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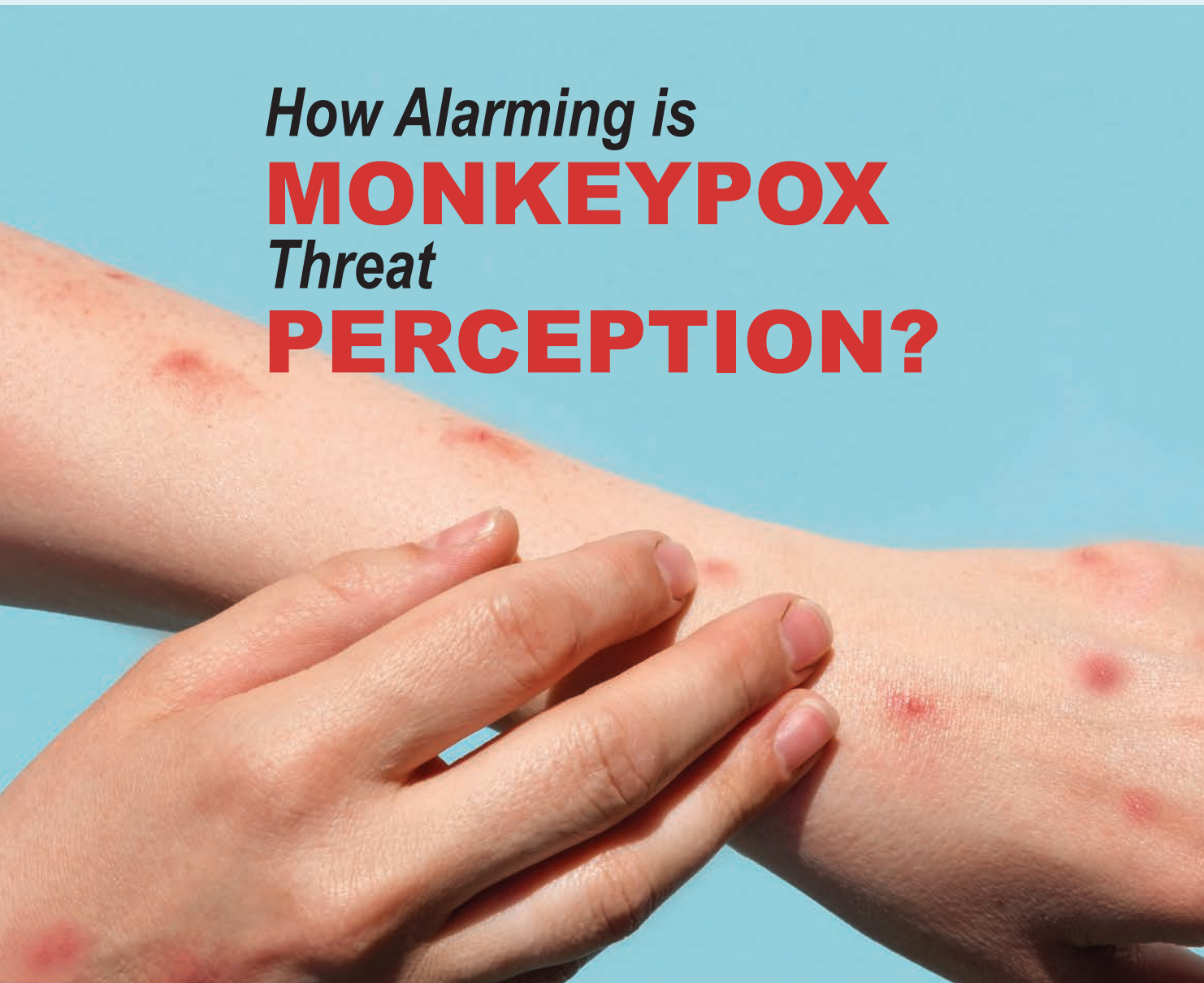
How Alarming is MONKEYPOX Threat PERCEPTION?



"The ongoing alignment of clinical trial regulations across APAC with global standards is significant"
- Anthony Costello, CEO, Medidata, USA

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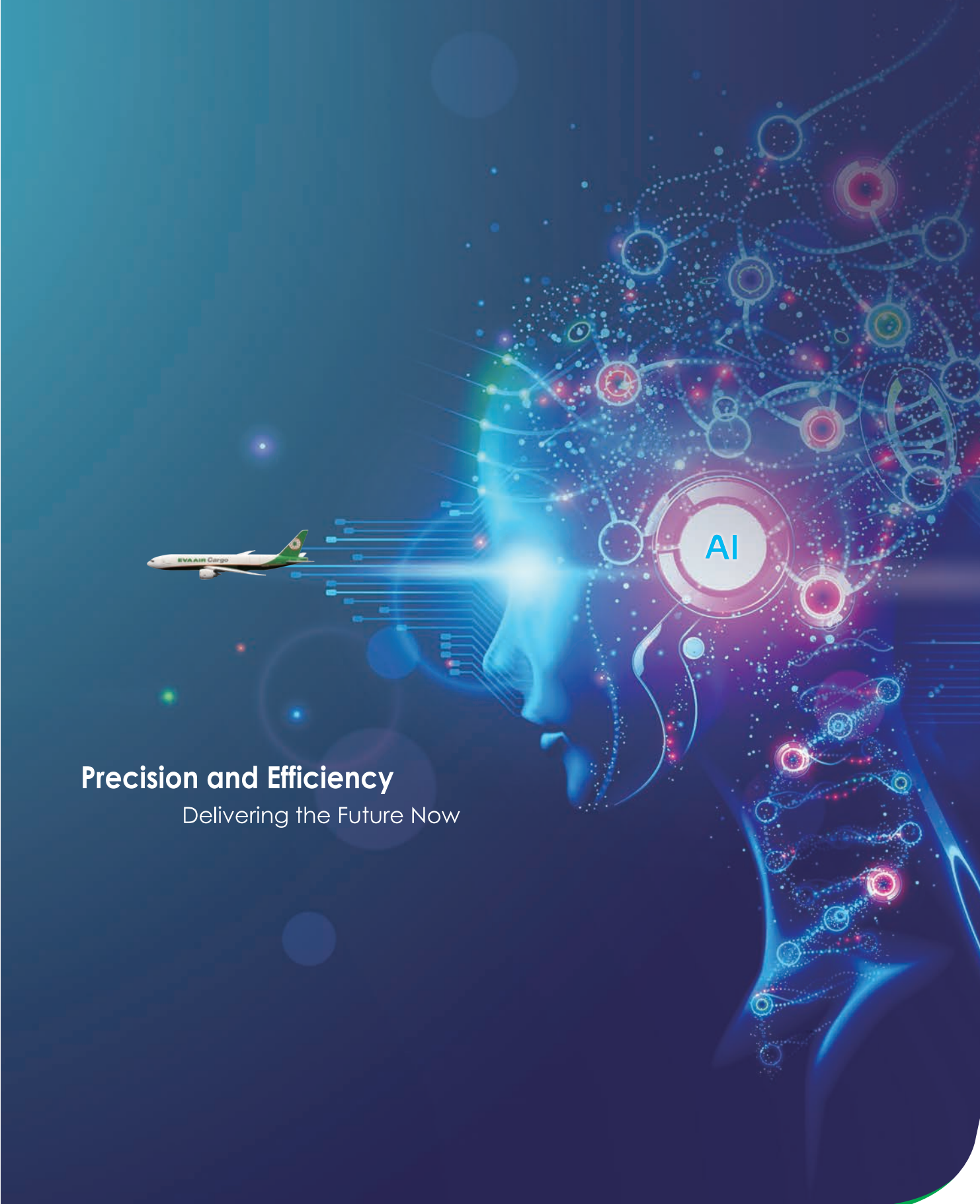

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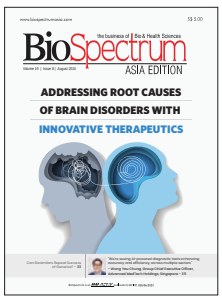

Acknowledgement/ Feedback

Thanks so much for publishing the article on Strategies for Success in Japan's Biotech Ecosystem.

- Stefan, Japan

Thanks, BioSpectrum Asia for the interview feature on Proto Axiom, in your September edition.

- William, Australia

Thank you BioSpectrum India for organising an exclusive event for the Indian BioSupplier sector on August 23 in Mumbai. All the panel discussions were very engaging and fruitful. Looking forward to more such events from your side.

- V Sankaranarayanan, India

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Letter from Publisher

Ravindra Boratkar
Publisher &
Managing Editor,
MD, MM Activ Sci-Tech
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Dear Readers,

A more lethal variant of the Mpox, known as clade 1b, surfaced in the Democratic Republic of the Congo (DRC) in September 2023, two years after the World Health Organisation (WHO) declared a global health emergency due to an outbreak. This occurred only a few months after the WHO declared the global health emergency of 2022 to be over in May 2023. The current outbreak, which is mostly centred in the DRC and its neighbouring African nations, was deemed a Public Health Emergency of International Concern (PHEIC) by August 2024, raising fears that it may expand farther and resemble the 2022 pandemic, which impacted 122 countries.

Since the beginning of Mpox monitoring in 2022 and up to August 2024, over 106,310 confirmed cases of Mpox due to MPXV clade I and clade II, including over 234 deaths, were reported by more than 123 countries globally, according to WHO. The Asia-Pacific region has also reported a few cases of Mpox, with Australia being the worst affected. Considering the growing seriousness of the issue, our content team has looked into the preparedness of the Asian countries in tackling the crisis and how they have responded to the WHO's announcement by introducing various measures, such as enhancing surveillance and public health education, to monitor potential cases and prevent outbreaks.

Ransomware payments in 2023 surpassed the $1 billion mark, the highest number ever observed. Although 2022 saw a decline in ransomware payment volume, the overall trend line from 2019 to 2023 indicates that ransomware is an escalating problem, according to the Chainalysis 2024 report. An industry veteran pointed out that now organisations need a combination of tools to detect, protect and recover from ransomware attacks - and most importantly remain cyber resilient. As threat actors look to gain any advantage they can to hit pay dirt through ransom payments, healthcare facilities need to remain vigilant in their data security prowess and establish or maintain cyber resilience.

Asia is poised to become a biomanufacturing powerhouse, building on its success in clinical trials and biotechnology innovations. While China has already established itself as a manufacturing leader, other countries in the region are following suit. Our correspondent has done a story on how the region is gearing up for a significant transformation in its biomanufacturing capabilities as nations like Singapore, South Korea, China and India have been launching ambitious policies to boost the biomanufacturing sector.

Nearly one billion people globally live with mental health conditions, and about 260 million of them reside in the WHO South-East Asia Region. Governments across Asia are ramping up efforts to combat the rising mental health crisis. As October 10 will be observed as World Mental Health Day, our correspondent covered a feature with the region's focus on policy reforms to address the growing burden of mental healthcare across Asia.

All this and much more in this month's edition for an interesting reading.

Thanks & Regards,

Ravindra Boratkar
Publisher & Managing Editor

COVER 19

How alarming is **Monkeypox Threat Perception?**

As the world finally emerges from the grip of COVID-19, a new threat looms: Mpox (formerly known as Monkeypox). In August 2024, the World Health Organisation (WHO) declared Mpox a global health emergency due to the rising cases of the new strain, clade I Mpox in Africa and Sweden, underscoring the urgent need for coordinated global action to monitor and contain the virus. As of September 2024, 2082 confirmed Mpox cases were reported globally, marking the highest number of monthly cases globally since November 2022. Nearly 400 cases have been reported in Asia Pacific this year.How are Asia Pacific countries stepping up surveillance measures and preparing their healthcare systems to combat Mpox? And just how significant is the threat posed by this outbreak? Let's explore.

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Chen Pengfei,
Vice President, Healthcare,
Singapore Economic Development Board

Mental Health

Speaking With

Ransomware

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Event Report

REGULARS

CHINA'S TWO-WAY APPROACH

Dr Milind Kokje
Chief Editor
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Integrating traditional knowledge with modern science and exploring new frontiers in modern science for domestic production of innovative drugs appears to be a two-way approach adopted by China in healthcare and medicines. Around mid-September, at the 2024 China International Fair for Trade in Services at Beijing's National Convention Centre, a humanoid robot caught the attention of the expo visitors. The robot with a box shaped facial diagnosis device uses its mechanical fingers to check and gather pulse signals from a patient's wrist, copying the TCM's pulse diagnosis technique. The pulse activity sensed by the robot is also displayed on a screen. The collected data of pulse, complexion and tongue coating is then compared by the robot with that of the healthy individual of the same age and gender allowing formation of reports of physical conditions and treatment within the TCM space.

The purpose is to perform the four fundamental diagnostic methods of Traditional Chinese Medicine (TCM) system, namely inspection, auscultation and olfaction, inquiry and palpation. Using a robot for the diagnosis method of TCM, Chinese healthcare professionals, scientists and authorities are integrating modern scientific approach and technology with old systems of diagnosis. The objective is to enhance the thousands of years old TCM system using artificial intelligence (AI) and other state-of-the-art technologies.

But it is not only one type of robot involved in diagnosis that was displayed at the expo. Robots dedicated to acupuncture and meridian massage have also been displayed. TCM experts feel that integration with modern technology will help promote TCM as an important part of healthcare and will also aid in enhancing TCM system's presence abroad. However, there have been apprehensions from some experts over the accuracy of the robot system. Experts feel that the TCM Shared Decision Making (SDM) is an important approach that encourages patients to participate in discussion about their diagnosis and treatment which is lacking in integration. In a research paper published in June 2024, some experts pointed out that AI's application in TCM comes with various risks and challenges. Robots lack the ability to understand emotions, moods, demands and sufferings of patients. This puts restrictions on making individualised medical decisions.

One more problem envisaged by experts is that there are no clear legal definitions regarding disputes caused by technology assisted TCM diagnosis. They feel there is a need to define accountability. Several such challenges exist, and the answers will have to be found out for them. It is true that its level of perfection and accuracy is yet to be known. But no doubt it is opening a new chapter in TCM.

While integrating traditional medicine with modern drugs, China's drug regulator, National Medical Products Administration (NMPA), has planned to double the efforts to facilitate research and market registration of homegrown innovative drugs. This calendar year till August, it approved 31 innovative drugs, 20 per cent more than the same period last year. In case of market clearance, 46 innovative medical devices were approved during the same period, registering 12 per cent increase.

Chinese drug makers are also making efforts to get overseas market registrations for their domestically produced novel medicines like molecular targeted therapy, immunotherapy and cell therapy. While promoting domestic production of innovative drugs, the regulator conducts supervision to ensure quality is maintained. It conducted 21,000 spot checks till August with a passing rate of over 99 per cent.

Meanwhile, Chinese researchers also claimed to have developed pioneering groundbreaking cell therapy treatment for diabetes. A diabetic patient was successfully cured, not requiring him to take insulin and even oral medicine for blood sugar control.

When efforts are on from the US to ban Chinese biomedicine and bioengineering companies, China's stride in traditional and modern integration and developing innovative drugs domestically may give it a helping hand to recover losses that if and may be caused by the proposed biosecurity action by the US. BS

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UAE to create national scientific guide to tackle obesity and weight management

The Ministry of Health and Prevention (MoHAP), in the United Arab Emirates (UAE), has teamed up with Novo Nordisk Pharma Gulf, a major player in global healthcare, to create a national scientific guide to tackle obesity and manage weight. Both sides will also collaborate to launch an awareness campaign to boost understanding of cardiovascular diseases and their complications. The partnership is part of the Ministry's ongoing efforts to improve public health and support the national plan

for tackling non-communicable diseases and their early detection, aiming to enhance the quality of life with a top-notch health system. The deal provides for the use of innovations to build effective capacities for developing a national scientific guide on combating obesity and managing weight in adults. All health authorities across the country will take part in charting out the guide, under a unified framework that strengthens coordination and collaboration between the Ministry and its strategic partners to reduce both the health and economic impacts of obesity while raising awareness about cardiovascular diseases and their complications.

New Zealand to update clinical trial regulatory guidelines

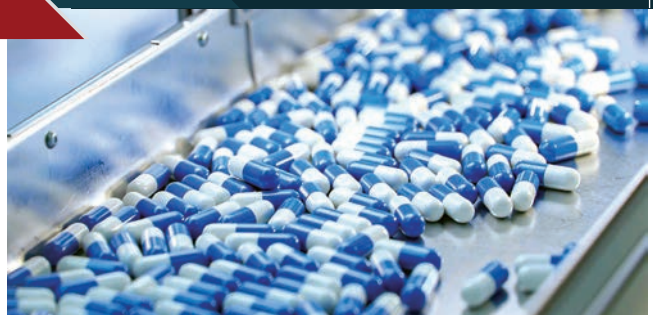
Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, is seeking public feedback on a series of proposed updates to the regulatory guidelines for people conducting clinical trials for medicines and medical devices. A key change will be the provision of guidance for conducting first-in-human trials. These trials, where a medicine is administered to humans for the first time, are an important part of medicine development, but they are also the phase of trials associated with the greatest risk for participants. Medsafe has also been working with the New Zealand Association of Clinical Research (NZACRes) to produce a simple guide to safety reporting requirements for those conducting clinical trials. This guide is also being consulted on. Other updates aim to keep guidance in line with current best practice. For example, involving consumers and patient advocacy groups in the design and conduct of trials, encouraging the implementation of pharmacovigilance systems and clarifying the responsibilities of those involved in clinical trials.

Singapore and Hong Kong sign MoU on prevention and control of communicable diseases

At the invitation of the Ministry of Health of Singapore, the Director of Health, Dr Ronald Lam, led a delegation from the Centre for Health Protection (CHP) of the Department of Health (DH), Hong Kong to Singapore for a three-day visit recently. The CHP of the DH signed a Memorandum of Understanding (MoU) on the prevention and control of communicable diseases with the interim Communicable Diseases Agency (iCDA) of Singapore. The delegation conducted work exchanges with the Ministry of Health of Singapore, and also visited National Centre for Infectious Diseases, National Environment Agency and Health Promotion Board to reinforce mutual ties and strengthen exchanges and co-operation on public health between the two places. The MoU aims to enhance cooperation between both sides in communicable diseases prevention, monitoring, epidemiological investigation, and response to infectious diseases with significant public health impacts, as well as in combating antimicrobial resistance actions, research and development, manpower capacity building and training, as well as exchange views on public health emergency response plans and exercises.

Rigel inks $162.5 M oncology deal with Kissei for Japan, Korea and Taiwan markets

US-based Rigel Pharmaceuticals, Inc., a commercial stage biotechnology company focused on hematologic disorders and cancer, has entered into an exclusive license and supply agreement with Japan's Kissei Pharmaceutical to develop and commercialise REZLIDHIA (olutasidenib) in all current and potential indications in Japan, the Republic of Korea (Korea) and Taiwan. REZLIDHIA is commercially available to patients in the US for the treatment of relapsed or refractory (R/R) mutated isocitrate dehydrogenase-1 (mIDH1) acute myeloid leukemia (AML). Rigel has an existing agreement with Kissei to develop and commercialise TAVALISSE (fostamatinib disodium hexahydrate) for the treatment of chronic immune thrombocytopenia (ITP) and in all other potential indications in Japan, China, Taiwan and Korea. Under the terms of the agreement, Rigel will receive an upfront cash payment of $10 million from Kissei, with the potential for up to an additional $152.5 million in development, regulatory and commercial milestone payments.



UCB to divest mature neurology and allergy business in China for $680 M

UCB, a global biopharmaceutical company based in Belgium, has announced a strategic divestment deal in China, underscoring its strategic shift towards innovation and partnership in one of the world's fastest-growing pharmaceutical markets. This transaction involves the sale, divestment and license of UCB's mature business (neurology and allergy) in China, including Keppra, Vimpat, Neupro, Zyrtec, Xyzal, and the Zhuhai manufacturing site, to CBC Group, Asia's largest healthcare-dedicated asset management group, and Mubadala, the Abu Dhabi based investment company, for an amount of $680 million. This medicine portfolio, consisting of well-established and trusted solutions, continues to deliver value and reliability to patients in China. UCB decided to evolve China's focus and sell the mature neurology and allergy business to a reputable investor with deep-rooted healthcare expertise and a commitment to improving efficiencies in fulfilling unmet medical needs. This partnership will allow more patients to benefit from UCB's past innovations as the new leading neurology company that CBC Group and Mubadala develops and operates at scale in China.

CSL sells plasma collection and fractionation operations in China for $185 M

Australia-based biotechnology company CSL Limited has entered into an agreement with Chengdu Rongsheng Pharmaceutical to sell its Wuhan Zhong Yuan Rui De Biologicals Products (Ruide) plasma collection and fractionation operations for cash proceeds of $185 million. Ruide develops, manufactures and commercialises plasma-derived products for the Chinese market, including albumin and immunoglobulin. Ruide's

operations include five plasma collection centres and one plasma manufacturing facility in Wuhan, Central China. The sale of Ruide is not expected to materially affect CSL's operations or its overall business in China. The transaction is expected to close by the end of calendar year 2024, subject to regulatory approval by relevant government authorities. In accordance with IFRS accounting standards, the assets and liabilities of Ruide were classified as held-for sale in the financial year 2024 (FY24) statutory accounts. Upon completion of the transaction a non-material gain on disposal will be recorded in CSL's statutory accounts.

Neovantage Innovation Parks secures Rs 300 Cr for life sciences real estate portfolio in India

Neovantage Innovation Parks, South Asia's largest private owner and operator of life sciences-focused real estate, has secured its inaugural green loan of Rs 300 crore from HSBC India. This is HSBC's first green loan facility in the life sciences real estate sector in India. Neovantage Innovation Parks, located in Genome Valley in Hyderabad, is home to leading Pharma and Life Sciences Research and Development (R&D) companies and is South

Asia's leading privately operated life sciences real estate portfolio. The portfolio is set up as a joint venture (JV) between Ivanhoé Cambridge, the real estate group of CDPQ, and Lighthouse Canton, a global investment institution. Refinancing of existing debt with the green loan facility is aligned with the company's ongoing initiatives to maintain an environmentally responsible and operationally efficient real estate portfolio. The portfolio consists of 8 world class, Grade 'A' facilities with premier multi-national and large Indian companies as tenants.

Takeda offers over $32 M for five new global CSR partnerships

Japanese pharma firm Takeda has awarded JPY 4.6 billion (approximately $32 million) to five new partners in the field of global corporate social responsibility (CSR). This is part of the company's ongoing commitment to improving the resilience of healthcare systems in low- and middle-income countries around the world. By 2030, these new collaborations are expected to expand Takeda's impact to 27 million people in 93 countries. This brings the total contribution of Takeda's global CSR programme to over JPY 28.8 billion (approximately $199.1 million) across 34 significant partnerships since its inception in 2016. The five new partners were selected by more than 22,000 Takeda employees in 80 countries and regions through a company-wide vote. The new partnerships include JPY 1,007 million to Population Services International (PSI) to expand access to vaccines through pharmacy-assisted vaccinations in Ethiopia, Kenya and Nigeria; JPY 310 million for Bulungula Incubator to integrate a community-based, holistic healthcare approach into the national health system in the remote Xhorha Mouth Administrative Area in South Africa.

Singapore opens ENgAGE to address age-related challenges with S$5M funding

The College of Design and Engineering (CDE) at the National University of Singapore (NUS) has established the Centre for Environment and Ageing Well (ENgAGE) to take the lead in enhancing living environments that foster the physical, psychological and social well-being of individuals across all age groups, particularly in response to the challenges brought about by demographic shifts and climate change. The establishment of ENgAGE was made possible through a generous S$5 million gift from Lee Li-ming, spouse of the late Associate Professor Lee Kip Lin, an architect and professor at NUS, who had devoted many years documenting Singapore's architectural heritage. ENgAGE will enhance Singapore's ongoing efforts to explore innovative ways to support older adults, as the nation prepares for an increasingly ageing population. The Centre will leverage robust research capabilities, including urban planning, architecture, social sciences, medicine and engineering, to coordinate and consolidate place-based, ageing-related research, education and resources locally and internationally.

GC Cell takes first anticancer drug cell therapy to Indonesia

South Korea-based GC Cell, a leading innovator in cell therapy, has announced the execution of a landmark 'Technology Transfer and License Agreement' with PT Bifarma Adiluhung (Bifarma), a premier stem cell therapy company in Indonesia. This strategic partnership, which began in June, solidifies approximately three months later with the signing of the final licence agreement. Under the terms of the agreement, Bifarma will be granted the exclusive rights to develop, manufacture, and commercialise Immuncell-LC for 15 years. Bifarma is recognised for operating Indonesia's first GMP-certified cell therapy production facility and possesses a comprehensive sales and marketing infrastructure focused on oncology, specialising in a cold chain distribution network that spans across Indonesia. This infrastructure is expected to maximise the accessibility and commercial success of Immuncell-LC. The initiation of technology transfer concurrent with the signing of the licence agreement sets Korea on a path to introduce Immuncell-LC in Indonesia by next year. This milestone is pivotal GC Cell works to introduce Immuncell-LC, South Korea's first anticancer drug cell therapy, to a global audience, offering new treatment avenues to a broader patient demographic.

Bora Pharma makes investment into Tanvex for global biomanufacturing services

Taiwan-based Bora Pharmaceuticals Co. has announced that its Board of Directors has approved a strategic investment into Tanvex Biopharma Co., whereby Bora Biologics, a wholly owned subsidiary of Bora and specialist large molecule Contract Development and Manufacturing Organisation (CDMO), and Tanvex will combine their biomanufacturing facilities to create a global solution for biologics development and supply. The investment will bring together Bora's extensive CDMO capabilities and total service culture with Tanvex's scale, development expertise and US FDA-approved commercial-scale facility in San Diego, California, and, upon completion, the appointment of Bobby Sheng, Chairman and CEO of the Bora Group, as Chairman of the merged organisation. Upon completion of the transaction, which is expected in Q1 of 2025, Bora will hold approximately 30.5 per cent of Tanvex's total outstanding shares based on current shareholding structure, becoming the single largest shareholder of Tanvex.

GSK launches Herpes Zoster vaccine 'Shingrix' in Malaysia

GlaxoSmithKline Pharmaceutical Sdn Bhd (GSK) has announced the launch of its Herpes Zoster vaccine, Shingrix, also known as Recombinant Zoster Vaccine, Adjuvanted (RZV) in Malaysia for the prevention of shingles (herpes zoster, HZ) and post-herpetic neuralgia (PHN) in adults aged 50 years and over. RZV is a non-live, recombinant subunit adjuvanted vaccine given intramuscularly in two doses. RZV will initially be available in Malaysia to adults aged 50 and over and those aged 18 and over who are at increased risk of HZ. Shingles is caused by the reactivation of the varicella zoster virus (VZV), the same virus that causes chickenpox. As people age, the cells in the immune system lose the ability to mount a strong and effective response to infection, increasing the risk of developing shingles. RZV is a vaccine designed to prevent shingles in adults aged 50 years and over and 18 years and over who are at increased risk in countries where the indication for this population has been approved. RZV has resulted in positive vaccination recommendations.

Medtronic opens Robotics Experience Studio in Singapore

Medtronic plc, a global leader in healthcare technology, expands the capabilities of Medtronic Customer eXperience Center (MCXC) in Singapore with the opening of its first Robotics Experience Studio in Southeast Asia. This underscores the commitment of Medtronic to enhance access to new technologies through collaboration, training and education within the healthcare ecosystem. Since the opening of MCXC in November 2022, Medtronic has made substantial strides in medical education and upskilling, having trained more than 2,000 healthcare professionals (HCPs) across Asia and conducted nearly 1,400 training and experience sessions. The addition of the Robotics Experience Studio is set to amplify these efforts by providing cutting-edge resources for HCPs to hone their skills in robotic-assisted procedures and artificial intelligence (AI) applications.

Olympus extends advanced bipolar surgical energy portfolio

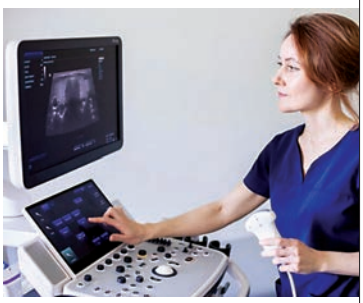
Japan-based Olympus Corporation, a global medical technology company, has announced the launch of two new jaw designs in the POWERSEAL Sealer/Divider family of advanced bipolar surgical energy products- the POWERSEAL Straight Jaw, Double-action (SJDA) and the POWERSEAL Curved Jaw, Single-action (CJSA). The first POWERSEAL device, launched in 2021, is the POWERSEAL Curved Jaw, Double-action (CJDA), which has established a strong foothold for Olympus in the advanced bipolar surgical energy market. The POWERSEAL Sealer/Divider family of devices now includes three jaw designs each available in three shaft lengths to support surgeon preference and technique for dissection, grasping, and sealing during surgical procedures. These devices are designed to meet the highest standards of clinical performance for advanced bipolar surgical energy devices by consistently delivering secure and fast vessel sealing. The devices are designed to promote procedural efficiency and surgeon comfort with a multifunctional feature set and carefully considered ergonomics. Each POWERSEAL design requires less squeeze force than competitor devices to close the jaws, without sacrificing jaw force or sealing capability.

Bharat Biotech to collaborate with Alopexx for development of broad-spectrum antimicrobial vaccine

Indian biopharma firm Bharat Biotech has announced a collaboration with US-based Alopexx, Inc., for the co-development and commercialisation of Alopexx's proprietary broad-spectrum antimicrobial vaccine, AV0328, in India and other low income and lower middle-income countries. As part of the collaboration, the companies will co-develop and commercialise AV0328, a synthetic vaccine targeting poly N-acetyl glucosamine (PNAG), in India and other licensed territories. Alopexx would be entitled to a one-time upfront payment and milestone payments, as well as royalties on future sales of AV0328 in the licensed territories. AV0328 is a synthetic vaccine designed to target poly N-acetyl glucosamine (PNAG), a substance found on the surface of a wide range of bacterial, fungal, and parasitic pathogens. In pre-clinical studies, targeting PNAG has shown effectiveness in preventing and treating infections caused by over 15 different pathogens.

See-Mode Technologies gets US FDA clearance for thyroid ultrasound AI analysis software

Australia-based startup See-Mode Technologies, a global innovator in artificial intelligence (AI) for ultrasound imaging, has announced the receipt of 510(k) clearance from the US Food and Drug Administration (FDA) for their thyroid ultrasound analysis and reporting software. See-Mode's AI solution aims to reduce reporting time and variation in delivery of care for thyroid ultrasound. The software detects nodules in single or multinodular thyroid ultrasound images, and automatically classifies each nodule in line with the American College of Radiology's (ACR) TI-RADS rating systems. A complete worksheet is automatically generated and preliminary impressions are sent to radiology reporting systems after clinician review and approval. Existing CPT codes relevant to the use of AI for analysis of thyroid ultrasound also provide greater reimbursement opportunities. This is the first FDA-cleared product for both detection and diagnosis (CADe/x) of thyroid ultrasound.



PolyU, Suzhou Kowloon Hospital to establish incubation platform advancing medtech in China

The Hong Kong Polytechnic University (PolyU) has signed a collaboration agreement with Suzhou Kowloon Hospital, a subsidiary of the Hong Kong Kowloon Group, to jointly establish the Suzhou Kowloon Hospital – The Hong Kong Polytechnic University Innovation Incubation Platform. The two institutions will leverage their respective strengths, sharing resources over the next three years to promote the translation and application of medical technology research outcomes. This will help drive innovation and clinical application research in the field and enhance the development and quality of the healthcare industry, enabling patients to enjoy better treatment and service. Under this agreement, PolyU and Suzhou Kowloon Hospital will strengthen their collaboration in accelerating research and clinical application in areas including medical engineering and artificial intelligence to foster innovation and translation in medical technology.

Respiree teams up with Roche Diagnostics to improve patient monitoring in APAC

Existing patient monitoring workflows often rely on nurses managing patients from centralised workstations, monitoring vitals and biomarkers at different intervals, and manually collecting vitals. This process can be inefficient, especially with limited workstations, multiple workflows, increased patient volumes, and nursing shortages. By the first quarter of 2025, Singapore and US-based startup Respiree will team up with Roche to launch pilot programmes across Asia Pacific (APAC) that offer a simplified approach to patient monitoring by combining Roche's cobas pulse system with Respiree's vital sign monitoring. The solution is also expected in future to integrate machine learning models that predict clinical deterioration using historical data with risk scores at the bedside. The cobas pulse system, a point of care device, equipped with digital health applications based on the Android operating system allows for real-time administration and visualisation, eliminating the need for centralised workstations.

Lotte Holdings unveils new healthcare and biopharmaceutical corporate venture capital

Lotte Holdings Co. has announced the establishment of a new Healthcare and Biopharmaceutical Corporate Venture Capital (CVC) dedicated to investing in biopharmaceuticals and next-generation modalities. Expanding its business across various fields, South Korea and Japan-based Lotte Group entered the healthcare and biopharmaceutical sector in 2022 by establishing Lotte Biologics, a Contract Development and Manufacturing Organisation (CDMO). To further strengthen its commitment to healthcare and biopharmaceuticals, Lotte Holdings has newly established a CVC dedicated to these fields. This CVC aims to gather cutting-edge insights to accelerate access to innovative technologies and promote investment in promising startups. In this first phase of investment, the CVC aims to target companies of all stages globally.

HKU Techno-Entrepreneurship Academy opens in Shenzhen Qianhai

A grand opening ceremony for the HKU Techno-Entrepreneurship Academy in Shenzhen Qianhai was held recently. This momentous occasion marks a significant milestone in the strategic cooperation agreement signed between University of Hong Kong and the Qianhai Authority in 2022. The strategic initiative seeks to promote innovation, entrepreneurship, and technological advancement in the Greater Bay Area. Located in the North District of the Qianhai Shenzhen-Hong Kong Youth Innovation and Entrepreneur Hub, the Academy is designed to be a hub for aspiring entrepreneurs & technologists, providing them with the resources, mentorship, & support needed to transform innovative ideas into successful ventures. The first batch of 11 startups in cutting-edge fields such as artificial intelligence, healthcare, new energy, & new materials will be based at the Academy. These ventures, founded by HKU professors, students, and alumni, were chosen through a rigorous selection process. EEF will serve as a mother fund to channel capital into top early-stage investment institutions both domestically & internationally, investing in deep-tech ventures of HKU at the seed and early stages to drive the development of promising startups, while the HKU Super Angel Network seeks to unite and mobilise HKU alumni to back early-stage HKU startups.

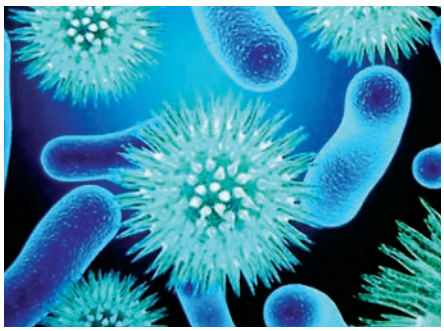
IIM Bangalore to have India's first Global Centre of Excellence on PE & VC

Professor U Dinesh Kumar, Dean, Faculty, at the Indian Institute of Management (IIM) Bangalore has signed a Memorandum of Understanding (MoU), with Mathew Cyriac, Executive Chairman, Florintree Advisors and alumnus of the PGP Class of 1994, to pave the way to the setting up of a global Centre of Excellence, the Tony James Centre for Private Equity (PE) and Venture Capital (VC), at IIM Bangalore. Tony James, former President, Chief Operating

Officer and Executive Vice Chairman of New York-based global asset management firm Blackstone, is one of the most well-known investment bankers on Wall Street. Through strategic investments and collaborative partnerships, the PE/VC industry can play a pivotal role in realising the vision of Atmanirbhar Bharat, and fostering entrepreneurship. The first-of-its-kind Centre will serve as a hub for cutting-edge research, education and industry collaboration in the field of PE/VC, where students will connect with industry leaders, gain hands-on insights, and explore the latest trends in PE/VC.

WHO launches global framework for understanding the origins of new or re-emerging pathogens

With the support of the Scientific Advisory Group for the Origins of Novel Pathogens (SAGO), the World Health Organization (WHO) has published a global framework to help Member States comprehensively investigate the origins of new and re-emerging pathogens. While there are a number of tools available for investigating infectious disease outbreaks, this is the first unified, structured approach to investigating the origins of a novel pathogen. This framework aims to fill that gap by providing a comprehensive set of scientific investigations and studies. It is the first version of a "how-to" guide that will be updated as and when needed, based on feedback from users. As each outbreak and pandemic demonstrates, human and animal health is threatened by the increasing risk of the emergence of known (such as Ebola, Nipah, avian influenza, Lassa and Monkeypox viruses) and novel pathogens with epidemic and pandemic potential (novel influenza, MERS-CoV, SARS-CoV-1, SARS-CoV-2), the ability to prevent, and when we cannot prevent, to swiftly contain outbreaks and identify their origins is scientifically, morally, and financially more critical than ever.



WHO publishes global guidance to curb antibiotic pollution from manufacturing

The World Health Organization (WHO) has published its first-ever guidance on antibiotic pollution from manufacturing. The new guidance on wastewater and solid waste management for antibiotic manufacturing sheds light on this important but neglected challenge. The emergence and spread of antimicrobial resistance (AMR) caused by antibiotic pollution could undermine the effectiveness of antibiotics globally, including the medicines produced at the manufacturing sites responsible for the pollution. Despite high antibiotic pollution levels being widely documented, the issue is largely unregulated and quality assurance criteria typically do not address environmental emissions. In addition, once distributed, there is a lack of information provided to consumers on how to dispose of antibiotics when they are not used, for example, when they expire or when a course is finished but there is still antibiotic left over.

WHO prequalifies first vaccine against mpox

The World Health Organization (WHO) has announced the MVA-BN vaccine as the first vaccine against mpox to be added to its prequalification list. The prequalification approval is expected to facilitate timely and increased access to this vital product in communities with urgent need, to reduce transmission and help contain the outbreak. WHO's assessment for prequalification is based on information submitted by the manufacturer, Bavarian Nordic A/S, and reviewed by the European Medicines Agency, the regulatory agency of record for this vaccine. The MVA-BN vaccine can be administered in people over 18-years of age as a 2-dose injection given 4 weeks apart. After prior cold storage, the vaccine can be kept at 2–8°C for up to 8 weeks. While MVA-BN is currently not licensed for persons under 18 years of age, this vaccine may be used "off-label" in infants, children and adolescents, and in pregnant and immunocompromised people. This means vaccine use is recommended in outbreak settings where the benefits of vaccination outweigh the potential risks.

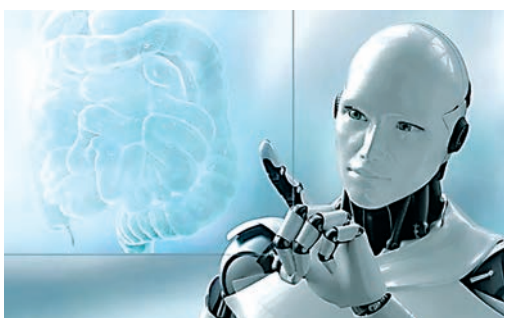
PAHO and Alzheimer's Disease International join forces to end stigma around dementia

The Pan American Health Organization (PAHO) and Alzheimer's Disease International (ADI) have launched a new campaign, a joint initiative to raise awareness about dementia and to address the stigma that surrounds the condition in the region of the Americas. Alzheimer's disease and related disorders affect an estimated 10.3 million people in America and are among the leading causes of death in individuals aged 60 and older. Regrettably, persons living with these conditions are often subject to stigma and discrimination, and with the number of people living with dementia set to almost triple by 2050, now is the time to promote a better understanding of this condition. This joint campaign aims to raise awareness by opening discussions about dementia on television, social media, newspapers and radio, and to address current perceptions and attitudes about this condition.

G20 leaders to prioritise diagnostics in fight against climate-driven diseases

Climate change is supercharging disease spread and intensity, leaving communities in low- and middle- income countries (LMICs) at increasing risk to climate and health threats. Diagnostics serve as a critical first line of defence in safeguarding health, particularly for communities underserved and most vulnerable to the climate crisis. G20, comprising the world's largest economies, are being urged to take a bold stance on diagnostics to address the growing burden of climate-related diseases. FIND is working to scale equitable access to climate-resilient diagnostics and calls on the G20 to invest in assessing the impact of climate change on disease prevalence, invest in innovation, research and development of improved or adapted, climate-tolerant diagnostic tests, and leverage multiplex diagnostic platforms, genome sequencing and digital health tools to strengthen integrated surveillance systems across human, animal, agricultural and environmental samples.

First cloud-based AI endoscopy system for colonoscopy gets US FDA clearance



Odin Medical, an Olympus Corporation company, has received US Food and Drug Administration (FDA) 510(k) clearance for the first cloud-based Artificial Intelligence (AI) technology designed to assist gastroenterologists in detecting suspected colorectal polyps during colonoscopy procedures, the CADDIE computer-aided detection (CADe) device. A prospective, multi-centre randomised controlled trial successfully demonstrated the efficacy and safety of the CADDIE device, underscoring its potential to enhance detection capabilities and patient care without increasing procedural risks or duration. The trial was conducted across eight medical centres in Europe. The CADDIE device works by analysing colonoscopy video in real-time and using visual markers to alert the endoscopist to the potential presence of polyps. The endoscopist is responsible for reviewing the CADDIE device's suspected polyp areas and confirming the presence or absence of a polyp based on their own medical judgment. The CADDIE device is limited to use with standard white-light endoscopy imaging only.

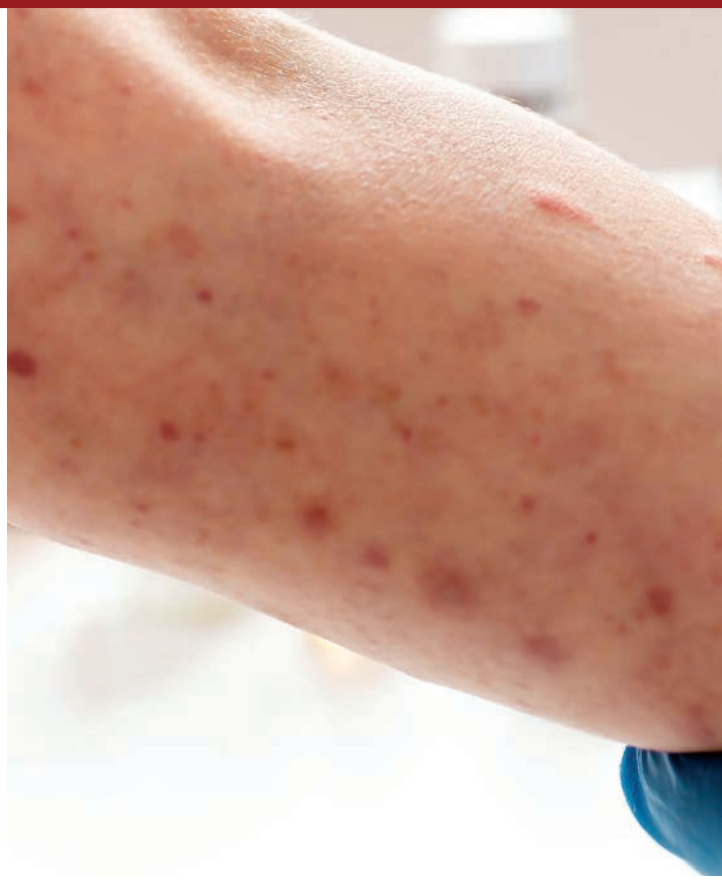
How alarming is **Monkeypox Threat Perception?**

As the world finally emerges from the grip of COVID-19, a new threat looms: Mpox (formerly known as Monkeypox). In August 2024, the World Health Organisation (WHO) declared Mpox a global health emergency due to the rising cases of the new strain, clade I Mpox in Africa and Sweden, underscoring the urgent need for coordinated global action to monitor and contain the virus. As of September 2024, 2082 confirmed Mpox cases were reported globally, marking the highest number of monthly cases globally since November 2022. Nearly 400 cases have been reported in Asia Pacific this year.How are Asia Pacific countries stepping up surveillance measures and preparing their healthcare systems to combat Mpox? And just how significant is the threat posed by this outbreak? Let's explore.

Two years after the World Health Organization (WHO) declared a global health emergency over an Mpox outbreak, a deadlier strain, clade 1b, emerged in the Democratic Republic of the Congo (DRC) in September 2023. This came just months after the WHO had ended the 2022 global health emergency in May 2023. By August 2024, the new outbreak, largely concentrated in the DRC and its African neighbours, was declared a Public Health Emergency of International Concern (PHEIC), sparking concerns of a wider spread similar to the 2022 outbreak, which affected 122 countries.

There are two clades of Mpox: clade I and clade II. Endemic to Central Africa, clade 1 is the most deadly, causing a severe illness and – in past outbreaks – killing up to 10 per cent of those who become unwell. Clade II, on the other hand, which had spread globally in 2022, has a survival rate of over 99.9 per cent and is endemic to West Africa. Five countries in Africa (Burundi, DRC, Kenya, Rwanda and Uganda) and three countries outside of Africa (Sweden, Thailand, India) have reported clade Ib monkeypox virus (MPXV) as of September 22, 2024.

Since the beginning of Mpox monitoring in 2022 and up to August 2024, over 106,310 confirmed cases of Mpox due to MPXV clade I and clade II, including over 234 deaths, were reported by more



than 123 countries globally, according to WHO.

The Asia-Pacific region has also reported a few cases of Mpox, with Australia being the worst affected. In 2024, Australia recorded 257 confirmed cases, with the majority concentrated in Victoria (114 cases) and New South Wales (102 cases). Other affected regions include Queensland (24 cases), the Australian Capital Territory (12 cases), South Australia (4 cases), and the Northern Territory (1 case).

Singapore too has recorded 14 cases, Vietnam has documented 49 cases, while the Philippines has seen 18 cases. In Indonesia, 88 Mpox cases were confirmed, South Korea 11 cases. Elsewhere in the region, Malaysia, Thailand and India each reported one case.

Asia Responds

The WHO's designation of Mpox as a public health emergency underscores the urgency of addressing the disease's potential for rapid spread, particularly in populations with low immunity due to the end of smallpox vaccination programmes. The emergence of Mpox cases in non-endemic regions has raised concerns about public health preparedness. The Asian countries have responded to the WHO's announcement by introducing various measures, such as enhancing surveillance and public health education, to monitor potential cases and prevent outbreaks.

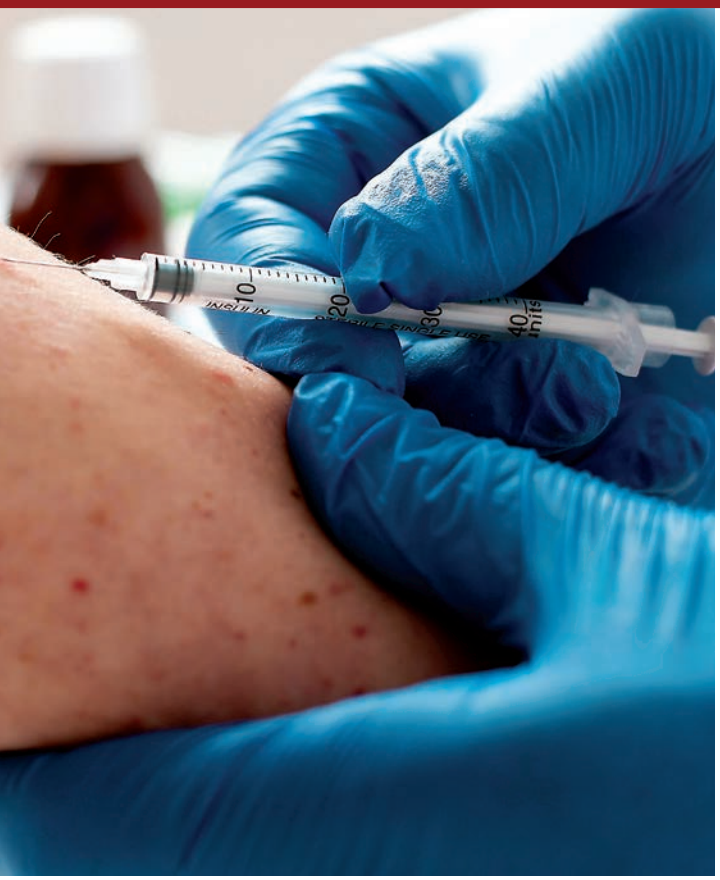
In response to the Mpox threat, Singapore has announced a series of measures following the WHO declaration of Mpox as a global public health emergency in August. Singapore's comprehensive response plan includes vaccinating two high-risk groups, implementing temperature screenings at select locations, and establishing protocols for handling suspected and confirmed cases. As part of a coordinated, whole-of-government effort, the Ministry of Health (MoH) has enhanced public health preparedness to address a potential Mpox clade I outbreak.

All healthcare practitioners and institutions have been instructed to remain vigilant in detecting and reporting Mpox cases, especially those suspected to be clade I infections. Suspected cases will be promptly transferred to hospitals for further evaluation and treatment if needed. Upon confirmation of a clade I case, the Ministry of Health will initiate immediate contact tracing, and close contacts will be quarantined in a government-designated facility for 21 days, consistent with the observed incubation period in Africa. To strengthen containment efforts, Singapore has also tightened border controls and begun screening incoming passengers at airports for early detection of Mpox cases.

China too has announced strengthened surveillance at ports of entry in response to the Mpox outbreak. Travellers arriving from regions with confirmed Mpox cases who show symptoms such as fever, headache, back pain, or rashes must declare their condition to customs. In addition, aircraft, vessels, and cargo arriving from affected areas will undergo sanitation procedures. These measures, which took effect from August 2024, will be enforced for the next six months to monitor people and goods entering the country for Mpox.

South Korea's Korea Disease Control and Prevention Agency (KDCA) stated that the Mpox situation remains manageable under current protocols. However, South Korean authorities have decided to ramp up quarantine and surveillance measures.

India has been taking proactive measures against Mpox. The country has implemented a comprehensive strategy involving expert consultations, enhanced surveillance, laboratory preparedness, and awareness campaigns. While remaining vigilant, Indian health authorities have assessed a low risk of a large-scale outbreak, demonstrating a balanced approach to public health



management in the face of emerging infectious diseases.

Australia has implemented a response plan for Mpox that involves surveillance, contact tracing, and vaccinations for high-risk groups. A vaccination programme for Mpox was initiated in Australia in August 2022. By the end of 2022, 30,346 people received 1 dose of JYNNEOS, with another 16,954 people completing a course of Mpox vaccination (2 doses) in that year. In 2024, there has been a resurgence of clade II cases in Australia. Most cases have been acquired in Australia and a small number have been in people who were fully vaccinated.

The Australian Technical Advisory Group On Immunisation (ATAGI) recommendations for Mpox vaccination have been updated in August 2024 to remove the age restriction; people of all ages who are at risk of exposure to Mpox are recommended to receive the Mpox vaccination. The ATAGI noted that it is monitoring the evolving Mpox epidemiology in Australia and other affected regions. Vaccine recommendations will continue to be reviewed and updated if required.

Indonesia is reactivating the COVID-era health tracking system, previously known as PeduliLindungi. This initiative is part of the government's preventive measures against Mpox. Countries such as Vietnam and Malaysia have strengthened the monitoring and detection of suspected cases at border checkpoints and within public and private healthcare establishments.

Preparedness

Regarding Mpox prevention, vaccinations are the most effective strategy. The WHO has advocated for targeted vaccinations of high-risk populations rather than mass immunisation. Currently, the WHO recommends the use of Bavarian Nordic's MVA-BN vaccine and Japan-based KM Biologics' LC16 vaccine, the latter being the only Mpox vaccine licensed for children. If these vaccines are unavailable, the WHO suggests using Emergent BioSolutions' ACAM2000 vaccine, which recently received approval from the US Food and Drug Administration (FDA) for a supplemental Biologics License Application (sBLA). This approval allows ACAM2000 to be administered to individuals considered at high risk for Mpox infection. Bavarian Nordic's MVA-BN vaccine is also approved by Singapore and Australia.

Unlike the COVID-19, big pharma isn't rushing to develop treatments for Mpox. The effort is largely being led by smaller biotech companies.

US-based NanoViricides Inc highlighted the need for new treatments to manage the recurring Mpox, since there is a short supply of the limited vaccines that are available, which are developed as smallpox vaccines. Following the WHO's PHEIC announcement, the company considered that its novel investigational antiviral NV-387 is eligible for evaluation for Monitored Emergency Use of Unregistered and Investigational Interventions (MEURI), as a treatment for the virus. The experimental drug has completed a phase I study. Promising animal studies of NV-387 have shown that the drug was as effective as the current approved drug tecovirimat when emulating the direct skin infection by the virus. This is notable because direct skin infection is thought to be the major mode of transmission of the virus in the current epidemic of Mpox clade 1 and clade 1b.

Another promising vaccine candidate for Mpox, TNX-801, developed by Tonix Pharmaceuticals, has similarities to the original smallpox vaccine. This drug was the only vaccine to successfully eliminate a contagious viral pathogen, according to Tonix. In contrast to mRNA vaccines, TNX-801 is designed to elicit a robust T-cell response, "facilitating long-term immunity and potentially eliminating the need for repeated boosters. For example, pre-clinical data shows that the drug significantly reduced viral shedding, suggesting that it can block forward

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- David Dodd,
CEO, GeoVax, USA

"Ongoing trials throughout the world are working to demonstrate the benefit of treating Mpox patients with tecovirimat. One of the biggest challenges is that, similar to antiviral therapies for flu and COVID-19, treatment likely needs to be initiated soon after infection to reduce pain, rash, and other complications of Mpox infection."

- Dr Jay Varma,
Former Executive Vice President and Chief Medical Officer, SIGA Technologies, USA

"The streamlined regulatory processes established during COVID-19, such as the US FDA's Emergency Use Authorizations (EUAs), have set a precedent for fast-tracking vaccines and treatments for emerging diseases. These allow trials to start faster without compromising safety. Additionally, streamlined processes are now aiding Mpox treatment trials, expediting approval timelines while ensuring rigorous review standards are taken into action."

- Dr Seth Lederman,
Co-Founder, CEO and Chairman, Tonix Pharmaceuticals, USA

transmission. On August 26, 2024, Tonix announced a collaboration with Bilthoven Biologicals (Bbio) to develop GMP manufacturing processes for its Mpox vaccine. Bbio is part of the world's largest vaccine manufacturer, the Cyrus Poonawalla Group, which also includes the Serum Institute of India.

"The streamlined regulatory processes established during the COVID-19 pandemic, such as the US FDA's Emergency Use Authorizations (EUAs), have set a precedent for fast-tracking vaccines and treatments for emerging diseases. These also allow trials to start faster without compromising safety. Additionally, streamlined processes are now aiding Mpox treatment trials, expediting approval timelines while ensuring rigorous review standards are taken into action.This has equipped Tonix to engage with regulatory bodies efficiently, ensuring that TNX-801 is evaluated swiftly," said Dr Seth Lederman, Co-Founder, CEO and Chairman of Tonix Pharmaceuticals.

Another American biotech GeoVax Inc has the cGMP Master Seed Virus for GEO-MVA (GeoVax-Modified Vaccinia Ankara) and is exploring options to accelerate production of the MVA-vaccine (against Mpox and Smallpox) through cGMP clinical grade production.

In Asia, both China and India are actively developing Mpox vaccines. The Serum Institute of India is working on its own vaccine, while China has approved its first Mpox vaccine for clinical trials, which began on September 9, 2024. The vaccine, developed by the Shanghai Institute of Biological Products—a subsidiary of the state-owned pharmaceutical giant Sinopharm—has shown promising results in early studies, indicating effective immunity against the highly infectious virus. Sinopharm is also known for creating China's first COVID-19 vaccine in 2020.

Currently, the only antiviral agent approved for Mpox treatment is tecovirimat (TPOXX), which has been authorised by regulators in the UK and European Union for Mpox and other orthopoxviruses. Originally developed for smallpox, tecovirimat has been repurposed for Mpox treatment.

"Ongoing trials throughout the world are working to demonstrate the benefit of treating Mpox patients with tecovirimat. One of the biggest challenges is that, similar to antiviral therapies for flu and COVID-19, treatment likely needs to be initiated soon after infection to reduce pain, rash, and other complications of Mpox infection. In many parts of the Democratic Republic of Congo (DRC) and other African countries experiencing outbreaks, patients

often do not seek care until they have been sick for many days, limiting the potential benefit of antiviral treatment. In those situations, optimising other forms of clinical care, such as good wound cleaning and antibiotics for skin infections, is paramount," said Dr Jay Varma, Former Executive Vice President and Chief Medical Officer, SIGA Technologies. Tecovirimat recently missed critical clinical endpoints on a major clinical trial addressing it as a therapy against Mpox.

Much of the research on Mpox is focused on developing preventive vaccines, with comparatively less emphasis on therapies and diagnostics. "Progress on developing and approving new Mpox diagnostics and therapies has been limited. The primary focus has been on getting existing vaccines approved by WHO and affected countries, as well as addressing research gaps related to vaccines, such as efficacy of those for use in individuals under 18 years of age and the development of new vaccines including using new vaccine platforms. WHO is currently reviewing six Mpox diagnostic products. On the contrary, there is already a WHO-prequalified vaccine for Mpox prevention," said Javier Guzman, Director of Global Health Policy and Senior Policy Fellow at the Center for Global Development.

Despite the availability of diagnostics and treatments, the irony is that they remain inaccessible to the African populations most affected by this disease. Similar to the COVID-19, developed nations have begun hoarding vaccines. The Africa Centres for Disease Control and Prevention (Africa CDC) reported that its request for $245 million (£187 million) to address the outbreak is only 10 per cent funded. Although Mpox was first identified in humans in the DRC in 1970, African nations vulnerable to its spread are still dependent on vaccine donations from the stockpiles of wealthier countries. Not only are vaccines scarce, but people in these nations also lack sufficient diagnostic kits to identify the disease. According to FIND, an organisation specialising in the development of new diagnostics, only 16 per cent of suspected cases in the DRC are undergoing testing. It is a stark reminder of the inequities in global health access.

"Similar to what happened during the peak of COVID-19, the biggest challenge for healthcare providers in the DRC and other low-income settings is access to supplies and equipment to collect, transport, and diagnose Mpox. There needs to be a greater global effort to manufacture and distribute these, as well as to support validation and supply of fully-automated diagnostic assays. An important area of research is developing rapid diagnostic tests

that can be used at the point-of-care, such as those that detect viral antigens," said Dr Jay Varma.

How big of a threat is it?

There are two clades (groups) of Mpox: clade I (prevalent in central Africa) and clade II (prevalent in west Africa). Just 1 day after WHO's second declaration, the first case of Mpox was reported from Sweden and Thailand. This is the first time an Mpox case of clade I was reported outside Africa (clade Ib). Considering that the estimated case fatality of clade I is higher (10 per cent) than clade II (1–3 per cent), there could be a major risk to global health.

Some experts in India have criticised the WHO's declaration for potentially inciting unnecessary panic and emphasised the importance of raising awareness among high-risk groups, including individuals living with HIV. Given that the monkeypox virus is closely related to the smallpox virus, these experts believe that individuals over 44 who received the first-generation smallpox vaccine during early vaccination campaigns may have some immunity to Mpox. Several studies suggest that the cellular and humoral immunity provided by first-generation smallpox vaccines is long-lasting.

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However, there are experts who are of the opinion that it's better to be prepared. "The WHO declared Mpox as a Global Health Threat in August 2024, recognising the migration of the virus throughout Africa, expanding to Europe and North America and Asia. The current strain (clade) is more virulent than that of the 2022 outbreak and is more casually transmitted, with approximately 70 cent of reported cases in Africa occurring among children. Mpox is a global threat that knows no boundaries, no race, no creed. Now is the time to apply everything we learnt from the COVID-19 to monkeypox, by trying to get ahead of this virus, before it reaches the other territories it has not touched yet, but in a most likely scenario will in a matter of time," said David Dodd, CEO, GeoVax Inc.

Also, as the old adage goes, viruses know no boundaries. The past 20 years—in which there have been global outbreaks of SARS, influenza H1N1, Ebola, MERS, COVID-19, and Mpox—shows that an outbreak anywhere can lead to outbreaks everywhere. Therefore, it is important that all countries and people working in health-related fields prepare for Mpox.

"The current global outbreak has shown the potential for global transmission, especially in non-endemic countries. Its spread through close contact poses risks, in particular vulnerable populations," said Dr Lederman.

"The 2022 emergency was declared because Mpox had spread from Nigeria to all continents. This was the first time the virus had spread to so many regions and caused numerous illnesses. The 2024 emergency was declared due to a severe, uncontrolled outbreak in the Democratic Republic of the Congo caused by a potentially more dangerous strain of Mpox. This strain has now spread to several neighbouring countries in Africa, as well as one in Sweden and another in Thailand," said Dr Jay Varma.

He added, "When a new strain or variant of a virus emerges, we focus on two major questions/areas of concern. First, does it spread more easily from one person to another? Second, does it make people sicker? Regarding transmission, we do not believe that clade I spreads more easily than clade II. However, the situation is complicated by the detection of a new variant (clade 1b) in the DRC. This variant was first identified in men visiting female sex workers, and researchers are concerned it may spread more easily through heterosexual sex, although this has not been confirmed. In terms of severity, we have long known that clade I causes more severe rashes and higher death rates than clade II. The current DRC outbreak has a death rate of around 3.7 per cent for clade I infections, compared to less than 1 per cent for clade II infections globally. This aligns with laboratory studies indicating that clade I is more severe than clade II."

The risk of Mpox spreading further is a real and present threat. Although the risk is low to medium, it could be higher if community transmission occurs in multiple countries. Swift action can make a critical difference in controlling the outbreak.

While it is essential for other countries to have strategies and action plans in place, it is absolutely crucial to address the epicentre of the current outbreak—Africa—through equitable vaccine distribution. Ten million doses are needed for the entire continent. Without these vaccines, Mpox will continue to spread.

"This outbreak involves a new, more lethal strain of the Mpox virus that spreads more efficiently from person to person. Unlike the 2022 outbreak, this strain is not restricted to a specific group and is rapidly spreading beyond the Democratic Republic of Congo to other African countries and even outside of the continent. Despite this, and the fact that vaccines and diagnostic tests are available, demand still exceeds supply, and current donations are insufficient. A total of 3.6 million vaccine doses have been pledged (620K of the Bavarian Nordic vaccine and 3 million of the LC16 vaccine), but this falls short. Fractional dosing could be a potential solution to address the shortage, but African countries are hesitant due to indemnification and liability issues," said Guzman.

The vaccines have not arrived yet, and addressing this is crucial for tackling broader health inequalities.

While it's good for other countries to be prepared, it is of utmost importance that the African region is prioritised for response efforts. Because no one is safe till everyone is safe. BS

Ayesha Siddiqui

How Asia's Emerging As Biomanufacturing Powerhouse

Asia is poised to become a manufacturing powerhouse, building on its success in clinical trials and biotechnology innovations. While China has already established itself as a manufacturing leader, other countries in the region are following suit. With nations like Singapore, South Korea, and India recently launching ambitious policies to boost the sector, the region is gearing up for a significant transformation in its bio-manufacturing capabilities.

Countries like South Korea, Singapore, and others in Asia are making strides in enhancing their bio-manufacturing capabilities. The collective effort made by the respective countries helps to position Asia as a key player in the global biopharma industry towards fostering innovation, international collaborations and investments, as well as improving the regulatory environment. According to Market Data Forecast, the Asia Pacific biopharmaceuticals market was valued at $44.3 billion in 2023 and is expected to be worth $78.69 billion by 2029 with a CAGR of 10.05 per cent from 2024 to 2029.

"Asia-Pacific has emerged as a dynamic and influential region in the global biopharma industry in recent years and this transformation is driven by a confluence of factors, from rapid economic growth and significant government investments to a highly skilled workforce and a supportive regulatory environment," said Chua Keng Hock, Senior Vice President of Process Solutions, Asia Pacific, Life Science Business of Merck.

The support of the local government and investment are pivotal in driving the growth of the biopharma sector in Asia. "The local governments in Asia have made substantial investments in the biopharma sector, focusing on building infrastructure and creating life science hubs to foster collaboration and innovation. For example, South Korea's 'Bio-Health Industry Promotion Plan' aims to enhance the country's biotechnology capabilities through initiatives like the National Synthetic Biology Initiative, which seeks to transition 30 per cent of the manufacturing industry to the bio-industry within a decade. Similarly, Singapore has built the Biopolis, a research and development hub, and Tuas Biomedical Park, a purpose-built estate for pharmaceutical and medical technology companies," said Chua Keng Hock.

A skilled workforce is another crucial driver of biomanufacturing growth in Asia. Specialised training programmes and educational initiatives are in place offering targeted courses in biotechnology and bioprocessing. Additionally, Singapore and South Korea for example emphasise a close alignment between educational programmes and industry needs through industry-academic partnerships. These partnerships offer students' hands-on experience via internships and industry projects to bridge the gap between academic learning and real-world applications in bioprocessing.

To facilitate biopharma companies in navigating the market, Asia has streamlined its regulatory environment to align with international standards, significantly enhancing its appeal for biopharma investments.

"Recent reforms in countries like China and India have improved the speed and transparency of drug approval processes, including accepting international clinical data and streamlining approvals. For example, China's regulatory changes have reduced the average drug approval time from 2-3 years to about 12 months, while South Korea has implemented fast-track approval processes to shorten new drug approval times. These improvements attract foreign investment, encourage domestic innovation, and ensure quicker market entry for new

therapies," said Chua Keng Hock.

Strategic partnerships between government agencies and biopharma companies are forged to enhance research capabilities, develop new bioprocessing technologies, and support industry growth, to accelerate drug development and commercialisation. In May 2024, Merck signed a non-binding Memorandum of Understanding (MoU) with the Korea Advanced Institute of Science and Technology (KAIST) in Korea on a multi-dimensional programme aimed at advancing the research and development ecosystem in South Korea for industrial applications.

Bullish on Biomanufacturing

Singapore: The Biomedical Sciences industry, which comprises the biopharmaceutical and medical technology sectors, is a key contributor to Singapore's economy. In 2022, the industry accounted for 2.3 per cent of Singapore's Gross Domestic Product and manufactured close to S$39 billion worth of products for the global market.

The Singapore government has taken various initiatives to boost biomanufacturing in the country. The Biologics Pharma Innovation Programme Singapore (BioPIPS) aims to strengthen local manufacturing capabilities and transform Singapore's biologics manufacturing facilities into agile factories of the future. It works through a consortium model consisting of leading biopharma companies and Singapore's public sector R&D agencies and universities. BioPIPS is modelled after PIPS.

"Singapore's pro-business environment, skilled talent, strong manufacturing capabilities and thriving research ecosystem have drawn global biopharmaceutical and medical technology firms here. These companies have significant innovation, manufacturing, and commercial presence in Singapore to serve global patients," said Chen Pengfei, Vice President, Healthcare, Singapore Economic Development Board.

The bets are paying off. In recent months, Singapore has solidified its position as a key hub for biopharmaceutical manufacturing, with almost all major pharma companies establishing operations in the region. Notable developments include Pfizer's expansion of its manufacturing footprint with a new state-of-the-art facility announced on July 23, 2024. Wuxi Apptec also marked a milestone by breaking ground on a new R&D and manufacturing centre focused on active pharmaceutical ingredient (API) services for small molecules, oligonucleotides, peptides, and complex synthetic conjugates, which was reported on May 23, 2024.

Besides, AstraZeneca unveiled plans for a $1.5 billion manufacturing facility dedicated to antibody-drug conjugates (ADCs) on May 20, 2024. Wuxi Biologics is also investing in the region with a new Contract Research, Development and Manufacturing Organisation (CRDMO) centre, which will provide integrated biologics services, as announced on March 19, 2024. Novartis expanded its biopharmaceutical manufacturing site in March 2024, while AbbVie announced a $223 million investment to enhance its biologics manufacturing capacity on January 25, 2024. Hilleman Laboratories opened a $20 million facility in November 2023 to strengthen vaccine manufacturing resilience.

Singapore-based Biosyngen launched a new manufacturing facility in June 2023, with plans to hire 200 employees. Additionally, a new Thermo Fisher Scientific drug facility dedicated to vaccine manufacturing opened on May 26, 2023. Takeda also contributed to Singapore's biomanufacturing landscape by opening its first platinum positive energy building on March 30, 2023. Finally, GSK established its first high-potency manufacturing and testing facility for next-generation cancer treatments in Singapore on November 17, 2022. These developments underscore Singapore's commitment to becoming a leading destination for biopharmaceutical innovation and production.

Australia: Australia aims to be an RNA manufacturing hub. In 2023, the Prime Minister of Australia highlighted his role as chair of the Expert Advisory Group, which is focused on developing an RNA Sector Development Plan. This plan aims to capitalise on new investments across the country to manufacture mRNA vaccines, including the Moderna facility, and to establish a comprehensive RNA research and development ecosystem. Australia is set to become one of the few countries globally with end-to-end mRNA manufacturing capabilities, presenting a significant opportunity to advance RNA technologies for both human and animal health. The plan emphasises improving commercialisation, building necessary skills, maximising enabling infrastructure, and translating world-class research into practical applications.

The Australian Government has established the National Reconstruction Fund Corporation (NRFC), a $15 billion initiative aimed at supporting seven priority areas of the economy. One of the key focus areas is medical manufacturing.

Government's efforts are paying off. Pfizer, Moderna, and BioNTech are all establishing mRNA manufacturing plants in Australia, underscoring the country's growing prominence in the biotechnology

Lessons from Singapore's Success

« **Chen Pengfei,**
Vice President,
Healthcare,
Singapore Economic
Development Board

The Biomedical Sciences industry, which comprises the biopharmaceutical and medical technology sectors, is a key contributor to Singapore's economy. In 2022, the industry accounted for 2.3 per cent of Singapore's Gross Domestic Product and manufactured close to S$39 billion worth of products for the global market. Singapore's pro-business environment, skilled talent, strong manufacturing capabilities and thriving research ecosystem have drawn global biopharmaceutical and medical technology firms here. These companies have significant innovation, manufacturing, and commercial presence in Singapore to serve global patients.

Biopharmaceutical manufacturing hub

Singapore hosts best-in-class manufacturing facilities from seven out of the top 10 pharmaceutical companies. In 2022, the biopharmaceutical sector produced more than S$19 billion worth of products for global markets - a threefold increase over the past 20 years. There are over 60 biopharmaceutical manufacturing facilities in Singapore across diverse modalities – from Active Pharmaceutical Ingredients to Biologics (Therapeutics and Vaccines) and Cell Therapies. These facilities hire more than 9,000 workers, 70 per cent growth over the past 10 years.

In the first half of 2024, several leading biopharmaceutical companies have announced manufacturing investments in Singapore.

Building biopharmaceutical manufacturing capabilities

Singapore welcomes biopharmaceutical companies to tap our ecosystem to develop, manufacture and commercialise products and solutions that can contribute to better healthcare outcomes not just in the region, but also globally. We are continuing efforts to strengthen our biopharmaceutical manufacturing capabilities in several ways:

1. Growing our Talent Pool: The availability of talent with the right capabilities and skill sets is critical so that companies can undertake process innovation and manufacture different modalities in Singapore. Besides ensuring a steady flow of STEM talent in our Institutes of Higher Learning, the Singapore Government supports companies' in-house upskilling of existing workers in new capabilities and re-training of mid-career talent from adjacent manufacturing industries. One example is the Career Conversion Programme for Biomedical Manufacturing Industry, which supports the training of workers to take on new job roles in the industry.

2. Encouraging Technology Innovation and Adoption: To ensure the continued best-in-class standing of manufacturing facilities in Singapore, companies will need to innovate and adopt new technologies continuously to enhance productivity and efficiency. Singapore has set up enablers in private-public pre-competitive consortiums, such as the Pharma Innovation Programme (PIPS) and Biologics Pharma Innovation Programme (BioPIPS), led by the Agency for Science, Technology and Research and supported by the Singapore Economic Development Board. PIPS focuses on small molecules manufacturing and brings together leading pharmaceutical companies such as GSK, MSD and Pfizer, to partner local research institutes and universities to develop and implement new technologies such as biocatalysis, continuous manufacturing, particle engineering and digital twins for process operations. Such technologies will improve manufacturing processes and boost efficiency of manufacturing facilities in Singapore.

BioPIPS focuses on improving the productivity and sustainability of biologics manufacturing, and was launched in March this year with workstreams focusing on sensing and modelling, sustainability and compliant agility. Initial participating companies include GSK, Sanofi and BioNTech.

3. Sustainability in Manufacturing: Sustainability has been a growing focus within the biopharmaceutical sector. To support these companies in their decarbonisation journey, Singapore is helping companies to improve energy efficiency and reduce emissions, in line with the Singapore Green Plan 2030 and our national target to achieve net zero emissions by 2050. We are also facilitating access to cleaner, low-carbon sources of energy. BS

"Asia-Pacific has emerged as a dynamic and influential region in the global biopharma industry in recent years and this transformation is driven by a confluence of factors, from rapid economic growth and significant government investments to a highly skilled workforce and a supportive regulatory environment."

- Chua Keng Hock,
Senior Vice President of Process Solutions, Asia Pacific, Life Science Business, Merck

"Singapore's pro-business environment, skilled talent, strong manufacturing capabilities and thriving research ecosystem have drawn global biopharmaceutical and medical technology firms here. These companies have significant innovation, manufacturing, and commercial presence in Singapore to serve global patients."

- Chen Pengfei,
Vice President, Healthcare, Singapore Economic Development Board

sector. In addition to these significant investments, other initiatives are also taking shape. Monash University has launched Australia's first dedicated mRNA workforce training centre with a $10 million grant, aimed at equipping professionals with the necessary skills for this emerging field. Furthermore, a new biotech research and manufacturing hub was opened at the University of Queensland, further enhancing the nation's capabilities in mRNA technology. The University of Sydney has announced the launch of its Biomanufacturing Incubator, a cutting-edge initiative aimed at bridging the gap between biological research and industrial application. Together, these developments position Australia as a leader in biomanufacturing and mRNA innovation.

Korea: South Korea has initiated several strategic efforts, including 'The Advanced Biotechnology Initiative,' a national strategy aimed at positioning the country as a leader in the biotechnology sector by 2035. This initiative leverages South Korea's accumulated scientific, technological, and ICT capabilities in response to the rapid growth of the global biotechnology market and intense competition for technological supremacy. Additionally, the 'National Synthetic Biology Initiative' has been launched to nurture synthetic biology and enhance innovative capabilities in biomanufacturing.

South Korea also aims to become a global vaccine hub. The government is promoting public-private partnerships to expand vaccine production capacity to meet both current and future needs, domestically and in low- and middle-income countries (LMICs). To bolster this strategy, the government has partnered with international organisations, including the WHO, ADB, and IVI, by establishing training hub programmes for a global biomanufacturing workforce.

Big pharma firms are taking a note. Merck has announced an investment of over €300 million in a new life science production site in Korea, signalling strong confidence in the market. Sartorius is investing substantially in expanding its activities in South Korea. The site is in South Korea's major Biopharma hub Songdo in Incheon.

India: In August 2024, India launched the BioE3 Policy, a strategic framework designed to propel the country into the next era of industrialisation through high-performance biomanufacturing. This policy outlines a roadmap for making India a global biomanufacturing hub by promoting innovation in bio-based products and developing the necessary infrastructure for scale-up and commercialisation.

The policy aims to empower Indian institutions, universities, startups, and industries to engage in transformative innovations by boosting domestic biomanufacturing capabilities by enabling synergy between science, technology, engineering, and manufacturing. The policy lays out plans for accelerating the transition to biomanufacturing by promoting integrated use of AI, digitalisation with 'omics', and upstream biotechnology innovations through bio-AI hubs, biofoundries, and biomanufacturing hubs across the country.

The BioE3 Policy emphasises six thematic areas of focus, with a particular spotlight on 'Precision Biotherapeutics. The policy draws attention to biologics/biotherapies like Cell and Gene therapy, mRNA therapeutics, monoclonal antibodies, immunotherapy, as well as next-generation vaccines.

Asia already has considerable biomanufacturing capabilities, driven by China and Singapore, with other countries ramping up their capacities to move toward this goal. It's only a matter of time before the region is known as a bio-manufacturing powerhouse. BS

Ayesha Siddiqui

How Asia is Addressing Mental Health Issues?

Nearly one billion people globally live with mental health conditions, and about 260 million of them reside in the World Health Organization (WHO) South-East Asia Region. Governments across Asia are ramping up efforts to combat the rising mental health crisis. As October 10 will be observed as World Mental Health Day, we take a look at the region's focus on policy reforms to address the growing burden of mental healthcare across Asia.

Mental health issues are well-documented, affecting nearly one billion people worldwide, with approximately 260 million residing in the WHO South-East Asia Region. Insufficient investment in mental health services and the healthcare workforce has led to significant treatment gaps in the region, a situation further worsened by the COVID-19 pandemic. Global estimates indicate the WHO South-East Asia Region accounts for around 27 per cent of all cases of depression and 23 per cent of all cases of anxiety.

Despite its inclusion in the Sustainable Development Goals (SDGs), only 2 per cent of total government health expenditure and 1 per cent of global development assistance for health are dedicated to mental health, according to the WHO's Mental Health Atlas 2020.

Mental illness presents a significant health and socioeconomic burden, accounting for over 20 per cent of total Years Lived with Disability (YLDs) and 9.3 per cent of Disability-Adjusted Life Years (DALYs) in the Asia-Pacific region. As per a report by The Royal Australian and New Zealand College of Psychiatrists (2016), even advanced economies like Australia and New Zealand face GDP deficits of 3.5 per cent and 5 per cent, respectively, linked to mental illness. Furthermore, it is estimated that by 2030, mental illness will result in a loss of $11 trillion in economic growth for India and China alone, according to a report 'Provision for Supporting People with Mental Illness: A Comparison of 15 Asia-Pacific Countries,' prepared by The Economist Intelligence Unit (EIU) and sponsored by Janssen Asia Pacific.

To address these growing concerns, policymakers and health systems across the region are taking a note. Various countries have developed national strategic plans and made investments to strengthen mental healthcare.

"I've witnessed the growing focus on mental health across Asia, where governments, organisations and the community are increasingly addressing the rising mental health challenges. Significant reforms have been introduced to improve access to care, reduce stigma, and integrate mental health into broader healthcare systems. There are quite a few notable reforms that have been introduced in Asia that left me feeling hopeful and encouraged," said ***Theodoric Chew, CEO and Co-founder, Intellect, Singapore.*** Intellect is Asia's largest mental health platform serving 3.5 million members in 60+ countries. Let's look at some of them in detail.

National Policy Initiatives in Asia

Singapore: In 2023, the Ministry of Health introduced the National Mental Health and Well-being Strategy. This was a comprehensive plan to improve Singapore's mental health ecosystem and outlined planned whole-of-government and whole-of-society efforts to increase accessibility for mental health support. This will include efforts to expand capacity of mental health services, like having more general practitioners (GPs) be trained to provide mental health services like assessment and medical treatment.

There are other initiatives as well. In 2024, a white paper by ground-up initiative Project Hayat (led by advocacy group SG Mental Health Matters) was released. This white paper comprised of 23 recommendations including a national public awareness campaign on suicide prevention and integrating suicide prevention education into school curriculum. The Beyond the Label campaign (launched in 2018) by the National Council of Social Service aims to reduce stigma associated with mental

health conditions.

"Additionally, there have been initiatives introduced by the Tripartite Alliance for Fair and Progressive Employment Practices (TAFEP) that focus on workplace wellbeing programmes. One of the notable initiatives is the guidelines that companies must consider if an employee requests for flexible work arrangements. This has since been adopted by the Ministry of Manpower," said Chew.

South Korea: The country is making strides in enhancing its mental health policies with the establishment of a Mental Health Policy Innovation Committee. This initiative aims to develop and implement effective strategies to improve mental health care across the country. As part of these efforts, Korea has also launched a collaboration project with the World Bank to improve mental health awareness. This project will share case studies of successful mental health stigma reduction programmes from different countries, allowing for discussions on their applicability in the Korean context.

"To tackle the country's high suicide rates, South Korea rolled out a plan to offer mental health checkups every two years for Koreans aged 20 to 34. The aim is to detect warning signs of mental distress early. This is a huge improvement from their previous plan, which was to provide mental health checkups for Koreans aged 20 to 70, every ten years," said Chew.

Australia: The country boasts a robust mental health policy, continually prioritising reforms and investing millions to enhance mental health services. In April 2024, the government announced $4.6 million to support youth mental health research.

The 2021–22 Federal Budget allocated $2.3 billion over four years to the National Mental Health and Suicide Prevention Plan, responding to recommendations from the Productivity Commission's Inquiry Report on Mental Health and the Royal Commission into Victoria's Mental Health System. Most recommendations emphasize collaboration between the Australian Government and state and territory governments through the National Mental Health and Suicide Prevention Agreement.

This plan is built on five key pillars: prevention and early intervention, suicide prevention, treatment, support for vulnerable populations, and workforce development. In the 2022–23 Budget, an additional $547 million was allocated to reinforce these pillars, followed by a further $586.9 million in the 2023–24 Budget to expand and enhance ongoing projects.

China : In recent years, the Chinese government has implemented various policies and initiatives designed to improve the mental health service system and promote equitable access to these services. The release of the Fourteenth Five-Year Plan for National Economic and Social Development in 2020 highlighted key national strategic priorities, which encompass mental health education for adolescents and the enhancement of mental health services. China is dedicated to bolstering prevention and treatment to prevalent mental health disorders while expanding public mental health services, especially for the youth, to significantly improve the overall health literacy of the nation.

India: In the past decade, the Government of India has implemented various measures to address the gaps in mental health services and promote equitable access. The National Mental Health Policy (NMHP), introduced in 2014, along with the Mental Healthcare Act (MHCA) of 2017, establishes strategies aimed at enhancing mental health care and protecting the rights of individuals. The NMHP emphasises the importance of providing comprehensive care that includes both outpatient and community-based services. It advocates for increased resource allocation to make these services more accessible and for their integration into general healthcare systems. Additionally, the policy highlights the significance of research, including national surveys, to inform effective policy planning and implementation.

Japan: The country has a robust mental health policy that is continually being improved. In 2019, the Health and Global Policy Institute (HGPI) launched its Mental Health Policy Project to incorporate the perspectives of citizens and those affected by mental health issues. Despite ongoing progress, challenges persist. HGPI convened an advisory board of experts and individuals with lived experience to identify key issues, resulting in the proposal 'Mental Health 2020 – Proposal for Tomorrow.' This proposal outlines five perspectives: enhancing mental health literacy, developing integrated community care systems, creating supportive community living environments, establishing data-driven policymaking, and fostering ongoing stakeholder engagement in mental health discussions.

These efforts reflect a progressive approach to addressing mental health concerns. A proactive, collaborative, and research-informed strategy is essential for making mental healthcare universally accessible and effective. BS

Ayesha Siddiqui

"The ongoing alignment of clinical trial regulations across APAC with global standards is significant"

Celebrating 25 years of ground-breaking technological innovation across more than 34,000 trials and 10 million patients, Medidata, a Dassault Systèmes brand headquartered in New York City and having strong presence in the United Kingdom and the Asia Pacific (APAC) region offers industry-leading expertise, analytics-powered insights, and the largest patient-level historical clinical trial data set in the world. More than 1 million registered users across approximately 2,200 customers trust Medidata's seamless, end-to-end platform to improve patient experiences, accelerate clinical breakthroughs, and bring therapies to market faster. In an interaction with BioSpectrum Anthony Costello, Chief Executive Officer, Medidata shared insights on APAC clinical trial landscape, regulatory reforms and Medidata's growth strategy for the region. ***Edited excerpts:***

« **Anthony Costello,**
Chief Executive Officer,
Medidata,
USA

Can you elaborate on Medidata's growth strategy for the APAC region? What specific factors are driving the expansion of your business in this market?

Since entering APAC in 2005, Medidata has expanded into several key markets, including Japan, China, India, Korea, Singapore, and Australia. This growth has been driven by a deep understanding of the region's diverse regulatory landscapes and its market dynamics and specific challenges. With each country presenting their own unique opportunities, we've successfully developed tailored strategies to capitalise on their changing aspects. Factors driving our expansion include the rising demand for digital innovation in clinical trials, particularly in areas such as patient centricity, trial diversity, and AI integration.

Our Medidata Unified Platform is the cornerstone of our growth, offering a comprehensive, integrated solution that streamlines the clinical trial process from start to finish. Additionally, our AI solutions, and advanced wearable and sensor technologies are meeting the increasing need for complex data capture and personalised study designs in the region.

Medidata also benefits from strong local partnerships and a legacy of innovation that positions us to quickly adapt to a rapidly evolving healthcare environment. By focusing on these areas, Medidata is well-equipped to seize new opportunities and maintain its leadership position in the APAC region.

How do you see the role of APAC in the global clinical trial landscape evolving over the next few years? What factors contribute to the region becoming a more prominent hub for clinical research?

APAC is rapidly emerging as a central hub in the global clinical trial landscape, driven by its strong R&D capabilities, advanced technological infrastructure, and alignment with global regulatory standards.

One key factor is the impending expiration of over 50 blockbuster drug patents in the next decade, which will intensify competition among global pharmaceutical companies. This will likely expand the biosimilar clinical trial market, with APAC positioned to play a pivotal role.

Additionally, APAC's significance is bolstered by its vast population and economic growth, particularly in countries like India and China. These rapidly expanding markets are attracting substantial investment from multinational pharmaceutical companies eager to tap into the region's potential.

The region's technological and healthcare infrastructure, especially in countries like Singapore, Japan, and Korea, also plays a critical role. These nations boast world-class systems that are well-suited for conducting complex and sophisticated trials. Medidata's platforms, designed to streamline clinical trial data management, are well-positioned to capitalise on these strengths.

Finally, the ongoing alignment of clinical trial regulations across APAC with global standards is significant. Simplified approval processes and strengthened ethical standards are making the region increasingly attractive for global clinical trials. As these trends continue, APAC is expected to see a surge in research activities and investment,

solidifying its position as a key player in global clinical research.

APAC has seen significant growth in clinical trials over recent years. What challenges and opportunities does this region present, and how is Medidata addressing them?

The APAC region's role in the global clinical trial landscape is growing rapidly. According to Clinical Trials Arena, clinical trials increased from 11,571 in 2019 to 14,346 in 2023. In 2022, 58 per cent of all global Phase I clinical trials occurred in APAC, driven by the region's strong R&D capabilities, vast talent pools, world-class healthcare infrastructure, and robust regulatory standards. However, this growth has also brought challenges, particularly in navigating diverse regulatory environments, which can complicate cross-border trials. Medidata is helping to address these complexities with a unified platform that efficiently manages multinational trials, while adhering to each country's specific regulations.

As the clinical trial landscape evolves, companies must innovate and respond quickly to stay competitive. Rising costs and challenges in patient recruitment and retention demand new solutions. Medidata's AI tools streamline processes, ensure site consistency, accelerate insights, and even create synthetic patients to reduce exposure to experimental therapies. APAC's diverse populations present challenges in data consistency but also offer opportunities to enhance participant diversity in clinical trials. Medidata's Diversity Program is addressing this by integrating diversity into every trial stage, ensuring that historically underrepresented groups are included in clinical research.

Given the diverse regulatory environments across APAC countries, how does Medidata adapt its solutions to meet the specific needs of different markets within the region?

Medidata's Global Compliance and Strategy (GCS) program is responsible for overseeing Quality Management and Regulatory Compliance for our customers. This team provides valuable insights into current and emerging policies, shapes regulatory strategies in collaboration with governing bodies, and advocates on behalf of our clients. They also manage Medidata's Quality Management System, ensuring that our products are developed, implemented, and maintained in strict compliance with clinical trial regulations. Given the complex and ever-changing regulatory environment in APAC, Medidata has a dedicated team that actively monitors and evaluates the global regulatory landscape, focusing on the implications for R&D, legal/privacy, and information security. To ensure we remain compliant, we work with external providers to regularly assess our controls. Additionally, Medidata offers extensive resources to help customers understand and meet regulatory requirements in China, APAC, and the rest of the world.

How does Medidata collaborate with local partners, such as CROs and research institutions, to enhance the clinical trial process in the APAC region?

Medidata collaborates globally with over 260 CROs and more than 230,000 Rave (EDC) certified clinical research coordinators and principal investigators. This extensive network enhances clinical trial efficiency and quality at every stage, with partnerships that ensure smoother trial management across APAC while meeting each country's regulatory requirements. Collaboration with stakeholders is crucial as trials grow larger, more complex, and globally distributed. Medidata supports stakeholders with comprehensive solutions that break down silos and provide real-time, data-driven insights. Our cloud-based Medidata Platform enables timely and informed decision-making, improving trial processes, and outcomes.

In APAC, we're streamlining clinical trials and helping customers bring new treatments to market faster. For instance, Japan's Kurashiki Central Hospital fully implemented our Medidata Rave Companion system, reducing query rates by 36 per cent and cutting data entry time per field by 19 per cent. Medidata also prioritises a patient-focused approach, directly integrating patient perspectives into our software development through our Patient Insights Program. As the first company in APAC to formalise this process, we offer sponsors, CROs, and sites access to our proprietary Patient Centricity by Design process, ensuring that clinical trials are more inclusive and aligned with patient needs.

Any additional information to share?

Looking to the future, there are many opportunities for companies in life sciences that are willing to push innovation and consistently challenge traditional ways of collecting and utilising research data.The future of our industry requires a different type of relationship with patients—one that is less transactional and more longitudinal. One that finds creative new ways to develop trust so that patients are increasingly willing to share their vast healthcare data with researchers to create an ecosystem of new discovery that is mutually beneficial to both. BS

Ayesha Siddiqui

"Developing capabilities to profile the next gen compounds in new modalities is expected to drive preclinical CRO growth"

The preclinical Contract Research Organisation (CRO) sector in India is witnessing massive transformation with huge investments being made in this sector by domestic and multinational players to cater to the global needs. A significant boost to the Indian economy is expected over the next five years by the foreign and domestic investments being made in the preclinical CRO segment. In an interaction with BioSpectrum Dr Satinder Singh, Associate Director, DMPK Aragen Life Sciences, shared his insights about future growth drivers of preclinical CROs based out of India. ***Edited excerpts;***

« **Dr Satinder Singh,** Associate Director DMPK, Aragen Life Sciences, India

What is Preclinical CRO?

Preclinical is a stage of drug development that ensues before clinical trials (testing in humans) and during which drug potency, efficacy, pharmacokinetics, tolerability and safety data are collected, in laboratory settings to determine a starting, safe dose for FIH study, and forecast potential toxicity of the drug product in humans.

The preclinical phase utilises a range of in-vitro platforms and in-vivo animal models to simulating human physiology and generate valuable insights into the biological activity, pharmacological effects, and potential toxicity of investigational drug candidates. Most pharma companies do not want to invest their time and resources in this domain and rather opt for professional expertise extended by the preclinical CROs. Preclinical CROs offer their expertise in the multifaceted management of this initial stage of the compound screening and evaluation process, which includes selection of suitable invitro profiling platforms, animal models, and the execution of pharmacokinetic, efficacy, mutagenicity, genotoxicity and in-vitro and in-vivo toxicity assays.

At Aragen Life Sciences, we support discovery, preclinical profiling and clinical candidate selection of NCEs for example small molecules and TPDs and NBEs for example peptides, mAbs, Oligos, RNA Therapeutics or therapeutic proteins. This also includes drug testing in rodents and non-rodents like minipigs, rabbits, beagle dogs or non-human primates like rhesus or cyno monkeys for assessing the pharmacokinetics, efficacy and safety of lead compounds.

What is the revenue forecast for preclinical CROs based out of India?

The global drug discovery research outsourcing market was valued at $3.8 billion in 2022 and is increasing @ CAGR of 7.3 per cent to touch $6.2 billion by 2031. The Indian preclinical CRO market size was around $183.3 million in 2023 and is slated to grow @ CAGR of 11.4 per cent in next six years to reach $393.6 million by 2030. The key factors driving this growth are increasing trends of preclinical R&D outsourcing by pharma and biotech companies to reduce drug development expenses, low operational costs in India compared to western countries, availability of technically and scientifically sound workforce, specialised resources, infrastructure, high throughput state of the art screening equipment in preclinical CROs based out of India. Amongst different verticals of preclinical CRO, biology service segment is expected to attain the fastest growth @ 7.5 per cent during the next six years.

How is revenue share structured amongst different preclinical CRO verticals?

The two broad verticals of preclinical CRO are chemistry and biology. In chemistry, custom synthesis and process development generate maximum revenue. In biology, Non-rodent animal toxicology studies contribute to the largest revenue share followed by bioanalysis and DMPK;

because of the technological advancements in bioanalytical equipment, techniques and automation. Furthermore, DMPK studies and bioanalysis are conducted throughout the drug research and development process, thus contributing a good share to preclinical CRO's total revenue.

Did COVID-19 impact business revenue of Indian preclinical CROs?

Prior to COVID-19, China was the front runner in the preclinical CRO segment. However, as a result of complete lockdown, movement restrictions and distancing norms during COVID-19 in China, the preclinical CROs, API and drug product manufacturing were temporarily closed. This disruption due to COVID-19 impacted the revenue and operations of CROs in China and timelines committed to clients were indefinitely stretched. Pharma and biotech companies shifted preclinical contract research to India and revived the projects at a fast pace to make up for the delay. So, business revenue of Indian preclinical CROs registered a positive trend during COVID-19.

What are the business models preclinical CROs practice?

It largely depends on the requirements of the client. Pharma or biotech MNC can partially or fully outsource their R&D activities to the preclinical CROs. The clients then don't have to invest into laboratory infrastructure, high end equipment and skilled manpower and thus, these companies can focus on their core competencies and areas of expertise. In another model, the preclinical CROs do some groundwork and establish early POC into particular disease segments and then approach pharma companies having potential interest in that therapeutic area to secure the funds for late-stage drug development. This type of business arrangement generally involves upfront payment followed by milestone payments as the compound progresses through different stages of development, and eventually royalty payments on sales if the compound gets marketing approval. The intellectual property in this case is jointly owned.

Do preclinical CROs based out of India face domestic and global market competition and price war?

Pharma and biotech MNCs do bargain for the project cost, especially when they have various state-of-the-art CROs offering HQ services and time bound delivery at their disposal. A good number of preclinical CROs both domestic and international, operate in the Indian market. These CROs can cater to the concept of commercialisation requirements of pharma and biotech companies. There is intense competition amongst existing players. Additionally, there is a threat of new entrants too. Hence pricing needs to be very competitive. The other decisive factors are brand image, TAT, access to the test site, infrastructure and scientific capabilities, expertise in particular therapeutic areas, existing clientele, global footprint and client relationships. The established CROs capitalise on already well-fortified client relationships, and expertise in liaisoning with regulatory agencies across different geographies; thus, impeding the sustenance of new players.

The future ready CROs which are on path of continual innovation and expansion of service portfolio, having some key differentiators in kitty, improving research quality and efficiency, and maintaining solid client relationships will sustain in this competitive environment.

What therapeutic areas are expected to generate good business in the near future for preclinical CROs?

The key therapeutic areas including oncology, CNS disorders, autoimmune diseases and infectious diseases will generate more interest among the local and MNCs in near future for preclinical CROs.

How important is data confidentiality at preclinical CRO?

Preclinical CROs handle sensitive information and confidential data generated during the drug discovery process. Maintaining the privacy and confidentiality of research data generated for respective clients is paramount and any breach of data confidentiality can have legal and financial implications along with reputational damage. Therefore, ensuring confidentiality, whilst handling data of multiple MNC clients is imperative to the future of preclinical CROs.

What is the competitive advantage the Indian ecosystem offers to pharma & biotech MNCs intending to outsource preclinical R&D work?

India is a pharma hub, the pharmacy of the world; catering to 20 per cent of the global generics supply by volume and 60 per cent of the global demand for vaccines. India is the largest provider of generic drugs and the Indian pharmaceutical industry is currently ranked third in pharmaceutical production by volume and growing at a CAGR of 9.43 per cent since the last nine years. One of the key factors contributing to India's success in the pharmaceutical sector is its strong chemistry research base. The complexities

and resource-intensive nature of medicinal chemistry require special technical and scientific expertise, compound libraries, infrastructure and equipment. The increasing chemistry R&D expenditure worldwide has propelled the growth of India's preclinical CRO market, as pharma and biotech MNCs continue leveraging India's resources and chemistry expertise to advance their drug development pipelines. So, India is steadily emerging as an important CRO destination due to its scientifically and technically skilled workforce and cost advantages.

What is the likely impact of Artificial Intelligence (AI) and Machine Learning (ML) on the growth of preclinical CROs?

AI, particularly Gen AI, emerged as an efficient alternative tool to the traditional screening methods and navigates drug hunters in the development of new therapeutics. A transformative approach, Gen AI expedites drug discovery by contributing to target identification, predicting drug target interactions, compound generation, in-silico pharmacology analysis, drug formulation design and revolutionising clinical trials by better patient selection, predicting safety and tolerability signals for early action and this improving clinical trial success rate. Gen AI predicts physicochemical properties, binding affinity, bioactivity, multi-target effects and assists in prioritising compounds for further validation. ML and molecular dynamics (MD) simulations aid de novo drug design. Gen AI also helps in generating study protocols, comprehensive reports and drawing meaningful conclusions out of the voluminous data generated during the course of drug development thus saving cost and time.

Adaptyv Bio's Gen AI-based virtual screening platform, for example, predicts the binding affinity of compounds to target proteins. DeepMind's AlphaFold module helps understand biological processes and drug-protein interactions. PandaOmics identify and prioritise significant disease-related targets. Chemistry42 designed potential drug candidates that specifically targeted the identified proteins.

Gen AI driven drug development helps discover drug candidates faster by synthesizing ~1/10 the number of chemical moieties based on predictive druggability attributes and the ability to "fail fast" in preclinical development to drop unfit molecules early, thus saving cost and time.

What would be key growth drivers for futuristic preclinical CRO?

It is easy to make a mark but takes huge perseverance to sustain that; and sustainability is the key to success. Long term strategic collaborations and partnerships with Tier-I and Tier-II pharma and biotech MNCs shall boost the sustainability. Keeping the operational cost as low as possible, making rational investments based on realistic business forecasts and using the infra and equipment to maximum will fuel long term viability. 60:40 ratio of perennial Full-Time Equivalent (FTE) programmes and short-term Fee for Service projects [FFS] may impart better sustainability in the long run.

MNC pharma and biotech companies prefer to work with CROs

- Having well-equipped labs with advanced research tools to generate HQ data.
- Equipped with Next gen tech like HTS, molecular profiling and advanced imaging systems.
- Having implemented automation, robotics, assay miniaturisation and innovative assay formats for enhanced preclinical research efficiency, reduction of human errors and the turnaround time
- Capable of screening large compound libraries quickly and cost-effectively
- Having scientifically and technically sound staff
- Having seasoned project management team which can communicate effectively and provide updates on real time basis
- Having access to futuristic AI tools to support various stages of the drug development process.
- Practicing HQ electronic documentation
- Offering in-house validated Organs-on-chip, Organ on Chip/Organ Tox Platform, 3D Organoids, 3D Spheroid and 2D Cell Cultures to test the safety and efficacy of new drugs and establish PK/PD
- Specialised in preclinical services, such ADC quantification, multi-drug and metabolite-based bioanalysis and large molecule PK studies

New modalities, for example cell and gene therapy, ADCs, DNA and RNA therapy (mRNA, RNAi) based products are churning max revenue. Developing capabilities to profile the next gen compounds in these areas is expected to drive the growth of preclinical CRO over the next decade. Further, the CROs employing Artificial and Machine tools for virtual screening, lead optimisation, prediction of drug-target interactions, and identification of novel drug candidates will certainly have an edge over others. BS

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"ICMR has committed to funding all aspects of Phase I trials of Zika vaccine"

Dr K Anand Kumar, Managing Director, Indian Immunologicals Limited

Hyderabad-based Indian Immunologicals Ltd (IIL) has signed an agreement with the Indian Council of Medical Research (ICMR) on September 12 for clinical development of India's first codon de-optimised live attenuated Zika vaccine. According to the Ministry of Health, as on July 22, 2024, 537 Zika cases were registered. Since no vaccine exists for Zika, this collaboration represents a crucial step in safeguarding public health against this emerging threat. In an interaction with BioSpectrum, Dr K Anand Kumar, Managing Director of IIL shares the latest developments and future goals of the company related to their vaccine portfolio. ***Edited excerpts:***

IIL launched India's first codon de-optimised live attenuated Zika vaccine in collaboration with ICMR. How significant is this for the Indian public health landscape?

The rise of emerging infectious diseases, particularly Zika, which poses serious risks to pregnant women, has been a growing concern. Zika can lead to severe birth defects like microcephaly, and in some cases, it causes neurological disorders such as Guillain-Barré syndrome. While no vaccine exists globally to prevent Zika, we recognised the need to take proactive measures in India. Our partnership with ICMR is a key milestone in addressing this challenge. The codon de-optimised live attenuated Zika vaccine we've developed has undergone extensive pre-clinical trials, and with ICMR's support, we are now moving into Phase I clinical trials. This vaccine marks a major step in strengthening India's defence against potential epidemics and pandemics.

Could you elaborate on the role of Griffith University and ICMR in the Zika vaccine's development and how the partnership accelerates clinical trials?

Our collaboration with Griffith University in Australia laid the groundwork for developing the vaccine, particularly in leveraging the codon de-optimisation technology, which enhances the safety profile of the virus. On the Indian front, ICMR's involvement is crucial. Their extensive trial network across India allows us to conduct first-in-human safety studies domestically, which accelerates the process and reduces dependency on international trials. This aligns perfectly with the vision of 'Atmanirbhar Bharat' by ensuring that innovations are trialled and developed here in India. ICMR has also committed to funding all aspects of Phase I trials, which is a great boost to this mission.

IIL being the first to develop an indigenous Hepatitis A vaccine, 'Havisure,' how do you envision its impact on India's immunisation efforts, especially for paediatric care?

The launch of Havisure is a proud achievement for IIL and for India. Until now, Hepatitis A vaccines were mostly imported, which made them less accessible to the masses. Havisure is the first indigenous vaccine for Hepatitis A, and it's available in both paediatric and adult doses. This is a significant step in enhancing immunisation coverage, particularly for children, who are most vulnerable to the disease. The paediatric dose ensures early protection, and we're working closely with healthcare professionals and government agencies to raise awareness about its benefits. This launch supports our mission to make vaccines affordable and accessible for everyone.

What are your future goals for expanding your vaccine portfolio?

Through our innovations, we aim to tackle the challenges head-on. Looking forward, we are continuously expanding our vaccine portfolio, not only for human health but also for animal and aquaculture sectors. Our goal is to remain a global leader in vaccine production, supporting both India and the world. BS

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Why Cyber-resilience is Crucial

In recent years, ransomware attacks have become more regular, stealthy, and expensive. They have also been developing swiftly. Even for those lacking experience, new ransomware-as-a-service (RaaS) models provide pre-made avenues for financial gain for would-be threat actors. Attackers are also reinventing traditional strategies at the same time. Some are combining data theft and encryption into double extortion, increasing the strain on their victims. Some have invented "encryption-less" attacks, concentrating only on the possibility of a leak. Traditional ways of decrypting and recovering files are becoming less practical as new techniques develop.

« **Sathish Murthy,** Senior Systems Engineering Lead, Cohesity ASEAN & India

Over $1.1 billion - that's how much ransomware gangs raked in last year, according to blockchain analyst Chainalysis. Does this astronomical figure say more about the sophistication of the adversary, or is it an indictment of our overall resilience to cyberattacks? Realistically, it's a bit of both.

The healthcare sector exemplifies this reality. While healthcare facilities must continually ramp up cybersecurity efforts , the high value of personal health information (PHI) has made them an attractive target for cyber attackers. According to the Singapore Ministry of Health, PHI is 50 times more valuable on the black market than financial data because of its immutable nature, as it follows one throughout their lifespan, and can be exploited for identity theft to make fraudulent insurance claims or gain illegal access to prescriptions; among other nefarious purposes.

In the past few months alone, cyberattacks have disrupted operations in numerous hospitals across the world. One of these attacks disrupted operations at major US healthcare network Ascension and forced hospitals to incur significant debt due to their inability to connect with insurance providers to get reimbursement. Several London hospitals have also experienced disruptions in services related to blood transfusions following a ransomware attack on a provider responsible for managing medical testing services and lab operations, causing delays to surgery plans.

In Singapore, medical records must be safely and securely accessible across various settings and providers. The National Electronic Health Record (NEHR) system supports this by centralising patient medical summaries, enabling licenced healthcare providers, including family doctors, hospitals, and nursing homes, to share information seamlessly. As smart hospitals, data sharing and artificial intelligence (AI) become increasingly integrated into daily operations, the attack surface for cyber threats expands because increased data footprints mean there is more critical data that can be targeted - particularly when it is PHI data.

This data security risk threatens not only operations, but also patient data security, financial stability, and organisational reputation, especially given cyberattacks are a 'when' not 'if' likelihood. In healthcare, such cyber incidents can escalate to life-or-death scenarios, underscoring the necessity of cyber resilience. Cyber resilience ensures healthcare providers can sustain operational continuity, in an industry where every minute or hour counts, even amidst cyberattacks or IT system failures, which is essential for safeguarding patients.

Although paying a ransom is considered an action of last resort, a concerning revelation emerged from Cohesity's Data Security Report 2024 (Singapore and Malaysia data): 82 per cent of the respondents said their organisation would pay a ransom to recover data and restore business processes. Close to 3 in 5 (59 per cent) Singaporean respondents and almost 3 in 4 (74 per cent) Malaysian respondents said their company would be willing to pay over $1 million to recover data and restore business processes, with 16 per cent and 22 per cent respectively saying their company would be willing to pay over $5 million.

Ruthless scams ramp up pressure

Unfortunately, paying the ransom does not guarantee business-as-usual. Ransomware gangs often blackmail their victims four times over: first,

In the past few months alone, cyberattacks have disrupted operations in numerous hospitals across the world. One of these attacks disrupted operations at major US healthcare network Ascension and forced hospitals to incur significant debt due to their inability to connect with insurance providers to get reimbursement. Several London hospitals have also experienced disruptions in services related to blood transfusions following a ransomware attack on a provider responsible for managing medical testing services and lab operations, causing delays to surgery plans.

the victim's data is encrypted and if they don't pay the ransom to decrypt it, then the data is exfiltrated from the company network and they're threatened again that it will be published online.

Cyber criminals have also found novel ways to put even more pressure on victims via triple blackmail. Here, the data is not only encrypted and threatened with publication but in a third attempt to extract payment the criminals target everyone whose data has been stolen and harass them to exert even more pressure on the targeted organisation.

The hackers used stolen patient data to threaten these people with "swatting" - a ploy that begins by subjecting an individual to a report of a serious crime, which results in them being raided at their home by elite SWAT (Special Weapons and Tactics) teams or other law enforcement groups. Some of these incidents in the US have been fatal.

Ransomware attacks are also growing in sophistication and severity, with quadruple attacks now occurring whereby cyber criminals are now even threatening to involve authorities, as part of their blackmail and attack techniques. After the data is encrypted, then exfiltrated and published, the ransomware gang involved has harassed the victim organisation's customers and also threatened to expose the victim organisation to the industry regulatory authority for not reporting the cyber-attack.

Holistic Cyber Security Strategy

Fuelling a vicious cycle, the increasingly damaging consequences of a cyber-attack have turbocharged demand for cybersecurity employees, exacerbating the shortfall in this field. For many organisations, maximising the efficiency of their understaffed cybersecurity teams comes down to people, processes and technology.

One way to foster a skilled workforce equipped to detect and respond to threats effectively is to organise realistic tabletop exercises simulating ransomware attacks, which can help organisations find out where their cybersecurity gaps are and rehearse the best ways to respond. These processes, coupled with employee education and training, will enable the organisation to keep pace with the rising sophistication of cyber-attacks.

When it comes to technology, below are a few key ways that organisations can prevent attacks:

- Immutable backup snapshots – these unmodifiable backup snapshots provide a secure data copy for recovery, forensic analysis, compliance and maintaining data integrity.
- Access controls – such as AI-enabled multi-factor authentication (MFA) add extra security layers to ensure only authorised users can access sensitive information, extend the capability to include authentication to data risk levels, and automatically block users for abnormal access behaviour.
- Quorum - which requires at least two parties to confirm major changes or access; and
- Role Based Access Control (RBAC) – which helps stop unauthorised access and limits access to role-specific activities.

Organisations need a combination of tools to detect, protect and recover from ransomware attacks - and most importantly remain cyber resilient. As threat actors look to gain any advantage they can to hit pay dirt through ransom payments, healthcare facilities need to remain vigilant in their data security prowess and establish or maintain cyber resilience. BS

Dignitaries seen releasing the India BioEconomy Report 2024 at the inaugural session of Global Bio India 2024 on September 12 in New Delhi, India.

Global Bio India 2024

Bharat BioEconomy to touch $30 trillion by 2050: IBER 2024

"The Indian BioEconomy is projected to rise to $30 trillion by 2050, within a global economy valued at $228 trillion, representing a significant increase in its economic share from 4 to 13 per cent," according to the India BioEconomy Report (IBER 2024), prepared for 'Make In India Facilitation Cell for Biotechnology' of Biotechnology Industry Research Assistance Council (BIRAC), by Association of Biotechnology Led Enterprises (ABLE).

Releasing the India BioEconomy Report at the three-days Global Bio-India (GBI) 2024 event on September 12 in New Delhi, Dr Rajesh Gokhale, Secretary, Department of Biotechnology (DBT) said"With more than five sectors generating over $1 billion each month, India's BioEconomy reached a value of $151 billion in 2023. This growth is matched by a thriving entrepreneurial landscape, with 1,776 new biotech startups joining the ecosystem, showcasing India's robust innovation capabilities".

The report highlights the sector's increasing significance as it now accounts for 4.25 per cent of India's Gross Domestic Product (GDP) of $3.55 trillion in 2023. India's BioEconomy registered a 10 per cent growth rate in 2023, characterised by a strong industrial focus, with BioIndustrial and BioPharma collectively accounting for over 83 per cent of the sector's value.

Indian startups have developed over 800 products and raised more than $600 million in follow-on funding, as per the report. However, while 2022 saw 31 deals totalling $938.8 million, 2023 saw a dip, with only 16 deals worth $199.6 million. On a positive note, the medtech sector witnessed a robust growth in Foreign Direct Investment (FDI), rising from $370 million in 2022 to $480 million in 2023. In contrast, FDI in pharmaceuticals dropped from $2 billion to $1 billion in the same period, signalling shifting investment priorities.

The report predicts a surge in biotech startups, from 8,531 in 2023 to an impressive 35,460 by 2030. This growth will significantly boost employment, creating 35 million jobs. The report highlights five states as leaders in the biotech startups space, which includes Maharashtra (1,421), Karnataka (1,054), Telangana (872), Delhi (875), and Uttar Pradesh (699). These states account for over 50 per cent of all biotech startups in India.

Global Bio-India (GBI) 2024 opened in New Delhi as a much bigger event as compared to 2023 with participation from 30+ countries, 500+ exhibitors, 5000+ delegates, 1000+ startups, B2B, B2G, G2G meetings and much more. Science and Technology Minister Dr Jitendra Singh inaugurated the event virtually.

"There are a billion reasons to invest in India, the reasons being India has 60 per cent share of global vaccine production, and it has the second highest number of USFDA approved manufacturing plants outside the US. Opportunities for investments are available in Bio-Pharma, Bio-Agri, Bio-Industrial, Bio-energy, Bio-Services and Med-Tech sectors", said Dr Jitendra Singh, Minister for Science & Technology, Government of India.

The event witnessed the official launch of the BioE3 policy recently approved by the government. The goal of the policy is to fast-track innovation-to-technology in a sustainable manner by weaving together fragmented activities under the umbrella of biomanufacturing and to incentivise concrete options to build a sustainable future.

BIRAC signed Letters of Intent with leading international organisations in biotechnology namely- United States Pharmacopeial Convention (USP); UK Research and Innovation (UKRI); Danaher India; Mauritius Institute of Biotechnology (MIBL); La

BIRAC Innovators Awards

- Therapeutics & Vaccines- Immuneel Therapeutics
- Biomedical Devices & Diagnostics and Bioinformatics- Piscium Health Sciences; Sensivision Health Technologies, and Sunfox Technologies
- Agriculture- Indian Veterinary Research Institute and Genomis Carl
- Industrial Biotechnology- GPS Renewables and Shriram Institute for Industrial Research
- Innovation with High Social Impact- Genrobotic Innovations
- AI-based Innovation- Torchit Eigatronics
- Special Recognition- Interactive Research School for Health Affairs

Best Incubation Centre Awards

- Best Incubation Centre (Tier I cities)- BSC BioNEST Bio-Incubator, Regional Centre for Biotechnology (RCB)
- Best Incubation Centre (Tier II cities): PSG-Science & Technology Entrepreneurial Park (STEP), Coimbatore and Manipal - Government of Karnataka Bioincubator
- Best Incubation Centre (Tier III cities): Technology Innovation and Development of Entrepreneurship Society (TIDES), IIT Roorkee
- Best Incubation Centre Exhibit- E-Yuva Centre, Career College, Bhopal

BIRAC Best Startup Awards

- Agriculture- Ekosight Technologies
- Industrial Biotechnology- Rigel BioEnviron Solutions
- Healthcare Therapeutics- Apramitha Innovations
- Healthcare Devices and Diagnostics- Denovo Bioinnovations
- International Participant- Biopesticide Summit
- Women Entrepreneur- Inte-e-Labs (Sonia Madan)

Trobe University; Blockchain for Impact (BFI); US-India Strategic Partnership Forum (USISPF); IBioM (Indian Biotech MSME and Startup Foundation); and Bharat Startup and Innovation Society (BSIS)-Bharat Startup Festival; Children's Investment Fund Foundation; and IPE Global.

Further, special booklets namely BIRAC Compendium of Products and Technologies 2024, Insights into BIRAC Equity Fund and Amrit Grand Challenge JanCARE Innovations Report were also launched during the inaugural session of GBI 2024.

GBI 2024 also marked the Launch of Calls for Proposals under the i4 (Innovation for Industry) and PACE (Promoting Academic Collaboration and Entrepreneurship) programmes, furthering the government's commitment to fostering innovation.

The event also witnessed a series of discussions between DBT Secretary and State government representatives on the current challenges & opportunities in store for the biotech sector. With participation of 13 states namely, Odisha, Meghalaya, Assam, Kerala, Karnataka, Bihar, Punjab, Uttarakhand, Goa, Tamil Nadu, Telangana, Gujarat and UP, the State Showcase & Roundtable during GBI 2024 provided a platform and an interactive forum for states to highlight their investment ecosystem, policy framework, and research initiatives to drive accelerated growth of the Indian bioeconomy.

A similar roundtable session took place between the industry captains and the DBT Secretary where industry expectations and requirements were discussed to enhance innovation in India. Increased focus on faster regulatory mechanisms, clinical research, affordability, data informatics, biosimilar policy, bioprocess engineering, large scale manufacturing, use of bioplastics was conveyed by the industry players to the government.

Another key highlight at GBI 2024, among multiple sessions on new generation therapeutics, use of non-animal methods for biomedical research, clinical trial networks, global partnerships, was that the Indian biotech startups took centerstage by unveiling new products to showcase the country's emerging talent in biosciences. These included advancements in med tech, probiotics, skin care, zero-calorie sugar, animal-free proteins, foetal bovine serum alternatives, and many more.

Further, exceptional contributions to the biotech industry were recognised by the government with awards namely- BIRAC Innovators Awards; Best Startup Awards; and Best Incubation Centre Awards. A Science Quiz Competition was held for the first time for school students (11th &12th class) at the Global Bio India event. This interactive quiz was organised to challenge young minds, ignite curiosity, and deepen their understanding of the latest innovations, research, and advancements in biotechnology. In addition, the Expo at GBI 2024 showcased groundbreaking innovations, and cutting-edge biotech advancements, for shaping the future of the biotech ecosystem. BS

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TriMedSoc Alliance renews collaboration, uniting Singapore medical students

Student bodies from Singapore's three medical schools renewed their partnership, three years after the TriMedSoc Alliance was first established. The alliance unifies Singapore's medical student community, enhancing cooperation and advocacy through a formal platform for collective action. The agreement aims to develop programmes supporting the holistic development of medical students in Singapore, while also bolstering student-led initiatives in the wider community. A major development in this renewal is

the formation of an advisory board, comprising senior doctors, administrators and faculty from all three schools. The board, selected for their depth and breadth of expertise in local medical education and healthcare, will provide valuable long-term continuity and guidance for the Alliance. With the renewed MoU, the Alliance aims to strengthen its commitment to representing medical students and enhancing community bonds. Through engaging with key stakeholders, including medical schools, the Designated Institutional Officials of the three healthcare clusters and the Ministry of Health, the TriMedSoc Alliance will continue to address critical issues such as school learning facilities, financing medical education and clinical rotation experiences.

Korea announces first joint degree programme in AI in partnership with US

Korea Advanced Institute of Science and Technology (KAIST) and New York University, US have signed a Memorandum of Understanding (MoU) to introduce a graduate programme for a joint degree in the field of artificial intelligence (AI). This agreement was promoted based on the consensus between the two universities that strengthening capabilities in the field of AI and fostering global talent are essential elements that can lead to great development in the entire future society beyond simple technical education. The two universities have been operating joint research groups in various industrial fields related to AI and convergence with it, and based on this agreement, they plan to establish an operating committee within this year to design a joint degree programme for graduate school courses related to AI.

University of Melbourne launches Global Centre in Delhi, India

The Premier of Victoria, Jacinta Allan recently opened the University of Melbourne's first Melbourne Global Centre in Delhi, marking a significant expansion of its global presence. This milestone is part of a major delegation visiting India to enhance partnerships and engagement with local students, alumni, government officials, and educational partners. The Melbourne Global Centre – Delhi is strategically located in the heart of India's central government district; close to businesses, international agencies, and the Australian High Commission. The Centre will facilitate collaboration and knowledge exchange across education, research, industry, and the community, serving as the University's central hub in India. It will enable the University to showcase its extensive educational offerings, cutting-edge research, and community engagement programmes. The establishment of the Melbourne Global Centre - Delhi enhances the University's presence and engagement in India while supporting its broader global partnership model.

Zuellig Pharma: A Sustainable Approach to Healthcare Access Through Innovative Solutions

The equitable distribution of medicines and their accessibility are critical to the resilience of the healthcare system. However, disparities in access and equity continue to exist and these are pertinent to address, especially as healthcare disruptions can negatively impact an economy's public health and patient care.

As powerful catalysts of transformational change, the COVID-19 pandemic tested the resilience and flexibility of pharmaceutical supply chains. In the wake of the pandemic, the healthcare sector requires an agile and robust supply chain risk management system to address disruptions, ensure resilience, and smooth operations.

In recent years, supply chain risk management practices have been revolutionised by technology, with new innovations and risk management solutions reducing accessibility concerns through real-time insights and data-driven mitigation strategies. The use of disruptive technologies and Supply Chain Risk Management (SCRM) can help minimise risks by identifying disruptions, preparing contingency plans, and alleviating their overall impact.

Strengthening Healthcare SCRM Strategies to Overcome Accessibility Disparities

Blockchain-enabled healthcare supply chains and IoT sensors facilitate comprehensive, secure, and traceable real-time risk assessments. Predictive analytics and artificial intelligence algorithms can help identify and mitigate disruptions, ensuring patient accessibility.

Zuellig Pharma, a leading healthcare solutions company with a purpose of making healthcare more accessible, harnesses the transformative potential of disruptive technologies to enhance supply chain resilience, agility, and responsiveness to risks, developing a connected pharmaceutical ecosystem through innovative digital platforms.

Providing distribution, commercialisation, clinical trial management and patient care solutions across 16 markets, Zuellig Pharma works with over 450 clients, including 20 of the world's largest pharmaceutical companies. The company's core business efforts focus on improving health outcomes and access to quality healthcare for over 200,000 clinics, hospitals, pharmacies, and facilities in the firm's distribution network.

To increase coverage and access to healthcare in rural and remote areas, Zuellig Pharma continues to invest in R&D of cold chain solutions, especially in light of the increasing need for temperature-sensitive handling in emerging healthcare solutions. For example, **eZCooler**—an innovative, reusable passive packaging solution that facilitates the transportation of temperature-sensitive products—ensures product integrity for patient safety during challenging last-mile delivery while reducing freight carbon footprint. Zuellig Pharma's extensive cold chain capabilities boast over 18,000 cold room pallets, surpassing international standards for distributing biologics and vaccines and safeguarding patients' access to lifesaving medication in its intended condition.

Its Singapore-headquartered APAC Regional Distribution Centre meets the highest pharmaceutical and cold chain management standards, and is operated by GMP-certified workstations. Through its distribution network and cold chain reach, the company ensures seamless access to healthcare throughout the region. Its facilities in markets such as Malaysia, Hong Kong, the Philippines, Indonesia, and Korea also deploy state-of-the-art infrastructure to ensure quality and delivery excellence.

Fostering Healthcare Resilience, Agility, Access and Adaptability

A resilient supply chain requires agility and flexibility to adapt to evolving market dynamics. Data integrity and accountability exercises carried out by Zuellig Pharma are a testament to the company's commitment to uphold the highest standards.

To enhance supply chain efficiency and address Asia's fragmented healthcare ecosystem, the company has invested substantially in building a digital infrastructure. Its Data Analytics **ZiP platform,** for instance, empowers clients by providing real-time insights on treatment management, pricing, and healthcare trends. In addition, Zuellig Pharma uses a Transport Management System for load optimisation, consolidating orders and optimising delivery routes to ensure that the fewest numbers of vehicles are used while maximising the number of deliveries.

Zuellig Pharma has also developed several digital platforms such as **eZRx+** and **eZTracker** to ensure accessibility, traceability, and compliance while remaining resilient to supply chain disruptions.

eZRx+ is an end-to-end B2B interactive ecommerce portal that allows healthcare organisations to purchase medications digitally from anywhere seamlessly and efficiently. The platform provides full visibility with higher accuracy, transparency, and eliminating manual errors, as well as self-service capabilities. According to a representative from Zuellig Pharma's customer, Tep Nika pharmacy in Cambodia, patient confidence has increased as the platform improved their operational efficiency by 70% and reduced paperwork by almost 80%, allowing them to reallocate resources to better serve patients.

The issue of counterfeiting, parallel trade and diversions remains a key challenge in the pharmaceutical landscape and networks, which makes it imperative to build trust in the supply chain. **eZTracker,** Asia's first blockchain-powered end-to-end supply chain solution, allows users to verify the authenticity of pharmaceuticals, and offers a potential solution against expired, poorly stored, or counterfeit drugs. With over 200,000 scans to date, the eZTracker solution has successfully tracked $19 million worth of suspected counterfeits and diversions.

Providing strategic partnerships and industry collaborations is a key part of Zuellig Pharma's approach to enhancing oversight of pharmaceutical products and combating illicit activities. In partnership with technology firms, regulatory bodies, and industry associations, Zuellig Pharma deploys innovative solutions and implements best practices to safeguard pharmaceutical products' traceability, integrity, and authenticity.

Climate Governance and Sustainability Goals Outlook

To uphold operational excellence, Zuellig Pharma warehouses adhere to Good Storage Distribution Practices (GSDP) and compliance with ISO standards. Till date, Zuellig Pharma has achieved 7 industry certifications across different markets from the Transported Asset Protection Association (TAPA) and is working to secure certification across all markets by 2025.

Zuellig Pharma's latest 2023 Sustainability Report *(Cited period: 1st January 2023 to 31st December 2023)* has also conveyed its unwavering commitment to transparency and accountability in sustainability efforts. The organisation recently

achieved its fourth consecutive Platinum medal from EcoVadis, the world's most trusted provider of business sustainability ratings, with a score of 90 out of 100. This achievement places Zuellig Pharma among the top 60 companies out of 130,000 respondents worldwide, and the first organisation in Asia Pacific to reach this level.

In 2023, Zuellig Pharma reduced its carbon emissions by 38%, putting the company four years ahead of stringent Science Based Targets initiative (SBTi) greenhouse gases reduction targets. The company has made great strides in pivoting to more environmentally-friendly energy sources, with several pilots for electric vehicles and bikes for its delivery fleets, and more than 57% of its electricity use coming from renewable sources.

Zuellig Pharma aims to achieve zero waste going to landfills by following Circular Waste Management principles and promoting responsible waste management in pharmaceuticals and packaging, having already reduced the waste going to landfills by 24% in just two years.

Reliability and Patient Safety as a Cornerstone of Healthcare Accessibility

Through innovative solutions and collaboration with various stakeholders, Zuellig Pharma is strengthening across all facets, building a resilient cross-regional supply chain, improving regional infrastructure, and sharing data and knowledge across markets. By leveraging technology and investing in sustainable practices, Zuellig Pharma continues to bridge the gap between healthcare accessibility, patient safety and environmental responsibility. ◆

Scan the QR Code to access 2023 Sustainability Report

Tanvex BioPharma appoints Stephen Lam as CEO

Tanvex BioPharma, Inc., Taiwan-based biosimilar-focused biopharmaceutical company and a contract development and manufacturing organisation (CDMO,) has announced that its Board of Directors has appointed Stephen Lam as the company's Chief Executive Officer (CEO). Lam succeeds Henry Chen, who shall remain the Chairman until the closing of Tanvex's strategic alliance with Bora Pharmaceuticals. As a part of the new leadership initiated by Bora, Lam will be responsible for ensuring a successful integration, driving the company's strategic initiatives as well as overseeing Tanvex's day-to-day operations, including its global CDMO operations and the commercialisation of its biosimilar pipeline. With over 35 years in the biopharmaceutical industry at leading companies including Lonza, Amgen, and Patheon, Lam has built a strong track record of delivering results. More recently, he served as Vice President and General Manager, Head of Biologics at Thermo Fisher Scientific.

Amit Mookim steps in as CEO of Immuneel Therapeutics

India-based Immuneel Therapeutics, a pioneering cell and gene therapy platform, has announced the appointment of Amit Mookim as its new Chief Executive Officer (CEO). Mookim brings over two decades of extensive experience across life sciences, technology and private equity, making him ideally suited to lead Immuneel into its next phase of growth and innovation. Mookim joins Immuneel from IQVIA, a Fortune 500 global leader in clinical research, technology and analytics, where he served as Managing Director for South Asia. At IQVIA, he played a pivotal role in integrating two large organisations post-merger, overseeing the site operations for a combined workforce of 20,000+ professionals across India. His leadership was instrumental in growing the South Asia commercial business both organically and inorganically. Prior to his tenure at IQVIA, Mookim was Head of Healthcare at KPMG India. He built KPMG's healthcare business from the ground up and worked extensively with leading hospitals, PE funds and international healthcare companies to establish and grow their presence in India.

Novotech appoints Dr Yooni Kim as Managing Director for APAC region

Novotech, the leading global biotech Contract Research Organisation (CRO), has announced the appointment of Dr Yooni Kim as a new Executive position of Managing Director for the Asia-Pacific (APAC) region. The establishment of the Managing Director APAC role is a significant step, aligning Novotech's operations across key regions, including the United States, Europe, Mainland China, and APAC. Dr Yooni Kim brings extensive expertise and leadership experience to her new role, with over 25 years' experience in the clinical research sector of academia, CROs and pharmaceutical companies. Her leadership was proven by a quantum leap in business growth in the APAC region within the CRO industry. Dr Yooni joined Novotech in 2016 as Executive Director, where she played a pivotal role in the growth of the company's business in Asia.

Following the PPC group merger in 2019, she served as Vice President of Global Clinical Services, leading Novotech's global clinical services departments and harmonising Novotech's approach to clinical trials with stakeholders globally. In her new role as Managing Director for APAC, Dr Yooni will lead Novotech's APAC from providing strategic direction to diverse teams and ensuring operational excellence in the region.

Singapore's Health Sciences Authority appoints Adj A/ Prof. Raymond Chua as CEO

Adjunct Associate Professor Raymond Chua Swee Boon has been appointed as Chief Executive Officer-Designate of the Health Sciences Authority (HSA), Singapore and will officially assume the Chief Executive Officer (CEO) role from December 13, 2024. Dr Mimi Choong May Ling, the current CEO of HSA, will retire from public service with effect from December 13, 2024. Adj A/Prof. Chua is currently Deputy Director-General of Health (Health Regulation) at the Ministry of Health (MoH), overseeing the regulations of healthcare services and information in Singapore. He will continue with this appointment concurrent to his role as CEO of HSA, to better synergise regulatory operations and enforcement across healthcare services, information and products. He is also an Adjunct Associate Professor with the Saw Swee Hock School of Public Health in the National University of Singapore (NUS) and the Centre of Regulatory Excellence in Duke-NUS. In MoH, he has led multiple transformative regulatory initiatives, including the enactment and implementation of the Human Biomedical Research Act and Healthcare Services Act, which modernised the healthcare regulatory framework and enabled new modes of service delivery, making Singapore a pioneer in this area.

Vatroslav Mateljic steps in as General Manager of Takeda Canada

Takeda Canada Inc. has announced the appointment of Vatroslav (Vatro) Mateljic as its new General Manager to lead the Canadian operations of Japan's largest pharmaceutical company. Mateljic has held a number of executive leadership roles in sales, marketing and country management over his 25-year career in the pharmaceutical industry. Most recently, he served as Takeda's General Manager in Sweden. Vatro's commitment to driving business growth and implementing strategic initiatives that positively impact patient outcomes and organisational success make him a valuable asset for the company's Canadian business, as Canada is a critical market for Takeda's global operations.

BioDuro-Sundia appoints Dr Armin Spura as CEO

BioDuro-Sundia, a leading Contract Research, Development, and Manufacturing Organisation (CRDMO) based in the US and China, has announced the appointment of Dr Armin Spura as its new Chief Executive Officer (CEO). Dr Spura brings over two decades of experience in the life sciences and biotechnology sectors, with a proven track record of driving growth and innovation across global markets. Dr Spura joins BioDuro-Sundia from Crown Bioscience, where he served as the CEO for nearly five years, guiding the company through significant growth and strategic development. Throughout his career, Dr Spura has held senior leadership positions at several well-known organisations such as Thermo Fisher Scientific, WuXi NEXTCODE, CareDx and Ion Torrent. He also holds various advisory roles, serving as the chair of the board of directors for SeromYx Systems and as a life science investment advisor at K2X Technology and Life Science. Early in his career, Dr Spura helped to grow two startup companies: Ingenuity Systems (acquired by Qiagen) and ForteBio (now part of Danaher).

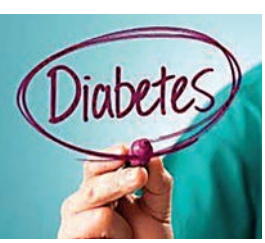
Singapore elevates analysis of genomic data with breakthrough mathematical technique

A novel approach for analysing single-cell RNA sequencing (scRNA-seq) data has been unveiled by researchers at the National University of Singapore (NUS). This method promises to enhance both the precision and speed of data interpretation, potentially accelerating progress in numerous areas of biomedical investigation, including studies on cancer and Alzheimer's disease. The innovative framework, dubbed scAMF (single-cell Analysis via

Manifold Fitting), was developed by a team of scientists led by Associate Professor Zhigang Yao from the Department of Statistics and Data Science at the NUS Faculty of Science. The framework employs advanced mathematical techniques to fit a low-dimensional manifold within the high-dimensional space where the gene expression data are measured. By doing so, scAMF effectively reduces noise while preserving crucial biological information. This allows for more accurate characterisation of cell types and states. This research was done in collaboration with Professor Yau Shing-Tung at Tsinghua University, China.

Hong Kong develops next-gen wearable continuous glucose monitoring system

An interdisciplinary research team, including the Faculty of Engineering and Li Ka Shing Faculty of Medicine at The University of Hong Kong (HKU), Zhejiang University, and Guangzhou Medical University, in China, has developed a groundbreaking continuous glucose monitoring (CGM) system which represents a major advancement in wearable health technology and is set to revolutionise diabetes management. The new CGM system, termed OECT-CGM, features a compact, coin-sized design integrating state-of-the-art biosensors, minimally invasive tools, and hydrogels. The core part of the device is the organic electrochemical transistor (OECT), a biochemical signal amplifier that significantly improves the signal-to-noise ratio (SNR) beyond traditional electrochemical sensors. This advancement is critical for providing accurate and reliable glucose readings essential for effective diabetes management. The OECT-CGM includes a microneedle array for subcutaneous glucose sampling with minimal pain and discomfort, addressing one of the major drawbacks of existing CGM devices, deemed invasive due to the requirement of a needle inserted under the skin, which can cause discomfort.



Australia develops finger-prick test to screen for early Alzheimer's disease

A team of engineers at Monash University, Australia has developed the first-of-a-kind finger-prick blood test with 'needle-in-a hay-stack' precision to detect the hallmark (protein) biomarkers in early Alzheimer's Disease (AD) before symptoms progress. The size of a credit card, it uses world-first patented sensor technology which can detect ultra low concentrations of disease markers in blood in minutes. With the number of Australians diagnosed with dementia set to double by 2054, the quick blood test could become a vital tool to streamline diagnoses by giving general practitioners unprecedented access to non-invasive diagnostics. Associate Professor Sudha Mokkapati from Monash Materials Science and Engineering, developed the proof-of-concept electronic sensor for point-of-care testing, removing the need for laboratory-based pathology tests, and making the process to diagnosis faster and more cost-effective. Key collaborator Associate Professor Matthew Pase, at Monash's School of Psychological Sciences, said the device may facilitate earlier, more efficient diagnosis, enabling timely intervention and management of AD.

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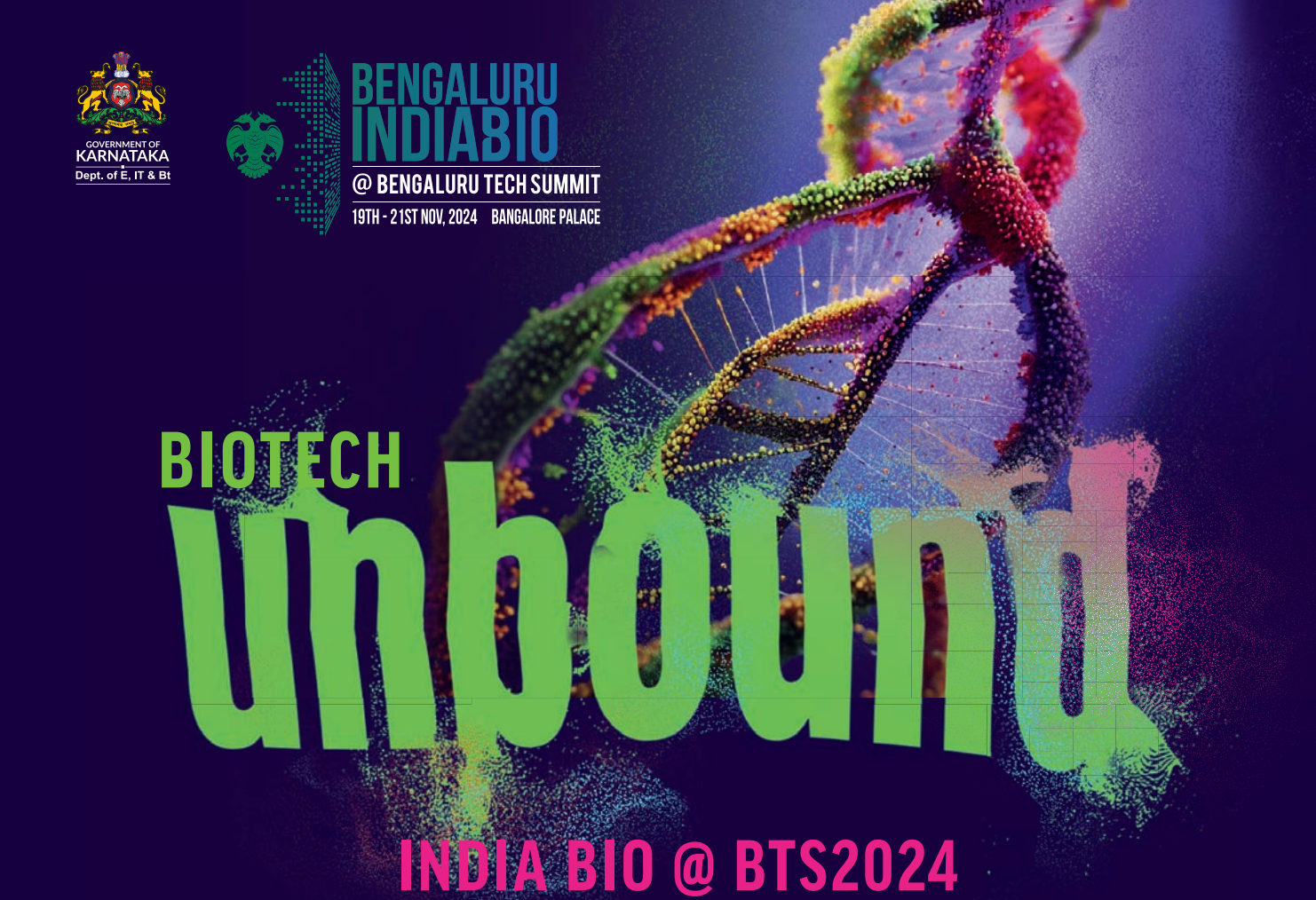

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EVENT SPECTRUM

- Multi-Track Conference
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- India Innovation Alliance
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- CEO Conclave
- R&D Lab2Market
- STPI IT Export Awards
- Smart Bio Awards
- Startup & Investors Awards
- Bio Posters Showcase
- National IT & Bio Quiz
- Product Launches
- World Leaders Dinner
- B2B, B2G Partnering Meets

INDIA BIO CONFERENCE TOPICS

- BioManufacturing E3
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- One Health & Pandemic Preparedness
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- mRNA Technologies
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IonOpticks announces partnership with Adelis Equity Partners

Australia-based IonOpticks, a leading global producer of high-performance chromatography columns, has announced its partnership with Adelis Equity Partners. The Nordic private equity firm is renowned for partnering with and accelerating the growth of companies in their focus sectors including healthcare and life sciences. The investment from Adelis will augment IonOpticks' global presence and drive innovation as the company expands closer to key markets and consolidates its leading position in the exciting and rapidly growing field of proteomics and adjacent applications. The strategic partnership will enable IonOpticks to scale its operations globally, enhancing product development and better positioning the company to serve its growing customer base. Being closer to its customers and collaborators while also ensuring compatibility across major LC-MS platforms is a key priority, allowing researchers worldwide to benefit from IonOpticks' class-leading chromatography. Adelis' extensive experience, industrial advisor network and resources will support IonOpticks in maintaining its position as the provider of the best solutions for LC-MS proteomics research.

Scopio Labs & Beckman Coulter to distribute digital bone marrow imaging and analysis app

US-based Beckman Coulter, a clinical diagnostics leader, and Scopio Labs, a medtech company based in Israel that develops digital cell morphology workflow solutions, have jointly announced expansion of its long-term partnership to include a global distribution agreement of Scopio's Full-Field Bone Marrow Aspirate (FF-BMA) Application. Scopio's X100 / X100HT with FF-BMA Application are CE-Marked. Scopio's FF-BMA Application transforms BMA analysis by combining high-resolution Full-Field imaging with a robust AI-powered decision support system into a fully digital workflow seamlessly integrated with Scopio's X100 and X100HT scanners. It also enables hematopathologists to review bone marrow smears remotely (via a secure hospital network), potentially reducing turnaround time, fostering collaboration, facilitating second opinions, and bolstering diagnostic confidence.

MilliporeSigma launches single-use reactor to accelerate ADCs manufacturing

MilliporeSigma, the US and Canada Life Science business of Merck KGaA, Darmstadt, Germany, has launched the first single-use reactor specifically designed to manufacture antibody drug conjugates (ADCs). ADCs are a rapidly emerging class of therapeutic agents that can target and selectively kill tumour cells, while protecting healthy ones. The Mobius ADC Reactor is tailored precisely to meet the unique requirements for linking the necessary components. It enables biopharmaceutical companies to produce their critical therapies faster and safer. Current ADC production methods use stainless steel or glass reactors which require labour-intensive and costly cleaning procedures. Single-use technology costs less, reduces risk, and is more flexible and faster than these traditional methods. However, the adoption of this technology in ADC manufacturing has been limited due to the unique chemical compatibility and quality requirements. The Mobius ADC Reactor changes this by offering faster turnaround times and fewer cross-contamination risks, all while maintaining high product quality.

Agilent unveils Biopharma CDx Services Lab to accelerate precision medicine

Agilent Technologies Inc., has announced the launch of its Biopharma CDx Services Lab (BCSL) in Carpinteria, California, US following receipt of California State clinical laboratory license and Clinical Laboratory Improvement Amendments (CLIA) certificate of compliance. These credentials signify that the lab operates in accordance with CLIA regulations, which are federal standards applicable to all US facilities testing human specimens for health assessment, diagnosis, prevention, or

treatment of diseases. The CLIA certificate of compliance ensures high standards for accuracy and reliability in laboratory testing, confirms regulatory adherence, boosts market credibility, and improves operational efficiency. The BCSL and Agilent's assay development model will support drug development from early clinical studies through regulatory approval with efficient, flexible, and streamlined companion diagnostic development. The BCSL will also provide access to innovative technologies for biomarker assessment with novel precision therapeutics in clinical trials, as well as high-quality assays that deliver robust data.

Shimadzu launches operations in Mexico

Japan's Shimadzu Corporation has established a subsidiary in Mexico and has begun its activities. To date, in Mexico, analytical and measuring instruments are distributed by a subsidiary in the United States, while medical systems are marketed through a subsidiary in Brazil. The establishment of Shimadzu México, S. A. de C.V. (SMX) in the capital, Mexico City, will enable sales and service activities in the vicinity of the distributors and users, regionally and in their own language for both analytical and measuring instruments and medical systems. In the autumn of 2025, SMX is scheduled to establish a laboratory equipped with training and showroom functionalities, strengthening support for distributors and customers. In response to robust capital investment, in terms of analytical and measuring instruments, Shimadzu is focusing on markets related to transport equipment, electrical appliances and electronics, pharmaceuticals, food products, and testing and inspection companies.

Qiagen to develop first QIAstat-Dx IVD panel for neurodegenerative applications

Qiagen has entered into a collaboration with Eli Lilly and Company to support the development of a QIAstat-Dx in-vitro diagnostic (IVD) to detect APOE genotypes which can play a role in the diagnosis of Alzheimer's disease. This collaboration represents a significant milestone as the QIAstat-Dx panel would be the first commercially available IVD for APOE genotyping. The panel will be integrated with Qiagen's multiplex testing platform QIAstat-Dx, marking the first publicly disclosed collaboration for a clinical application of the system in neurodegenerative diseases and adding to two more collaborations for diagnostics development programmes with other companies. The QIAstat-Dx system, designed for laboratory use, employs cost-efficient, single-use cartridges with built-in sample processing and on-board reagents. Utilising multiplex real-time PCR, it reliably detects genetic variants, with results in about an hour. With more than 4,000 instruments placed worldwide, QIAstat-Dx has a strong footprint in infectious disease testing, which is now expanded into other disease and application areas.

Decisive Actions to End AMR-Induced Deaths

Alexander Fleming won the Nobel Prize for his accidental discovery of penicillin almost 100 years ago. But he also knew about the threat of antimicrobial resistance (AMR), and warned the world about it. In his Nobel lecture in 1945, Fleming said, "It is not difficult to make microbes resistant to penicillin in the laboratory by exposing them to concentrations not sufficient to kill them." If he were here today, he would probably say, "I told you so."

"AMR is one of the most pressing threats to health and development of our time. AMR could reverse decades of medical progress, making common infections, routine surgeries, cancer treatment and organ transplants far riskier and even life-threatening. This is not a hypothetical risk for the future. It's here and now," said Dr Tedros Adhanom Ghebreyesus, World Health Organisation (WHO) Director-General in his opening remarks at the 79th United Nations General Assembly (UNGA) High-Level Meeting on AMR, on September 26.

The global leaders have approved a political declaration committing to a clear set of targets and actions, including reducing the estimated 4.95 million human deaths associated with bacterial AMR annually by 10 per cent by 2030. The declaration also calls for sustainable national financing and $100 million in catalytic funding, to help achieve a target of at least 60 per cent of countries having funded national action plans on AMR by 2030. This goal is to be reached through, for example, diversifying funding sources and securing more contributors to the Antimicrobial Resistance Multi-Partner Trust Fund.

On human health, the declaration sets a more ambitious target that at least 70 per cent of antibiotics used for human health globally should belong to the WHO Access group antibiotics with relatively minimal side effects and lower potential to cause AMR. It also includes targets around Infection Prevention and Control (IPC), such as 100 per cent of countries having basic water, sanitation, hygiene and waste management services in all health care facilities and 90 per cent of countries meeting all WHO's minimum requirements for IPC programmes by 2030. There are also commitments on investments to facilitate equitable access to and appropriate use of antimicrobials, as well as on reporting surveillance data on antimicrobial use and AMR across sectors.

It may be noted that in 2019 alone, 1.3 million deaths were directly attributable to antibiotic-resistant infections. Vulnerable populations, particularly children, are disproportionately affected. No country is immune to this threat, but low- and middle-income countries bear the greatest burden. Despite the rapid spread of resistance, we are facing an alarmingly dry pipeline for new antibiotics. The irony of AMR is that it's fuelled by the overuse of antibiotics; And yet more people die from lack of access to antibiotics.

Globally, AMR could result in $1 trillion of additional health care costs per year by 2050 and $1 trillion to 3.4 trillion of gross domestic product (GDP) losses per year by 2030, and that treating drug-resistant bacterial infections alone could cost up to $412 billion annually, coupled with workforce participation and productivity losses of $443 billion, with AMR predicted to cause an 11 per cent decline in livestock production in low-income countries by 2050.

The declaration emphasizes key aspects, including the importance of access to medicines, treatments and diagnostics, while calling for incentives and financing mechanisms to drive multisectoral health research, innovation and development in addressing AMR. A stronger, transparent partnership between the public and private sectors, as well as academia is critical.

The declaration also encourages countries to report quality surveillance data on AMR and antimicrobial use by 2030, utilizing existing global systems such as the Global Antimicrobial Resistance and Use Surveillance System (GLASS), the Global Database for Antimicrobial Use in Animals (ANIMUSE) of World Organisation for Animal Health (WOAH), and the International FAO Antimicrobial Resistance Monitoring (InFARM). It further calls for 95 per cent of countries to annually report on the implementation of their AMR national action plans through the Tracking AMR Country Self-assessment Survey (TrACSS). If translated into action, this declaration will help to track AMR, slow it down, expand access to antimicrobial medicines like antibiotics and spur the development of new ones. BS

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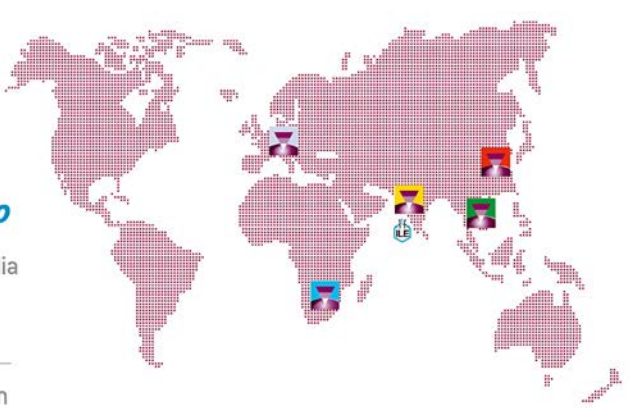

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