing

US-based Thermo Fisher Scientific Inc. has introduced the Gibco CTS OpTmizer One Serum-Free Medium (CTS OpTmizer One SFM), a novel animal origin-free (AOF) formulation designed specifically for clinical and commercial cell therapy manufacturing to deliver increased scalability and performance of T-cell expansion. As a result, cell therapy manufacturers can use CTS OpTmizer One SFM to help optimise their workflows and get T-cell therapies to patients faster. CTS OpTmizer One SFM's ready-to-use, one-part medium can help cell therapy manufacturers scale their manufacturing from process development to clinical trials and commercial manufacturing while maintaining consistent performance. As part of the cell expansion process, CTS OpTmizer One SFM delivers high cell viability, improved growth and maintains early memory T-cell phenotype. In addition, the AOF formulation can help in mitigating risk by reducing opportunities for contamination or inconsistency due to animal-origin (AO) components. The ability to more-rapidly expand less-differentiated T-cells to reach a desired dose can help manufacturers shorten the time to treatment, lower manufacturing costs, increase patient access, and enhance therapeutic efficacy.

New England Biolabs opens subsidiary in South Korea

US-headquartered New England Biolabs (NEB), a world leader in the production of reagents for the life science industry, has extended its global subsidiary network with the opening of New England Biolabs Korea Ltd (NEB Korea). The Republic of Korea is emerging as a global leader in the life science space, as a result of strong public sector support and private sector investments. NEB has supported researchers in South Korea for many years through its distribution network. NEB Korea will now bring a higher level of service to valued customers and local distributors in this important market. This new subsidiary office will provide the scientific research community in South Korea with more efficient access to the latest NEB products and technical support in the local time zone, as well as custom partnership opportunities. NEB also maintains subsidiary offices in Australia, Canada, China, France, Germany, Japan, New Zealand, Singapore and the United Kingdom.

Qiagen strengthens portfolio for cancer research

German firm Qiagen has announced a series of new products to further enhance cancer research as well as to enable urine collection and stabilisation as a new approach for liquid biopsy. These three new products, along with the IVD version of Qiagen's digital PCR platform QIAcuity, are set for launch in mid-2024. The QIAcuity dPCR PanCancer Kits will allow researchers using Qiagen's QIAcuity dPCR system to detect multiple EGFR and BRAF hallmark mutations at the same time and with high sensitivity. EGFR and BRAF are genes essential for normal cell growth and function, but mutations in these genes can result in cancer development. To advance research on how the immune system interacts with cancer, Qiagen has introduced the QIAseq Targeted RNA-seq Panel for T-cell receptors. T-cell receptors play a crucial role in the adaptive immune system, which is responsible for recognising and eliminating abnormal cells, such as cancer cells. Further, The PAXgene Urine Liquid Biopsy Set currently being developed by PreAnalytiX, a Qiagen and BD joint venture, will provide an easy-to-use, non-invasive sampling approach to liquid biopsy and address current preanalytical workflow gaps for cell-free DNA in urine (ucfDNA).

Why ABCD Steps Still A Necessity For Good Health

The Health Sciences Authority (HSA) recovered over 50 per cent more illegal health products in 2023 than in 2022. In 2023, the HSA did not let up in its efforts to stop the supply and sale of illegal health products, both online and in specific locations. Over 1.12 million illegal health product units were seized as a result of targeted operations, intelligence sharing, and cooperative enforcement activities with domestic and international organisations. These goods were either unlawfully added prohibited chemicals or had strong medicinal compounds that were either counterfeit or unlicensed.

The 50 per cent increase in products seized was due to heightened surveillance and enforcement in hotspot areas, including a major operation in June 2023 alongside the Singapore Police Force (SPF) to clamp down on a suspected illegal codeine syndicate. This operation was the biggest involving illegal codeine syndicates since 2019. Approximately 190 litres of codeine cough syrup (equivalent to about 2,100 90 ml prescription-sized bottles typically dispensed at clinics) and an assortment of pills were seized, making this one of the largest seizures in the past five years.

The HSA noted that the types of products seized remained similar, with sexual enhancement or male vitality products and addictive medicines such as codeine cough syrup, sedatives and other prescription medicines continuing to be the most common categories. According to reports, the number of units of codeine cough syrup seized in 2023 has crossed 400,000 mark as against 300,000 seized in 2022.

The multi-disciplinary regulatory agency responsible for applying medical, pharmaceutical, and scientific expertise to protect and advance public health and safety of Singapore, in 2023, worked with the administrators of local e-commerce and social media platforms to take down 12,474 listings of illegal health products. This was almost three times higher compared to 4,569 listings removed in 2022. The significant increase was largely due to two international operations led by INTERPOL that targeted the online sale of sexual enhancement products and other health products, which took place in June and October. In addition, HSA utilised technology including e-commerce surveillance tools which enabled offending listings to be identified and taken down much faster.

The majority of the removed listings were selling sexual enhancement or male vitality products (32 per cent), hair and beauty products (18 per cent) such as anti-hair loss treatment, facial fillers and adulterated skin whitening products, COVID-19 related products (9 per cent) such as test kits and symptom-relieving products, weight loss products (8 per cent), contraceptives (5 per cent), and products for management of chronic conditions (e.g., eczema, psoriasis, gout, diabetes, hypertension) (4 per cent). 1,895 sellers received warnings from HSA. It may be noted that based on the information available in these removed listings, approximately 48 per cent of sellers were based in Singapore.

From 2021 to 2023, HSA prosecuted 55 persons for the sale and supply of illegal health products. HSA will take stern enforcement actions against anyone who sells or supplies illegal health products. Sellers and suppliers who are selling such products are liable to be prosecuted and if convicted, may be imprisoned for up to 3 years and/or fined up to $100,000.

While HSA noted that as it is doing its job, it is important for consumers to be the stewards of their own health and safety by being aware of the dangers of illegal health products. It is not possible to know for sure whether a health product is illegal or harmful just by looking at a product or its packaging. Hence, consumers are advised to always be wary and follow the Avoid-Beware-Check-Discuss (ABCD) steps before buying or taking a health product.

At the global level the World Health Organization (WHO) reported that an estimated one in ten medical products in low- and middle-income countries are substandard or falsified (illegal health products). The WHO noted that substandard and falsified medical products contribute to antimicrobial resistance and drug-resistant infections. The WHO has issued 20 global medical product alerts and numerous regional warnings since 2017 and has provided technical support in over 100 cases. BS

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