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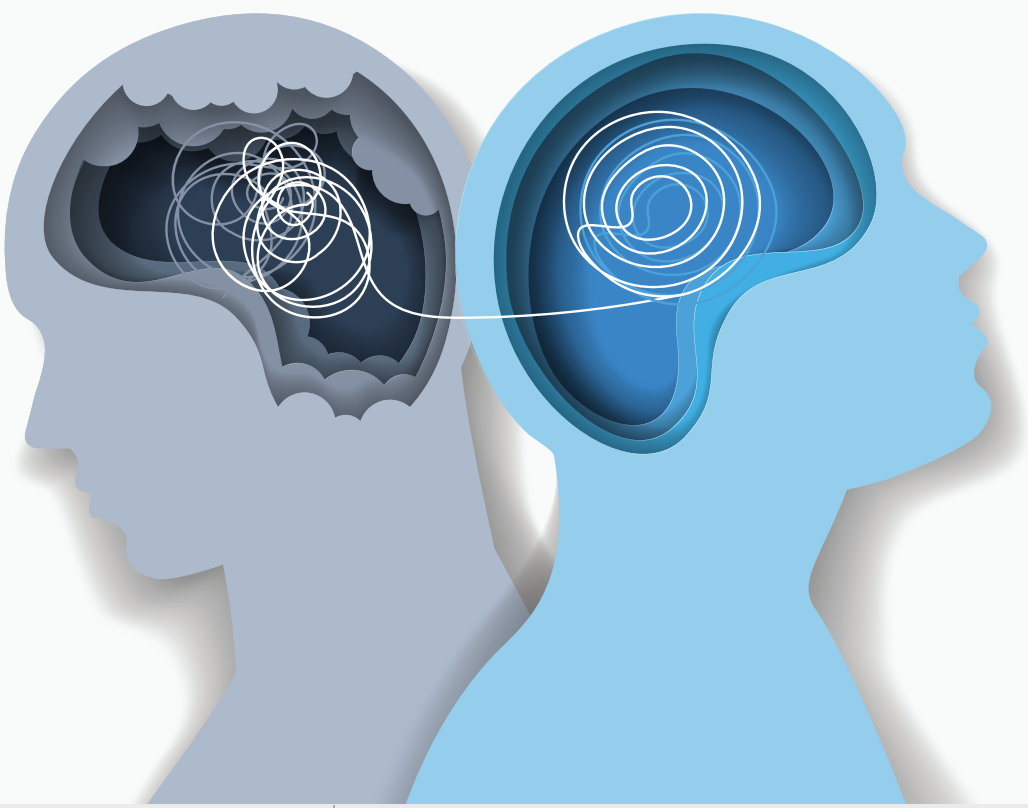
the business of Bio & Health Sciences
ASIA EDITION

Volume 19 | Issue 8 | August 2024

ADDRESSING ROOT CAUSES OF BRAIN DISORDERS WITH INNOVATIVE THERAPEUTICS



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Acknowledgement/ Feedback

Many thanks for the coverage on Rockwell Automation in the July edition of BioSpectrum Asia.

- Zulfekar, Singapore

Thank you for including Certara's comments in your obesity story. Looks good.

- Peyton, US

The story on hepatitis reads well.

- Ann, UK

Thank you BioSpectrum for publishing the story on Orchid Pharma and exploring a conversation about the urgent topic of Antimicrobial Resistance.

- Aayushi Sharma, India

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Letter from Publisher

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

While the oncology sector has seen remarkable progress with new therapies, neuroscience has historically lagged in providing effective cures or treatments for symptoms. However, there is now promising progress in understanding the intricate biology of these conditions and identifying new therapeutics. A wave of novel late-stage candidates is advancing through the development pipeline, offering hope for treating serious Central Nervous System (CNS) disorders and entering the market. Recent high-profile approvals, such as Leqembi for Alzheimer's and Kisunla (donanemab-azbt) for the same condition, have significantly bolstered the morale of firms dedicated to developing neurological treatments. This renewed focus has catapulted neuroscience into one of the most sought-after areas. In this edition the lead story talks about how big pharma has renewed its interest in CNS drug development that holds significant promise, although there still remain some challenges.

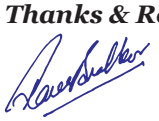
Respiratory diseases, worldwide, are major contributors to mortality and disability. Aside from the top five respiratory diseases - COPD, asthma, acute lower respiratory tract infections, TB, and lung cancer, several other respiratory disorders carry significant burdens, including pulmonary hypertension, sleep-disordered breathing, and occupational lung diseases. Artificial Intelligence (AI) has already integrated into conventional medical imaging and is now poised to revolutionise the diagnosis of respiratory diseases, which affect millions worldwide. We have an article that presents the advancements in analysing chest scans, interpreting sound patterns, etc. thereby simplifying and improving the precision of diagnostic procedures.

As more biologics lose patent protection, the influx of biosimilars is poised to expand, offering cost-effective alternatives and significantly impacting healthcare. The APAC region is currently experiencing a boom in biosimilars, with many companies actively developing them. The region currently holds 30 per cent of the global biosimilars market. Our team has covered a story that digs deep into whether biosimilars can repeat the success of generics that now represent 80-90 per cent of prescriptions filled around the world.

India's pharmaceutical industry is globally recognised for its capabilities in research and manufacturing and for its skilled workforce. The country's attractiveness as a destination for Global Capability Centres (GCCs) is underpinned by several key factors, including cost-efficiency, a vast talent pool, robust infrastructure, and strong regulatory support. Presently there are over 38 GCCs in India from healthcare and life sciences companies. We have an expert column that sheds light on how these hubs provide ample opportunities to explore emerging technologies and foster collaborations, leading to breakthrough discoveries and continuing to solve the healthcare challenges of India.

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

Thanks & Regards,



Ravindra Boratkar
Publisher & Managing Editor

COVER 20

Addressing Root Causes of Brain Disorders with Innovative Therapeutics

Neuroscience is a complex market encompassing a range of neurological conditions. Drug research and development for diseases related to the nervous system has always been challenging. While the oncology sector has seen remarkable progress with new therapies, neuroscience has historically lagged in providing effective cures or treatments for symptoms. However, there is now promising progress in understanding the intricate biology of these conditions and identifying new drug targets. A wave of novel late-stage candidates is advancing through the development pipeline, offering hope for treating serious Central Nervous System (CNS) disorders and entering the market. Recent high-profile approvals, such as Eisai's Leqembi for Alzheimer's and Eli Lilly's Kisunla (donanemab-azbt) for the same condition, have significantly bolstered the morale of firms dedicated to developing neurological treatments. The neuroscience sector is suddenly back in action, with pharma companies renewing their interest, spurred by recent US FDA approvals in neurodegenerative diseases like Alzheimer's. This renewed focus has catapulted neuroscience into one of the most sought-after areas. Let's explore the latest developments in detail.

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"Despite advancements, disorders of CNS continue to be difficult to treat and represent one of the largest unmet needs in healthcare"

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Saw Swee Hock School of Public Health,
National University of Singapore

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Anil Matai,
Director General,
Organisation of Pharmaceutical Producers of India (OPPI)

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Biotech Investment

Reviewing Global Biotech Investment

Surbhi Gupta,
Industry Principal, Healthcare & Lifesciences, Frost & Sullivan

REGULARS

CHINA FUELING US FENTANYL CRISIS?

Dr Milind Kokje
Chief Editor
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After the Wuhan lab leak COVID-19 controversy and issues related to biotech, the fentanyl crisis seems to be a new bone of contention between the US and China. However, the previous month, China announced its intention to help disrupt the global supply chain that is aiding the opioid (fentanyl) crisis.

China's initiative appears to be a fallout of the criticism from the US that Chinese chemical factories are partly responsible for the deadly scourge. The criticism was not just in informal or unofficial circles. The US Congressional Committee on the Strategic Competition between the US and the Chinese Communist Party (CCP) in its official report has alleged that China is directly subsidising production of illicit fentanyl precursors for sale abroad and fueling the US opioid crisis.

The committee has held the CCP responsible for the crisis in the US stating that China continues to provide subsidies in the form of value-added tax rebates to the companies manufacturing fentanyl analogue, precursors, and other synthetic narcotics when they sell them outside China. As a result of China's incentives, the People's Republic of China (PRC), under the leadership of the CCP, is the ultimate geographic source of the fentanyl crisis, the committee said in its report.

The committee claimed that its investigations established that China did not fail in prosecuting fentanyl and precursor producers, but it gave monetary grants and awards to companies openly trafficking illicit fentanyl materials.

For the US, fentanyl is a real crisis, claiming over 70,000 lives last year and 110,000 in 2022. The house committee called it one of the most horrific disasters the US ever faced, killing 200 Americans on an average every day. It is a leading cause of death for the people in the age group of 18 to 45. Even in the age group of 50 to 65, an extraordinary death rate due to fentanyl related causes is seen. It has even caused a historic drop in the US life expectancy. No wonder, the US system is worried and blaming the source.

Fentanyl is a synthetic opioid which has long been used as a powerful painkiller in hospitals. It is up to 50 times more potent than heroin. In 2014, the US FDA raised alarm over illicit supplies of the drug. By 2024, it is responsible for 70 per cent of overdose deaths. On one hand the medical profession is trying to reduce the overdose problem by using alternatives like buprenorphine. It is a synthetic opioid developed in the 1960s.

But such efforts are not adequate. What is needed is stopping the supply of fentanyl which requires Chinese initiative. The main obstacle was a long freeze in joint counternarcotics operations between the two countries. But this impasse was crossed at a summit in California in November between the two heads of state. Follow up meetings were held subsequently since January between the officials from both countries.

There were reports of even Chinese authorities silently shutting down some enterprises selling precursor chemicals used by Mexican cartels to make fentanyl. After that it recently announced to take further steps to impose new regulations to stop production and sale of the fentanyl precursor chemicals as well as three other chemicals.

On the medical side, there is a need to recognise that substance use disorder is a chronic illness and requires treatment. Despite recognising it, only 13 per cent of people with substance use disorder in the US are able to get treatment.

On the supply side, though, China has announced steps to stop supply. There are different methods of making fentanyl and it has several variants. When authorities try to stop the production, the producers turn to new variants making it difficult for the authorities to catch it. Between 2012 and 2015 six variants emerged, but in 2016 there were 63 variants. Putting an end to this lethal drug menace primarily depends on China's willingness and commitment to overcome such technical challenges. BS

Australia delivers first aged care digital plan

The Australian government has released its first Aged Care Data and Digital Strategy. The strategy sets out the vision for embracing innovation and harnessing the power of data and digital technologies to improve the care and wellbeing of older people in Australia. The focus is on preserving choice and leveraging technology to make in person and face-to-face services more accessible and efficient. Aged care workers and service providers will benefit from improved use of aged care data and a reduction in administrative burden, increasing the time workers can spend on direct, person-centred, care for older people. As well as short-term solutions, the strategy looks to build critical data and digital foundations, such as artificial intelligence (AI) frameworks for aged care and put in place appropriate measures to protect and secure privacy. A detailed action plan has also been published to provide further information on how the Strategy will be implemented.

Malawi, China sign MoU on health cooperation

The Malawian Ministry of Health and the National Health Commission of China have signed a Memorandum of Understanding (MoU) on cooperation between hospitals of the two countries. Malawian Minister of Health Khumbize Kandodo Chiponda and the Chinese Ambassador to Malawi Long Zhou represented the two sides in the signing of the MoU in Lilongwe, the capital of Malawi. The agreement ushers in a new era of strong cooperation between China and Malawi in the critical field of healthcare. The agreement focuses on strengthening key areas such as obstetrics and gynaecology of Malawi's Kamuzu Central Hospital and the first affiliated hospital of Xi'an Jiaotong University in northwestern China's Shaanxi Province. The collaboration between the two institutions will enhance local capacity for treating critically ill pregnant women, and improve diagnosis and treatment of gynaecological conditions, according to Chaponda. The agreement will also focus on radiology and clinical laboratory, whereby Malawian Mzuzu Central Hospital will partner with Xi'an Jiaotong University to cultivate a skilled workforce in the said fields.

Korea announces launch of mental health policy innovation committee

The South Korean government recently convened the inaugural meeting of the Mental Health Policy Innovation Committee at the National Center for Mental Health. Following the announcement of the establishment of the Innovation Committee at the Mental Health Policy Vision Declaration Conference on December 5, presided over by the President, the government has since prepared for its launch by formulating the statutory basis and determining the committee's composition. The Innovation Committee is to serve as a forum

for fostering societal dialogue and comprehensively innovating mental health policies. The Innovation Committee comprises private-sector chairman Shin Young-chul (currently a professor of psychiatry at Kangbuk Samsung Hospital), a government member (the Minister of Health and Welfare), individuals with mental illnesses, families of suicide victims, field practitioners, and 21 relevant experts as civil members. The Innovation Committee's mandate includes gathering cross-sectoral opinions on mental health policy innovation, providing consultations and policy/institutional recommendations, and developing a roadmap for implementing innovations through issue coordination.

Asia's first health research related pre-clinical network facility opens in Faridabad

Dr Jitendra Singh, Minister of State (Independent Charge) for Science and Technology and Earth Sciences, Government of India, has inaugurated Asia's first health research-related 'Pre-clinical Network Facility' under the Coalition of Epidemic Preparedness Innovations (CEPI) at the Regional Centre of Biotechnology under the aegis of the Translational Health Science & Technology Institute (THSTI), Faridabad. The CEPI has selected BRIC-THSTI as a pre-clinical network laboratory based on its capability to handle BSL3 pathogens. It will be the 9th such

network laboratory across the globe and the first such laboratory in the whole of Asia. The other labs are located in the US, Europe and Australia. The experimental Animal Facility is one of the largest small animal facilities in the country with a housing capacity of about 75,000 mice, including immune compromised mice and other species such as rat, rabbit, hamsters, guinea pigs etc. Dr Jitendra Singh also inaugurated the 'Genetically Defined Human Associated Microbial Culture Collection (Ge-HuMic) Facility' to act as a repository for providing microbial cultures to research institutes, universities, and industries for research and development. The facility will serve as a Nodal Resource Centre that will foster national and international collaborations between academic institutions, hospitals and industry.

Japan approves first post-transplant anti-cytomegalovirus infection treatment

Japanese Ministry of Health, Labour and Welfare (MHLW) has approved Takeda Pharma's LIVTENCITY (maribavir) for post-transplant cytomegalovirus (CMV) infection/disease that is refractory to existing anti-CMV therapies. LIVTENCITY is the first and only post-transplant anti-CMV treatment approved in Japan that targets and inhibits pUL97 kinase and its natural substrates. LIVTENCITY (maribavir), an orally administered (tablet) anti-CMV compound, is the first and only antiviral agent that targets and inhibits the CMV-specific UL97 protein kinase and thus its natural substrates. As of June 2024, LIVTENCITY is approved in more than 30 countries for post-transplant CMV refractory to prior therapies, including such major markets as Japan, the United States, Canada, Australia, the European Union and China.

New Zealand releases first Government Policy Statement on Health

New Zealand has released its first Government Policy Statement on Health. The Government Policy Statement (GPS) on Health 2024-27 is the public statement of what the Government expects the health system to deliver and achieve, and how success will be measured, monitored, and reported. The GPS outlines the government's vision for the health system- to increase life expectancy with quality of life, and a health system that provides all New Zealanders with timely access to quality health care. The GPS sets the direction for the health system as a whole and incorporates the government's priorities. It sets the expectations for health entities to make sure they are working towards common goals that matter for New Zealanders. The GPS highlights the need to prevent and reduce the impact of five non-communicable diseases- cancer, diabetes, respiratory disease, cardiovascular disease and poor mental health. Together, these account for about 80 per cent of deaths from non-communicable diseases in New Zealand.

Bio Innovation Hub with $8M investment opens in Australia

The $8 million Bio Innovation Hub, funded by the Victorian Higher Education State Investment Fund (VHESIF), was officially opened by Victorian Government Minister Colin Brooks, representing the Minister for Training and Skills Gayle Tierney, and La Trobe Vice-Chancellor Professor Theo Farrell at La Trobe's Melbourne campus in Bundoora. Startups and small to medium-sized biotechnology and agri-technology enterprises will have the opportunity to become tenants in the bespoke facilities located within the University's Research and Innovation Precinct, a key platform of La Trobe's University City of the Future. The first occupants of the Hub include La Trobe spin-out AlleSense, regenerative and preventative medicine company Aeterna Health, and VivaZome Therapeutics. VivaZome's focus is on developing and commercialising customised Extracellular Vesicles (EVs), tiny 'sacs' that have the potential to transport key medical supplies to targeted parts of the body. They specialise in targeted treatments for neurodegenerative diseases, including Traumatic Brain Injury (TBI) and stroke.

Bangkok Hospital invests 200 M baht to establish robotic surgery centre

Bangkok Hospital, a leading healthcare provider in Thailand, has invested over 200 million baht to establish a cutting-edge robotic surgery centre. The facility is equipped with multiple operating rooms integrated with the latest robotic platforms, including the da Vinci Xi Surgical System. This investment underscores the hospital's commitment to becoming the premier destination for robotic-assisted surgery in Southeast Asia, offering patients access to the most advanced minimally invasive surgery across a wide range of specialties. Recognising the achievements of robot-assisted surgery, Bangkok Hospital has successfully completed 200 cases, showcasing its expertise in leveraging state-of-the-art technology to deliver superior patient outcomes. The hospital's strategic vision is to become the robotic hub of Southeast Asia, making advanced surgical treatments more accessible to patients throughout the region at competitive prices.

Merck expands production capabilities for cell culture media with €6.6M investment in China

Merck has announced the start of commercial production of its first Good Manufacturing Practices (GMP) compliant manufacturing line for cell culture media (CCM) in China. The approximate €6.6 million investment at its Life Science Center in Nantong, a major industrial hub in the Yangtze River Delta region in China aims to address the growing local demand for quality custom CCM used in biopharmaceuticals, vaccines, and novel therapeutics.

Commercialisation of the local production line enables Chinese customers to access Merck's well-established custom CCM products and services in a reliable and efficient manner.

Leveraging extensive in-house formulation knowledge, Merck designs robust custom CCM for customers' specific processes and creates innovative solutions that enhance consistency and efficiency of their processes. Applying media components from qualified sources only, the Nantong GMP facility allows for a smooth transition from pilot to commercial-scale cell culture production with comprehensive regulatory documentation.

Taiwan's Bora Pharma buys Emergent BioSolutions' manufacturing site for $30M

The US-based Emergent BioSolutions Inc. has entered into a definitive agreement to sell its drug product facility in Baltimore-Camden to an affiliate of Taiwan's Bora Pharmaceuticals Co., a leading international pharmaceutical services company, for a total value of approximately $30 million. The Camden site, which is a part of Emergent's Contract Development and Manufacturing Organisation (CDMO), has clinical and commercial non-viral aseptic fill/finish services on four fill

lines, including lyophilisation, formulation development, and support services. Alongside the facility, approximately 350 current Emergent employees are expected to join Bora as part of the transaction. This divestiture, combined with Emergent's recently announced strategic operational changes to stabilise its financial position, are key steps to achieving improvement in Emergent's cost structure and performance by streamlining the broader manufacturing network to Lansing, Michigan and Winnipeg, Canada sites. The agreement includes a transfer of assets, equipment, and workforce associated with the Baltimore-Camden facility, and is expected to close in the third quarter of 2024.

AstraZeneca invests Rs 250 Cr to grow Global Innovation and Technology Centre in India

AstraZeneca India has announced an investment of Rs 250 crore ($30 million) to expand its Global Innovation and Technology Centre (GITC) in Chennai, India which includes close to 1,300 roles focused on driving innovation, enhancing efficiency, and streamlining operations across the company globally. The expanded facility was inaugurated in a ceremony officiated by Minister of Industries Tamil Nadu (a southern state of India), Dr T.R.B. Rajaa, British Deputy High Commissioner to India, Christina Scott CMG, AstraZeneca Vice President for Asia Area Sylvia Varela, as well as AstraZeneca's leadership team in India. The investment marks a significant milestone in AstraZeneca's growth story in India as it celebrates its 45th year in the country this month. With the highly skilled roles to be brought in by 2025, the expanded GITC will propel the company's vision to leverage technologies such as enterprise platforms, artificial intelligence, machine learning, data science, and supply chain analytics to shape healthcare outcomes.

Lotte Biologics injects 4.6 Tn won for new plant in South Korea

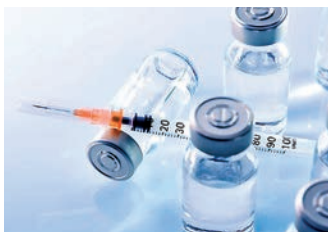
In a landmark event signalling its ambitious foray into the biopharmaceutical sector, Lotte Biologics, under the leadership of CEO Richard W. Lee, held a groundbreaking ceremony for its inaugural plant at the Songdo Bio Campus in Incheon International City, South Korea. This marked a pivotal moment in the company's trajectory towards becoming a global top 10 Contract Development and Manufacturing Organisation (CDMO). Lotte Group is currently expanding its businesses centred around four themes: 'Bio & Wellness,' 'Mobility,' 'Sustainability,' and 'Novel Life Platforms.' The Songdo Bio Campus, a cornerstone of the Bio & Wellness sector, represents an investment of approximately 4.6 trillion won. This state-of-the-art facility, spanning 202,285.2 square metres, is set to house three cutting-edge production plants alongside essential auxiliary buildings. Lotte Engineering & Construction will spearhead the design, procurement, and construction of the first plant, showcasing the group's integrated approach to this transformative project.

Miltenyi Biotec, THSTI collaborate to strengthen R&D in cell and gene therapy

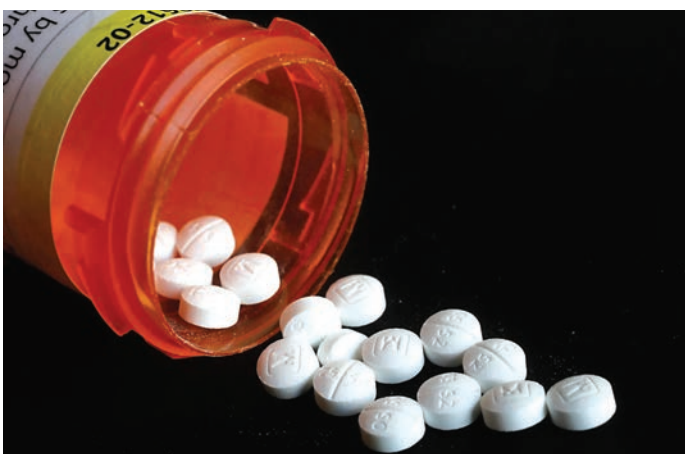
Miltenyi Biotec, a global leader in biomedical solutions, has announced the signing of a Letter of Intent with the Translational Health Science and Technology Institute (THSTI), an autonomous institute of the Department of Biotechnology, Ministry of Science and Technology, Government of India. With this partnership, both organisations aim to address the growing need for innovative treatments in the fight against cancer by developing innovative cell and gene therapies. The purpose of this collaboration is to focus on leveraging the strengths of both organisations to enhance research and development in cell and gene therapy (CGT) focusing on cancer and sickle cell disease. This collaboration would help in capacity building, technology transfer, training programmes, and joint research initiatives which would then be translated into medical therapies.

Mitsubishi to promote Moderna's mRNA respiratory vaccine portfolio in Japan

Moderna, Inc. and Mitsubishi Tanabe Pharma Corporation have entered into a joint agreement regarding the co-promotion of Moderna's mRNA respiratory vaccine portfolio in Japan, including Moderna's COVID-19 vaccine, Spikevax. Under the agreement, Moderna will handle the manufacturing, sales, medical education and distribution of its mRNA respiratory vaccines. Both companies will engage in activities to enable broad access to Moderna's mRNA respiratory portfolio to have the maximum impact on public health in Japan. The agreement has an initial term until March 31, 2029 and no further details on the financial terms of the deal are being disclosed. Mitsubishi Tanabe Pharma has a significant heritage in Japan and has long contributed to public health through numerous vaccines and possesses extensive experience and deep knowledge in this area.



GSK, MVV launch malaria medicine in Brazil and Thailand



GSK plc and Medicines for Malaria Venture (MMV) have announced that the first single-dose medicine for the prevention of relapse of Plasmodium vivax (P. vivax) malaria – tafenoquine, co-administered with chloroquine for radical cure, has now been launched in both Thailand and Brazil, in support of malaria elimination efforts. Tafenoquine is an 8-aminoquinoline, antimalarial drug targeting the liver-stage of P. vivax malaria. When used in combination with chloroquine for the blood-stage infection, tafenoquine provides what is known as radical cure: the treatment of both the blood- and liver-stages of the disease. Tafenoquine, like all 8-aminoquinolines, has the potential to cause acute haemolytic anaemia in people with glucose-6-phosphate dehydrogenase (G6PD) deficiency, therefore a G6PD test must be performed before prescribing. The Ministries of Health in both Thailand and Brazil sponsored feasibility studies on the routine use of tafenoquine after point-of-care G6PD testing within their public health systems, with the support of MMV. Evidence from these real-world studies has informed their decisions to introduce these anti-malarial tools in their drive to help eliminate malaria.

MGI Tech partners with Australian Research Council Training Centre to lead innovation in AMR solutions

MGI Australia, subsidiary of Chinese biotech company MGI Tech Co., has announced its strategic partnership with University of Queensland (UQ) led Centre for Environmental and Agricultural Solutions to Antimicrobial Resistance (CEAStAR) funded by Australian Research Council. This pioneering initiative aims to combat the global crisis of antimicrobial-resistant infections affecting human health, agriculture, and the environment. The World Health Organization (WHO) lists antimicrobial resistance (AMR) among the top 10 threats for global health. Headquartered at UQ's Institute for Molecular Bioscience (IMB), CEAStAR focuses on developing innovative approaches to tackle antimicrobial resistance. Led by Centre Director Professor Mark Blaskovich, CEAStAR emphasises the urgent need for alternatives to antibiotics in agriculture and veterinary medicine, crucially addressing the misuse and overuse of antibiotics globally. MGI's proprietary DNBSEQ technology, renowned for its high accuracy and efficiency in genetic sequencing, plays a pivotal role in CEAStAR's efforts.

Hyundai Bioscience develops multi-treatment drug to treat mosquito-borne viral infections

Korea-based Hyundai Bioscience, which is preparing for a dengue fever basket clinical trial in Brazil, has successfully developed a multi-treatment drug for mosquito-borne viral infections, including dengue fever, using niclosamide as the main ingredient. This treatment, which contains niclosamide as the main active pharmaceutical ingredient, can maintain a blood niclosamide concentration (IC50) to inhibit the proliferation of viruses such as the four serotypes of dengue virus, Zika, Chikungunya, and Yellow Fever, by 50 per cent. To effectively treat dengue fever, the antiviral must be administered early, before the viral load increases significantly. For early administration, the treatment must be effective not only against dengue fever but also against other mosquito-borne viral diseases with similar symptoms, such as Zika, Chikungunya, and Yellow Fever. Leveraging its patented technology, Korean firm Hyundai Bioscience has enhanced the bioavailability of niclosamide, enabling it to treat arbovirus infections caused by Zika, Chikungunya, and Yellow Fever viruses in addition to dengue fever.

Steris announces new ethylene oxide processing facility in Singapore

As part of long-term commitment to supporting global medical device manufacturing, Ireland-based medical equipment company Steris has announced a new ethylene oxide (EO) processing facility in Singapore through a strategic partnership with Tomoe Shokai. The addition of the EO facility to the Steris network complements its existing electron beam, gamma, X-ray, and microbiological testing services in Kuala Ketil, Kulim, Port Klang, and Rawang, Malaysia; Chonburi, Thailand; and Suzhou, China. Additional EO processing capacity in Asia furthers commitment to ensuring patient safety through a technology-neutral service offering that includes radiation and gas processing options, now and well into the future. The addition of EO capacity in Singapore allows for increased technology-neutral processing options in the APAC region and throughout its global network, and allows it to support customers with both routine services and processing redundancy.

NUS Medicine and 22Health Ventures announce joint health tech accelerator in Singapore

The Yong Loo Lin School of Medicine, National University of Singapore (NUS Medicine), and 22Health Ventures, an early-stage healthtech investment firm, have announced their joint accelerator programme, NUS Medicine Digital Advanced Technology Accelerator (DATA), an NUS Medicine – 22Health Ventures partnership. The objective of the Accelerator is to promote the development of promising ideas in digital healthcare and translate these into thriving businesses that elevate personal health and well being. The current scope of the Accelerator involves identifying and developing companies focused on digital health from Singapore and across Southeast Asia.

The Accelerator is focused on sourcing Singapore and Southeast Asian startups, including through hack-a-thons (such as NUS Medicine HealthHack); engaging with participants, in formal and informal sessions, over a 11-week period to allow entrepreneurs needed time to study, learn and evolve; offering workshops and other programmes across a wide range of components, including global entrepreneurship and business building skills, intellectual property, fundraising, business and financial models, market education and legal and regulatory matters.

AIRS Medical secures $20M to advance AI-powered preventive healthcare solutions

AIRS Medical, a pioneering force in artificial intelligence (AI) and robotics for healthcare applications, has announced the completion of its Series C funding round, securing $20 million from seven institutional investors in Korea. The investment, led by BSK Investment and Shinyoung Securities, underscores confidence not only in the company's flagship product, SwiftMR, but also in its larger mission to revolutionise preventive healthcare through technology innovation. SwiftMR uses deep learning technology to enhance magnetic resonance imaging (MRI) scan speeds by as much as 50 per cent compared to the standard of care. On average, radiology centres and hospitals that integrate SwiftMR achieve a 38 per cent increase in patient throughput and a 22 per cent reduction in business hours, leading to $44,000 per month in additional revenue and an $8,000 reduction in monthly operating costs. SwiftMR is a scan time reduction solution with whole pulse-sequence coverage and true super resolution.

Psylo partners with University of Sydney to deliver psychedelic treatments in Australia

The University of Sydney's Brain and Mind Centre has partnered with Psylo, a global biotechnology startup and pioneer in non-hallucinogenic psychedelic drugs, to develop innovative treatments for psychiatric and neurological disorders using advanced artificial intelligence technologies. Researchers at the University of Sydney's School of Psychology have developed machine-learning-guided behavioural analysis technology, which utilises high frame-rate cameras and sophisticated data-parsing techniques to predict the behavioural profiles and potential therapeutic properties of new drugs. Psylo will use this powerful platform, which is exclusively available to them, to enhance the capacity and efficiency of Psylo's drug development. This collaboration comes at a crucial time, as Australia has recently become the first country to allow psilocybin and MDMA (3,4-Methylenedioxy-methamphetamine) to be prescribed for the treatment of depression and post-traumatic stress disorder (PTSD), respectively.

National Cancer Society Malaysia partners with Gene Solutions to expand early detection access

National Cancer Society Malaysia (NCSM) and Singapore-based startup Gene Solutions have announced the signing of a Memorandum of Understanding (MoU) to collaborate on expanding awareness and enabling access to multi-cancer early detection (MCED) testing for the Malaysian population. The MoU marks a significant step forward in the fight against cancer in Malaysia.

By combining NCSM's extensive network and outreach capabilities with Gene Solutions' cutting-edge MCED technology, this collaboration is set to enhance awareness about the importance of early cancer detection and provide accessible testing options to a broader segment of the population. The collaboration will focus on joint initiatives to educate the public about the benefits and availability of MCED testing, emphasising the importance of early detection in improving treatment outcomes; Organising workshops, seminars, and health fairs to reach diverse communities to provide information and resources related to MCED testing; Developing strategies to make MCED tests affordable and accessible, ensuring that more Malaysians can benefit from advanced cancer detection technologies; and Collaborating on projects to gather data on the effectiveness and impact of MCED testing in the Malaysian context, contributing to knowledge and best practices in cancer detection.

SIIC, IIT Kanpur teams up with Boehringer Ingelheim India to support dementia care innovation

The Startup Incubation and Innovation Centre (SIIC) at the Indian Institute of Technology Kanpur (IIT-K) has signed a Memorandum of Understanding (MoU) with Boehringer Ingelheim India, a leading global pharmaceutical company, to advance solutions in the field of dementia care. Boehringer Ingelheim's grant supports Manastik Technologies, a SIIC-incubated startup at IIT Kanpur, in developing India's first tele neurorehabilitation app for dementia care and diagnosis. Using DADT technology, the app offers personalised assistance from doctors and neuro healthcare professionals, addressing the growing burden of dementia and mental health disorders in India. The grant will help validate the app, raise awareness, and support nationwide dementia screening campaigns. Previously, in 2023, Boehringer Ingelheim supported Lenek Technologies, another SIIC-incubated startup, in improving Tuberculosis screening with a handheld X-ray device.

Chinese startup Hasten Biopharma buys 14 products from Celltrion

China-based startup Hasten Biopharmaceutical has successfully acquired the asset rights of 14 branded products across Pan-Asia countries and regions from Celltrion, a Korean biopharmaceutical company. According to the agreement, Hasten will also own the Marketing Authorisation Holder (MAH) rights for these products in 8 countries and regions, including South Korea, Singapore, Thailand, Australia, China Hong Kong S.A.R.

The deal will enrich Hasten's product pipeline across 8 countries and regions outside mainland China, combined with a more qualified global supply chain and a quality management system, which will surely pave the way for access to more high-quality products in the Pan-Asia Area.

WHO prequalifies first self-test for hepatitis C virus

The World Health Organization (WHO) has prequalified the first hepatitis C virus (HCV) self-test which can provide a critical support in expanding access to testing and diagnosis, accelerating global efforts to eliminate hepatitis C. The product, called OraQuick HCV self-test, manufactured by OraSure Technologies, is an extension of the pre-qualified, OraQuick HCV Rapid Antibody Test which was initially prequalified by WHO in 2017 for professional use. The self-test version, specifically designed for use by lay users, provides individuals with a single kit containing the components that are needed to perform the self-test.

The WHO recommended HCV self-testing (HCVST) in 2021, to complement existing HCV testing services in countries. The recommendation was based on evidence demonstrating its ability to increase access to and uptake of services, particularly among people who may not otherwise test. National-level HCVST implementation projects, largely supported by Unitaid, have shown high levels of acceptability and feasibility, as well as empowering people through personal choice, autonomy and access to stigma-free self-care services.

WHO releases first-ever clinical treatment guideline for tobacco cessation in adults

The World Health Organization (WHO) recommends a comprehensive set of tobacco cessation interventions, including behavioural support delivered by health-care providers, digital cessation interventions and pharmacological treatments in a first guideline on tobacco cessation. The guideline focuses on helping the more than 750 million tobacco users who want to quit all forms of tobacco. The recommendations are relevant for all adults seeking to quit various tobacco products, including cigarettes, waterpipes, smokeless tobacco products, cigars, roll-your-own tobacco, and heated tobacco products (HTPs). Over 60 per cent of the world's 1.25 billion tobacco users, more than 750 million people, wish to quit, yet 70 per cent lack access to effective cessation services. This gap exists due to challenges faced by health systems, including resource limitations.

WHO introduces MeDevIS platform to boost access to medical technologies and devices

The World Health Organization (WHO) has introduced an online platform called MeDevIS (Medical Devices Information System), the first global open access clearinghouse for information on medical devices. It is designed to support governments, regulators and users in their decision-making on selection, procurement and use of medical devices for diagnostics, testing and treatment of diseases and health conditions.

The MeDevIS platform includes 2301 types of medical devices used for a broad-ranging health issues, including reproductive, maternal, newborn and child health, noncommunicable diseases such as cancer, cardiovascular diseases, diabetes as well as infectious diseases such as COVID-19. MeDevIS replaces paper-based literature search across multiple publications with non-standard device names which can add to the complexity. Along with providing a single platform, MedevIS also aims to help make the naming of the medical devices simpler. This is the first time WHO has developed such a global repository on medical devices, based on its experience with the WHO Priority Medical Devices List (MDL), which itself was based on the experience of creating the WHO Essential Medicines List (EML).

Namibia unveils national one health plan

The Namibian government in partnership with Africa Centres for Disease Control and Prevention (Africa CDC) has launched a five-year plan on One Health geared to address shared health threats between animals, humans, and the environment. The Tripartite One Health National Strategy 2024–2028 was developed by the Ministries of Health and Social Services, Environment, Forestry and Tourism, and Agriculture, Water and Land Reform in close collaboration with the University of Namibia, the United Nations Foods and Agriculture Organization (FAO), and the World Health Organization (WHO). The Tripartite One Health Strategic Plan is based on a vision to promote healthy ecosystems to minimise the risks and impacts of emerging and re-emerging health threats at the human, animal, plant, and environment interface. Its main goal is to establish and institutionalise a sustainable One Health Approach across all sectors in Namibia, starting at the community level.

PAHO and World Bank launch PROTECT project to strengthen pandemic response in South America

The Pan American Health Organization (PAHO) and the World Bank have launched the PROTECT Project, an initiative to improve pandemic response in seven South American countries. The initiative, funded by a grant from The Pandemic Fund of almost $17 million, will focus on optimising surveillance and laboratory systems in border regions of Bolivia, Brazil, Chile, Colombia, Ecuador, Paraguay, and Uruguay. The PROTECT Project, presented at the PAHO headquarters in Washington, D.C., aims to improve the early detection, characterisation, and response to emerging zoonotic diseases that can trigger a pandemic and will focus on rural and remote communities in the Amazon Basin. These areas face unique challenges, including a biodiversity with high potential for the emergence of pathogens that can drive epidemics or pandemics, such as animal reservoirs or vectors of diseases. Engaging a diverse coalition, PROTECT brings together Ministries of Health and Agriculture, PAHO/WHO, the World Bank, and PAHO's Pan American Foot and Mouth Disease and Veterinary Public Health Center (PANAFTOSA).

South Sudan launches R21 malaria vaccine rollout to protect children

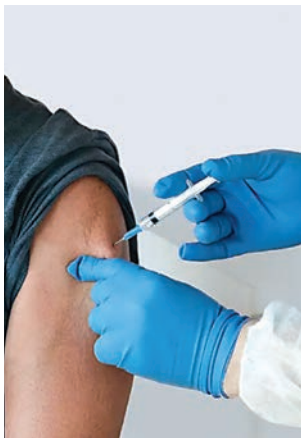
In a historic move to combat the devastating impact of malaria, the Ministry of Health in Sudan in partnership with UNICEF, the World Health Organization (WHO) and Gavi, the Vaccine Alliance (Gavi), has launched the nationwide rollout of the R21 malaria vaccine. This landmark event marks a significant stride in Sudan's efforts to safeguard the health and well-being of its children. The launch follows the arrival of the first consignment of over 645,000 doses of the R21 malaria vaccine in Juba on May 31, 2024. These vaccines will initially be distributed to the 28 counties with the highest malaria burden, with plans to scale up the rollout nationwide. WHO recommends the RTS,S/AS01, and R21/Matrix-M vaccines to prevent malaria in children. The rollout of the RTS,S, and R21 malaria vaccines will ensure an adequate supply to meet demand, significantly benefiting children living in areas where malaria poses a major public health risk.

US FDA permits marketing of first PoC HCV RNA test

The US Food and Drug Administration (FDA) has granted marketing authorisation to Cepheid for the Xpert HCV test and GeneXpert Xpress System, the first hepatitis C virus (HCV) test that can be used to bring diagnosis to appropriately certified point-of-care settings for individuals at risk for hepatitis C. The test may be performed in settings operating under a CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver, such as certain substance use disorder treatment facilities, correctional facilities, syringe service programmes, doctor's offices, emergency departments and urgent care clinics. Rather than requiring a sample to be sent to a central lab for testing, the test detects HCV RNA and delivers results in about an hour using a blood sample from the fingertip. The proposed fiscal year 2025 budget for the Department of Health and Human Services includes a proposed five-year programme to eliminate hepatitis C in the US. The programme aims to significantly expand testing, treatment, prevention and monitoring of hepatitis C infections in the US.

Lack of H5N1 influenza diagnostics undermines global pandemic readiness

Experts at FIND are warning that human cases of H5N1 avian flu could be going undetected because of poor surveillance and a lack of diagnostic testing in at-risk groups. Analysis of the diagnostic landscape reveals extensive diagnostic gaps for this subtype of the influenza A virus, leaving the world with little visibility on the scale or scope of current outbreaks and jeopardising containment measures. To mitigate the risk of an H5N1 pandemic, experts recommend enhancing global surveillance to monitor bird and animal populations to enhance visibility on how H5N1 is moving and potentially mutating. This includes training the workforce, simplifying reporting systems and making sure modern technologies such as artificial intelligence are being employed to enhance our predictive analytics. There is also a need to allocate resources to develop rapid, accurate, and affordable diagnostic tests for highly pathogenic avian influenza including H5N1.



UK announces national RSV vaccination programme

The United Kingdom (UK) will become the first country in the world to have a national programme that uses the same vaccine to protect both newborns and older adults against respiratory syncytial virus (RSV). The rollout, which will start from September 1, 2024 in England, includes a vaccine, developed and produced by Pfizer, for pregnant women over 28 weeks to help protect their newborn babies, a routine programme for those over 75 and a one-off campaign for people aged 75 to 79. These are the groups at the greatest risk from RSV, based on advice from the Joint Committee on Vaccination and Immunisation (JCVI). Wales and Northern Ireland will also start their schemes in September, while Scotland will begin its rollout from August 12.

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Addressing Root Causes of Brain Disorders with Innovative Therapeutics

Neuroscience is a complex market encompassing a range of neurological conditions. Drug research and development for diseases related to the nervous system has always been challenging. While the oncology sector has seen remarkable progress with new therapies, neuroscience has historically lagged in providing effective cures or treatments for symptoms. However, there is now promising progress in understanding the intricate biology of these conditions and identifying new drug targets. A wave of novel late-stage candidates is advancing through the development pipeline, offering hope for treating serious Central Nervous System (CNS) disorders and entering the market. Recent high-profile approvals, such as Eisai's Leqembi for Alzheimer's and Eli Lilly's Kisunla (donanemab-azbt) for the same condition, have significantly bolstered the morale of firms dedicated to developing neurological treatments. The neuroscience sector is suddenly back in action, with pharma companies renewing their interest, spurred by recent US FDA approvals in neurodegenerative diseases like Alzheimer's. This renewed focus has catapulted neuroscience into one of the most sought-after areas. Let's explore the latest developments in detail.

The global CNS disorders market, in 2022, was valued at $116 billion, ranking it as the fourth largest therapy area behind oncology ($189 billion), immunology ($138 billion), and diabetes ($134 billion). Looking ahead, with ongoing improvements in CNS innovation, growth is expected to accelerate. This growth trajectory could potentially expand the CNS market to between $147 billion and $169 billion globally by 2027. In the APAC region, China's CNS market is anticipated to reach $19.9 billion by 2030. Japan, on the other hand, is expected to grow at a rate of 5.5 per cent from 2022 to 2030, according to an IQVIA report.

The report further highlights the rapid advancement of the CNS innovation landscape, with a substantial 31 per cent increase in the pipeline over the past five years. Globally, CNS research now comprises 14 per cent of the overall industry R&D pipeline, positioning it as the second largest therapy area following oncology. Alzheimer's and

Parkinson's diseases alone contribute to 25 per cent of all projects. Rare disorders like Huntington's disease, ALS, and Duchenne muscular dystrophy also hold a significant 14 per cent share, underscoring substantial unmet medical needs. Noteworthy developments include ongoing research into psychedelics-derived treatments for various CNS disorders, alongside emerging cell and gene therapies aimed at achieving disease-reversing or curative effects in neurodegenerative and neuromuscular diseases.

Big pharma has renewed its interest and there has been a flurry of activity in this space. Some significant deals include Bristol Myers Squibb's $14 billion acquisition of Karuna Therapeutics in March 2024. Karuna's lead product, KarXT, is expected

"The development of neurostimulation devices, such as RNS, TMS, and DBS, has made it possible to treat diseases including epilepsy, Parkinson's disease, depression, and chronic pain with minimally invasive or non-invasive methods. By modulating brain activity, these devices greatly enhance patient outcomes and overall quality of life."

- Soo See Ann,
Head Psychologist, Neurowyzr, Singapore

"In the next five years, we can anticipate new drug approvals focused on truly disease-modifying treatments and a shift toward regenerative therapies that address the root causes of these diseases. This evolution holds the promise of more effective treatments and better quality of life for individuals affected by neurological disorders."

- Dr Stella Sarraf,
Founder & CEO, Spinogenix, USA

to launch in late 2024 in the US as a treatment for schizophrenia in adults. In the same month, Boehringer Ingelheim and Sosei Heptares joined forces to develop first-in-class treatments targeting all symptoms of schizophrenia.

In 2023, AbbVie acquired Cerevel Therapeutics for $8.7 billion, bolstering its neuroscience pipeline with candidates for schizophrenia, Parkinson's disease (PD), and mood disorders. Also in 2023, Novartis spent $500 million to acquire DtX Pharma, enhancing its neuroscience capabilities. Additionally, Otsuka Pharmaceuticals acquired Mindset Pharma for CAD 80 million to strengthen its pipeline in neurological disorders. Pfizer's $11.6 billion acquisition of Biohaven, announced in 2022, was also a significant deal in this space.

The APAC scenario

In the Asia Pacific (APAC) region, several CNS drugs are progressing through clinical trials, with a strong emphasis on pain, depression, schizophrenia, and epilepsy treatments. Notably, APAC leads in conducting clinical trials for anxiety, bipolar disorder, depression, epilepsy, migraine, and schizophrenia compared to other regions.

Japanese drug makers are at the forefront of regional CNS development, with Eisai Co., Ltd. securing multiple approvals in the field. These include Eisai's Aricept and Leqembi for Alzheimer's disease, and Fycompa for epilepsy. Otsuka Holdings has also made significant strides with Abilify and Rexulti for treating schizophrenia and depression, respectively. Additionally, Takeda has successfully commercialised Azilect (developed by Teva Pharmaceuticals) for Parkinson's disease, and Trintellix (developed by H. Lundbeck A/S) for major depressive disorder in Japan.

The pharma majors also have a substantial

"A significant advancement in neurological disorder therapeutics has been the development of anti-amyloid mAbs as disease-modifying treatments for AD. The approval of aducanumab in 2021 ended a 17-year period during which no new AD therapeutics were approved."

- Clíona MacSweeney,
Neuroscience Program Leader, Nxera Pharma, England

pipeline, indicating that they will likely continue to play a prominent role in neurology. Eisai's robust pipeline features the E2814 anti-MTBR tau antibody for Alzheimer's disease in phase II/III, while Takeda progresses soticlestat in phase III, and Otsuka advances ulotaront in phase II/III, all aimed at various neurological conditions. In 2023, the Japanese government through the Ministry of Education, Culture, Sports, Science and Technology (MEXT) also initiated a brain and neuroscience integration programme with a budget of 9.3 billion yen. This programme aims to develop therapeutic drugs for dementia.

Advancements in CNS drug development

Monoclonal Antibodies (mAB)

Monoclonal antibodies lead the way in CNS drug development, with three approved treatments—aducanumab (Aduhelm; Eisai/Biogen), lecanemab (Leqembi; Eisai), and donanemab (Eli Lilly)—for Alzheimer's disease.

"A significant advancement in neurological disorder therapeutics has been the development of anti-amyloid monoclonal antibodies (mAbs) as disease-modifying treatments for Alzheimer's disease. The approval of aducanumab in 2021 ended a 17 year period during which no new AD therapeutics were approved. Along with the more recently approved agents lecanemab and donanemab, these mAbs act through the targeting and removal of Aβ plaques, lowering the amyloid burden within the brain and reducing clinical decline by approximately 30 per cent. This effect is clinically meaningful in terms of extended time spent in the mild phase of the disease, therefore improving quality of life for patients and carers," said Clíona MacSweeney, Neuroscience Program Leader at Nxera Pharma.

Japan-based Nxera Pharma, formerly known as Sosei Heptares, has a robust pipeline of candidates for neurological disorders, including schizophrenia.

"CRISPR-Cas9 and other gene editing technologies are being investigated for their potential to treat neurological diseases at the genetic level. These technologies offer precise modifications to the genes that cause disease in conditions like Huntington's disease, ALS, and some types of epilepsy."

- Nav Vij,
Chief Neuroscientist, Neurowyzr, Singapore

"It is important to recognise the contributing factor from recent technological advancements in areas such as gene therapy, personalised medicine, and digital health technologies, for example, that have led to improved diagnosis, as well as unlocking the discovery of newer therapeutic approaches."

- Dr Bob Dagher,
Executive Vice President & CMO,
BrainStorm Cell Therapeutics, USA

The company has also forged partnerships with big pharma firms such as AbbVie and Boehringer Ingelheim.

Further mAbs continue to be developed, with Roche reporting that its mAb trontinemab virtually abolished plaque in three months in a small dose-finding study. In June 2024, Roche also announced positive results from phase II clinical trials for the mAb prasinezumab, showing promise in slowing the rapid progression of parkinson's disease.

Immunotherapies

Immunotherapy is proving to be useful in treating neurological conditions like Parkinson's disease and Alzheimer's disease.

"Immunotherapies are also being developed for Parkinson's disease and a promising novel approach is Roche/Prothena's mAb, prasinezumab, which is directed against aggregated α-synuclein. If approved, prasinezumab is estimated to generate global sales of $2.1 billion by 2029, leading the Parkinson's disease market and reflecting the high unmet medical need for disease-modifying approaches," said Clíona.

Several companies are advancing immunotherapies for CNS disorders. For instance, in June 2024, Vaxxinity announced successful completion of phase I goals in patients with Parkinson's disease using its immunotherapy.

Furthermore, Takeda Pharmaceutical has secured an option for an Alzheimer's disease immunotherapy developed by AC Immune. AC Immune is expected to release its first phase II data soon.

Neurostimulation therapies

"The development of neurostimulation devices, such as responsive neurostimulation (RNS), transcranial magnetic stimulation (TMS), and deep brain stimulation (DBS), has made it possible to treat diseases including epilepsy, Parkinson's disease, depression, and chronic pain with minimally invasive or non-invasive methods. By modulating brain activity, these devices greatly enhance patient outcomes and overall quality of life," said Soo See Ann, Head Psychologist, Neurowyzr, Singapore.

Built on clinical evidence and powered by advanced analytics and AI, Neurowyzr provides a complete suite of gamified digital assessments and omni-platform care to bring brain health and mental wellbeing to everyone.

There have been several significant developments in this field. The University of Melbourne researchers have pioneered a technique to personalise TMS treatment for depression, potentially improving outcomes for Australian patients. Their research has identified specific brain pathways involved in depression, leading to the development of new methods that allow precise targeting of these brain circuits with TMS therapy.

Singaporean researchers have also initiated a groundbreaking approach to combat treatment-resistant depression. This pilot programme focuses on personalised TMS therapy, offering hope to individuals grappling with mental health conditions.

Headquartered in Israel, BrainsWay specialises in cutting-edge noninvasive neurostimulation therapies for mental health conditions, advancing neuroscience through its proprietary Deep Transcranial Magnetic Stimulation (Deep TMS) platform technology. The company is recognised as the pioneer and sole TMS provider with three FDA-cleared indications, backed by pivotal clinical trials that validate its effectiveness in treating major depressive disorder, including anxiety symptom reduction, obsessive-compulsive disorder, and smoking addiction. In 2023, BrainsWay announced the broadened accessibility of its Deep TMS technology in Taiwan.

Similarly, NeuroSigma, a US-based company, is leveraging eTNS technology to address neurological

"Despite advancements, disorders of CNS continue to be difficult to treat and represent one of the largest unmet needs in healthcare"

« **Dr Colin Kealey,** President & CEO, NeuroSigma, USA

US-based NeuroSigma utilises external Trigeminal Nerve Stimulation (eTNS) technology to treat neurological and neuropsychiatric disorders. The company is currently commercialising its lead product, Monarch eTNS System, the first non-pharmaceutical treatment for paediatric Attention-deficit/hyperactivity disorder (ADHD) cleared by the U.S. Food and Drug Administration (FDA). In September 2023, the firm established its first foreign subsidiary, NeuroSigma Pte Ltd, a Singapore corporation (NeuroSigma Singapore). Dr Colin Kealey, President & CEO of NeuroSigma, Inc., shares insights into the company, importance of APAC region for Monarch eTNS System, advancements in neurological disorder treatments, etc. ***Edited excerpts:***

Can you tell us about NeuroSigma?

NeuroSigma is a Los Angeles, California-based bioelectronic medical device company developing technologies to transform medical practice and patients' lives. The company's lead product is the Monarch eTNS System, which is the first non-drug treatment for paediatric ADHD cleared by the FDA. Pipeline indications for the Monarch include neurodevelopmental disorders such as Autism Spectrum Disorder (ASD), learning disabilities, and epilepsy. The Monarch is a wearable, home-use medical device with a daily disposable that is prescribed like a pharmaceutical. NeuroSigma is currently preparing to launch Monarch 2.0, which is the second generation version of its Monarch eTNS System.

How do you anticipate the FDA clearance of Monarch 2.0 will impact NeuroSigma's position in the market, and what steps are you taking to ensure widespread adoption of this device?

NeuroSigma's Monarch 2.0 will fuel the company's next leg of growth by providing a scalable platform for eTNS that can be deployed worldwide. Our strategy is to partner with CNS-focused pharmaceutical and device companies outside the United States, who can leverage their existing salesforce to quickly

and neuropsychiatric disorders. The company's Monarch eTNS System, approved by the US FDA as the first non-pharmaceutical treatment for paediatric ADHD. NeuroSigma recently expanded into Singapore, recognising Asia as a pivotal market for its neurostimulation therapies.

Gene Therapies

Gene therapy is one of the most important scientific advances; Novartis' Onasemnogene abeparvovec (Zolgensma), a treatment for spinal muscular atrophy (SMA), is one example. When a disorder's underlying genetic cause is corrected, gene therapy may be able to treat it once and produce long-term advantages, possibly even curing the condition.

"Similar to this, CRISPR-Cas9 and other gene editing technologies are being investigated for their potential to treat neurological diseases at the genetic level. These technologies offer precise modifications to the genes that cause disease in conditions like Huntington's disease, Amyotrophic lateral sclerosis (ALS), and some types of epilepsy," said Nav Vij, Chief Neuroscientist, Neurowyzr.

Swiss drugmaker Roche is set to collaborate with American biotech Ascidian Therapeutics to develop gene therapies targeting challenging neurological diseases. In a separate initiative, several biotechs including China-based startup Cure Genetics and Frametact, founded by a molecular neuroscience research team at The Hong Kong University of Science and Technology and Hong Kong Center for Neurodegenerative Diseases, have joined forces through a collaborative development and licensing agreement. This partnership will harness Cure Genetics' proprietary VELP platform to innovate Adeno-Associated Virus (AAV) vectors aimed at treating familial neurological diseases.

deploy the Monarch. In parallel, NeuroSigma will take responsibility for the U.S. market and continued clinical development in ADHD and our pipeline indications. We believe this strategy will position us as the global leader in treatment of paediatric neurodevelopmental disorders.

With the establishment of a subsidiary in Singapore, what are your strategic goals for expanding into international markets, and how do you plan to address the unique challenges and opportunities in these regions?

Singapore has established a reputation as a scientific thought leader and first adopter of new technologies. When this is combined with its business-friendly environment and strategic location for easy access to southeast Asia, Singapore became the logical choice for NeuroSigma to base operations in this part of the world. Our strategy is to work with Singapore's scientific and clinical leaders in the treatment of paediatric neurodevelopmental disorders to demonstrate the value of our product prior to expanding to other countries in the region.

What are the current trends in the treatment of neurological disorders, particularly ADHD, and how does NeuroSigma plan to stay ahead in this rapidly evolving market?

Over the past 75 years there have been remarkable advancements in humanity's understanding of biology and medicine on a molecular level. This has facilitated an explosion of pharmaceutical treatments that have improved health and increased life spans worldwide. Despite these advancements, disorders of the central nervous system (CNS) continue to be difficult to treat and currently represent one of the largest unmet needs in healthcare.

In parallel with the advancements described above, our ability to record, understand, and manipulate electrical activity in the CNS has improved exponentially, particularly over the past 20 years. At a fundamental level, the brain is an electrical network and the way that network functions changes as we age and as we experience various disorders and conditions. NeuroSigma views the future of treating CNS disorders as a combination of electromagnetic and pharmaceutical interventions where quantitative biomarkers of brain activity are used to diagnose and monitor these conditions.

NeuroSigma's Monarch is at the cutting edge of this trend because we have identified certain brain biomarkers that respond to eTNS therapy and have correlated those changes to clinical outcome. In the future, we envision more advanced technologies that combine AI-based treatment algorithms with real-time feedback and adjustment of stimulation to achieve a desired therapeutic effect.

Any other thing that you would like to add.

NeuroSigma views Singapore and countries throughout Asia as key to global adoption of eTNS therapy. We are open to partnerships throughout the region, and look forward to bringing this unique and important therapy to the patients and families who will benefit from the Monarch. BS

Meanwhile, Australia-based Celosia Therapeutics is employing gene therapies to address motor neuron disease (MND), epilepsy, and Alzheimer's disease, capitalising on advancements in gene therapy techniques and enhanced understanding of molecular pathways implicated in neurodegenerative conditions.

Psychedelics

Research into psychedelics-derived therapeutics has gained significant momentum in recent years. Clarivate data shows more than 270 psychedelic drugs currently in various stages of development. These treatments are primarily focused on mental health and addiction conditions, including depression, eating disorders, post-traumatic stress disorder, and alcoholism.

Several startups have mushroomed to tackle this trend, with venture capitalists also showing strong interest. Groups aiming to harness mind-altering substances such as MDMA, psilocybin mushrooms, and 5-MeO-DMT—a hallucinogen found in desert toad secretions—raised at least $163 million across five deals in January 2024, according to PitchBook and company data.

In APAC, Australia is at the forefront of this movement, with several biotechs securing significant funding. In April 2024, Seaport Therapeutics received $100 million for developing neuropsychiatric medicines. In 2023, Psychae Therapeutics secured a $4.5 million syndicated investment to explore medical-grade, botanically derived treatments and psychedelic-assisted therapies targeting serious mental health challenges like post-traumatic stress disorder (PTSD), anxiety, and addiction. Australia has also become the first country globally to permit doctors to prescribe drugs like psilocybin and MDMA for treating psychiatric conditions such as depression and PTSD.

Leading biotech companies in APAC

Singapore-based TauRx Pharmaceutical is a global leader in Tau-based research in Alzheimer's disease (AD). Its lead product, hydromethylthionine mesylate (HMTM), has shown positive results in various phase III results and the firm is seeking regulatory approval in various markets.

Cerecin is a Singapore-based clinical-stage biotechnology company focused on developing drugs that target the metabolic bases of central nervous system diseases. Cerecin's lead compound, CER-0001, is being developed for migraine, Alzheimer's disease and epilepsy. CER-0001 is entering phase III trials for mild to moderate Alzheimer's.

South Korea's AriBio is leading with its candidate AR1001, a small molecule featuring polypharmacological properties, showing promise for AD treatment. A Phase III programme is currently underway for early AD patients. In April 2023, AriBio was selected by the Ministry of Health and Welfare for the Electronic Drug Technology Development Project, which aims to utilise 'vibroacoustic stimulation' and gamma wave synchronisation for AD treatment.

Japan-based Nxera Pharma, formerly known as Sosei Heptares, has a robust pipeline of candidates for neurological disorders, including schizophrenia. The company has also forged partnerships with big pharma firms such as AbbVie and Boehringer Ingelheim.

China-based SciNeuro Pharmaceuticals has an established pipeline of novel therapeutic candidates to address neurodegenerative and other CNS diseases. In 2022, SciNeuro Pharmaceuticals (SciNeuro), a leader in CNS disease therapeutics, signed an exclusive global licence and option agreement with GlaxoSmithKline (GSK). The agreement targets inhibitors of Lp-PLA2, an enzyme linked to neurodegenerative diseases. Clinical data suggests these inhibitors could enhance cognitive function in Alzheimer's disease patients.

Disease Prevalence in APAC

Neurological disorders were the leading cause of disability-adjusted life-years (DALYs) and the second leading cause of deaths in Asia in 2019. The burden is expected to increase with the region's population growth and ageing demographics. The most burdensome neurological disorders in Asia by the absolute number of DALY's were stroke, migraine, and Alzheimer's disease (AD) and other dementias, according to a paper in Neurology.

Psychedelic-based startups are poised to see a continued influx of capital. According to a report by the Financial Times, Singapore's $300 billion investment fund Temasek and the venture capital arm of one of Abu Dhabi's largest sovereign investors, Mubadala, have engaged in discussions with biotechs to fund the development of psychedelic mental health treatments and clinics. This initiative reflects growing interest and investment in innovative therapies for mental health utilising psychedelic compounds.

Digital therapeutics

As with everything else, technology also holds promise in treating neurological disorders.

"Artificial intelligence (AI) and digital medicines are also revolutionising the treatment of neurological disorders. Incorporating digital or AI-based cognitive intervention allows for precision medicine. Technology can improve patient compliance to treatment through tailored treatment programmes. Novel approaches to medication administration, like liposomes, intranasal delivery, and nanoparticles, increase the effectiveness and targeting of neurological treatments while lowering side effects and improving therapeutic results," said Soo See Ann.

Big pharma is also exploring combinations of DTx with pharmacotherapeutics. In 2020, Boehringer Ingelheim secured exclusive rights to Click's CT-155, a digital therapeutic for schizophrenia. In 2022, the companies expanded their collaboration further for the development and commercialisation of a second prescription-based digital therapeutic (PDT). They will work together to create a novel mobile application that integrates multiple clinically validated therapeutic interventions. This application aims to be used independently or in conjunction with pharmaceutical therapy to improve clinical outcomes for individuals with schizophrenia. In the same year, Biogen and MedRhythms entered a licensing agreement to develop and commercialise MR-004, an investigational prescription digital therapeutic aimed at treating gait deficits in multiple sclerosis (MS).

Meanwhile, NERVTEX, a Chinese company specialising in digital therapeutics for brain disorders, secured approval from the China National Medical Products Administration in February 2023 for its AI-powered movement disorder analysis software.

South Korea is also bullish on digital treatments for depression, with the Ministry of Science and Information and Communications Technology planning a 30 billion won ($26.2 million) investment in a research programme for this purpose.

“We’re facing a significant challenge with an unmet need for medical professionals due to the growing and ageing population”

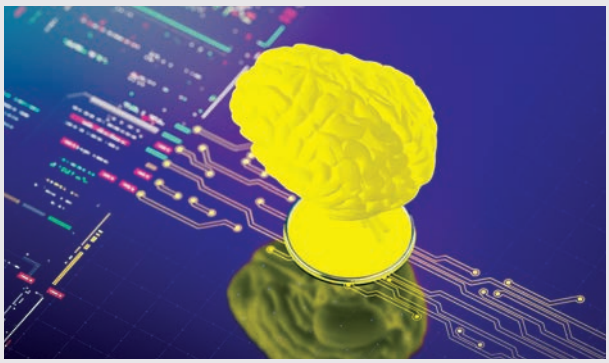
The Sydney Neuroimaging Analysis Centre (SNAC) is using artificial intelligence (AI) to better monitor brain diseases. iQ-Solutions, SNAC’s flagship product, provides precise analysis of the brain through MRI imaging. It gives doctors a real-time view of any changes that can then be managed more readily. The firm received funding from the Australian government in July 2024 to commercialise iQ-Solutions. Dr Tim Wang, Director of Operations at SNAC, discusses the profound impact of this advancement and digital health technologies in general. ***Edited excerpts:***

« **Dr Tim Wang,** Director of Operations, The Sydney Neuroimaging Analysis Centre (SNAC), Australia

How does your flagship product iQ-Solutions leverage AI to provide analysis of the brain?

IQ stands for intelligent quantification. It provides robust, quantitative analysis of brain structures from MRI images, delivering personalised monitoring and precision management for people with chronic neurological diseases. With iQ-solutions, both radiologists and physicians can accurately assess changes in a patient’s brain structure. For example, changes in the volume and location of ‘lesions’ in multiple sclerosis and cerebrovascular disease; and regional brain volume changes in Alzheimer's, dementia and other neurodegenerative diseases can be rapidly assessed, guiding management strategy and providing a quantitative evaluation of treatment response.

Another comparison that may help is how we go to a hospital to take a blood test and receive a report with various metrics that doctors use for diagnosis, monitoring disease progression, and evaluating treatment outcomes. Similarly, we analyse MRI scans using AI to obtain accurate and robust metrics of brain structures that are highly relevant to various neurological diseases and present the measurement to treating physicians to assist clinical management.



What specific goals and projects will the recent government funding support?

This project will support our commercialisation and rollout of IQ solutions across different jurisdictions. Currently, IQ-Solutions is TGA and FDA-approved. We are in the process of obtaining approval from other regions.

How do you see digital health technologies transforming the health system in the coming years, and what are your plans for further innovation and integration in the field of neuroimaging?

Digital health technologies, particularly AI-powered tools like IQ-Solutions, are positioned to play a transformative role in healthcare over the coming years. One of the primary objectives of these technologies is to enhance productivity and accuracy in medical practice.

We are facing a significant challenge with an unmet need for medical professionals due to the growing and ageing population. The rate at which new doctors are entering the workforce is not keeping pace with the increasing demand driven by these demographic changes. This gap is expected to widen, placing additional strain on healthcare systems worldwide.

AI and other digital tools offer a viable solution to this problem by assisting doctors in their work. These technologies can improve productivity by automating routine tasks, providing decision support, and enhancing diagnostic accuracy and efficiency. ultimately improving the quality of care delivered. BS

Uphill Task of Finding and Retaining Alzheimer's Study Participants

Cara Brant,
CEO,
Clinical Trial Media

The US Food and Drug Administration (FDA) has just approved the second drug in the past two years that's currently on the market for slowing the progression and impact of Alzheimer's Disease.

With each of these breakthroughs has come new energy and excitement around Alzheimer's research, resulting in a pipeline of nearly 200 clinical trials dedicated to testing new approaches. Each of these trials has an average of 150 candidates.

Which begs the question: Where are all the patients coming from? And how do we find more to fuel continued innovation in this space?

Here's a quick look at some of the recruiting challenges pharmaceutical companies face, how they can find new patients, and a tip for getting them to stay for the long haul.

Alzheimer's studies come with challenges

Alzheimer's is a notoriously difficult space to recruit for, and it's only getting tougher as more drugmakers seek participants. Fortunately, patients and their families are motivated to get involved.

But willingness is only half the battle. The strict and stringent requirements of Alzheimer's trials mean that not every person who wants to participate can. For instance, a patient with mild Alzheimer's might seem ideal at first, only to be disqualified based on their age or the existence of another health condition.

And, participants enrolled in Alzheimer's trials may require a partner throughout the trial, either a full-time caregiver for those living with progressed Alzheimer's or just a secondary person to attend visits for those with early memory loss. Because of this, enrolling a patient into a trial often comes with the added challenge of making sure that factors like location, scheduling and transportation work for participants' partners, too.

Finding new participant sources

With numerous clinical trials being conducted simultaneously, pharmaceutical companies are often dipping into limited patient pools from sites to find participants, but this doesn't need to be the case.

It's important to remember that only a small fraction of possible participants have already been identified or raised their hand to be contacted for trials. In the US alone, there are over 6.5 million people who have Alzheimer's disease–and there are millions more across the globe. Many of these people may qualify for trials but don't know how to get involved or what trials are available.

To reach these populations, social media and digital advertising can help reach people where they spend most of their time, even for older adults. Identifying partnerships with non-profit and advocacy organisations is another way to reach potential participants since these organisations can provide members with information about the latest available trials and how they can participate. This means going beyond simply targeting ads at populations within 10 miles of the trial site who meet the trial age criteria, which to be fair, isn't a bad place to start.

Retention often relies on the human touch

While new technologies are increasingly being deployed to identify and screen potential participants, keeping participants engaged and informed throughout trials calls for a human touch. The degenerative nature of Alzheimer's can result in frustration or confusion, especially as patients engage with a new trial site and physician they aren't familiar with. At Clinical Trial Media, we're addressing this issue with the hiring of 50 on-staff nurses who work hand in hand with patients to explain trial requirements, set expectations and work with them every step of the study to keep them on track. Navigating the nuances of Alzheimer's trials often comes down to using what you know about the potential challenges and pitfalls to create workarounds. Everyone's going to one pool of patients to identify participants? Find or create other sources of candidates. Patients dropping out mid-trial because they can't keep up with the logistics? Create additional touchpoints to offer support or answer questions beyond what the trial site offers. Through a mix of technology, personalised care and critical thinking, we can continue bringing even more Alzheimer's treatments to market. BS

Driving forces and future prospects

The key factors driving growth in the neurological disorder therapeutics market are factors such as ageing population, rising prevalence of neurological disorders, healthcare expenditure, advancements in digital screening and diagnostic tools, neuroimaging and genetic research, expanding digital therapeutic options and growing awareness among the public about neurological conditions.

"It is important to recognise the contributing factor from recent technological advancements in areas such as gene therapy, personalised medicine, and digital health technologies, for example, that have led to improved diagnosis, as well as unlocking the discovery of newer therapeutic approaches. Another contributing factor is the heightened focus placed on finding truly disease-modifying therapies, that target the underlying mechanisms of neurological disorders, and that can make a real difference in slowing the disease progression in these chronic, life-long, conditions. Finally, an important additional factor has to do with the rise in investments in research and development enterprises, with increased funding and research initiatives for developing novel neurological biomarkers and therapeutics," said Dr Bob Dagher, Executive Vice President & Chief Medical Officer, BrainStorm Cell Therapeutics, USA. BrainStorm Cell Therapeutics is a leading developer of innovative autologous adult stem cell therapeutics for debilitating neurodegenerative diseases.

Additionally, advancements in innovative therapies and expanded screening programmes aim to detect these disorders at earlier stages, improving treatment outcomes. Public and professional awareness has also improved, facilitating earlier diagnosis and intervention.

"Data are emerging which may allow the use of blood based biomarkers (BBMs) for diagnosis in primary care, increasing the number of people eligible for novel treatments for early Alzheimer's disease. In addition to their use in primary care, the use of BBMs in clinical trials will facilitate patient recruitment and improve trial quality by confirming the presence of the target disease. Importantly, it will reduce the cost of clinical trials and contribute to increased investment from smaller biotechs looking to develop drugs for neurological disorders," said Clíona.

While the majority of treatments available today focus on disease-modifying therapies, experts are hopeful that in the future we will have targeted therapies.

"In the next five years, we can anticipate new

drug approvals focused on truly disease-modifying treatments and a shift toward regenerative therapies that address the root causes of these diseases. This evolution in the therapeutic landscape holds the promise of more effective treatments and better quality of life for individuals affected by neurological disorders," said Dr Stella Sarraf, Founder & CEO, Spinogenix, USA.

Spinogenix has developed a platform of novel small molecules known for their unique ability to regenerate synapses. The company aims to reverse declines in cognitive and motor function associated with conditions such as ALS, Alzheimer's disease, and schizophrenia, targeting the root causes of these debilitating disorders. Currently, Spinogenix is advancing phase II clinical trials in Australia and the US to evaluate their lead synapse-regenerating small molecule, SPG302. This molecule is being studied for its potential in treating ALS patients, with an additional phase II trial underway in Australia focusing on Alzheimer's disease.

Although CNS drug development poses challenges, it also holds significant promise. Long-term epidemiological trends, such as increasing disease burdens and gaps in effective treatments for many CNS disorders, create opportunities for profitability, just as Deloitte expects the market to be worth $60 billion in future. BS

Ayesha Siddiqui

AI Breathes New Life into Respiratory Disease Diagnosis

Artificial Intelligence (AI) has already integrated into conventional medical imaging and is now poised to revolutionise the diagnosis of respiratory diseases, which affect millions worldwide. These advancements include analysing chest scans, interpreting sound patterns, etc. thereby simplifying and improving the precision of diagnostic procedures. Let's delve into this in detail.

Respiratory diseases are major contributors to global mortality and disability. Chronic obstructive pulmonary disease (COPD) affects approximately 200 million people worldwide, causing 3.2 million deaths annually, ranking it third globally. Asthma impacts over 350 million individuals, predominately in childhood. Pneumonia claims over 2.4 million lives annually, with high mortality among young children and older adults. Tuberculosis (TB) affects over 10 million annually, resulting in 1.4 million deaths. Lung cancer leads to 1.8 million deaths annually. In 2019, respiratory diseases were among the top 10 global causes of death, claiming over 8 million lives, with South Asia experiencing the highest mortality from chronic respiratory conditions, according to reports from Forum of International Respiratory Societies.

Besides the top five respiratory diseases - COPD, asthma, acute lower respiratory tract infections, TB, and lung cancer, several other respiratory disorders carry significant burdens, including pulmonary hypertension, sleep-disordered breathing, and occupational lung diseases.

Majority of the patients with chronic respiratory conditions remain undiagnosed unfortunately. The current test for conditions like COPD and asthma is spirometry, an archaic technology that is difficult to access, unpleasant for patients, and frequently inaccurate. Also, many of these conditions present overlapping symptoms, making accurate diagnosis challenging and delaying timely treatment. Consequently, patient outcomes suffer while healthcare costs continue to rise. Early initiation of treatment is crucial for lung conditions like asthma and COPD, as effective management reduces symptoms and hospital visits, including emergency admissions. Premature mortality rates from these diseases are highest in regions with less-resourced health systems per capita.

AI, which has already made significant strides in diagnosing cancer and other diseases, also holds promise for revolutionising the speed and accuracy of respiratory disease diagnoses and presents a compelling solution to these issues. By leveraging advanced algorithms, AI can streamline and enhance the precision of respiratory disease diagnosis.

Role of AI in Lung Disease Diagnosis

AI is transforming respiratory disease diagnosis by improving accuracy, streamlining workflows, and enhancing patient outcomes through faster and more precise diagnostics.

"AI and advanced technologies have immense potential to revolutionise lung-related health issues. These innovations analyse vast amounts of data with high precision, identifying patterns that streamline healthcare professionals' work, and extend their reach beyond the clinic, especially with remote patient monitors," said Adrian Ang, co-founder and CEO, Aevice Health, Singapore.

"AI-driven technologies also expedite the diagnostic process. Diagnosing diseases like asthma often involves observing patients' responses to medications, which are typically recounted during follow-ups and can be subjective. Devices like AeviceMD enable healthcare professionals to objectively track patients' responses to treatment, significantly speeding up the diagnostic process," Adrian added.

AI is becoming pivotal in diagnosing challenging diseases like idiopathic pulmonary fibrosis (IPF), a potentially fatal lung condition causing scarring. Early diagnostic methods for IPF have been eagerly awaited by doctors, as there are currently no established therapies beyond drugs that can delay its progression. Due to the complexities in diagnosis, specialists are often consulted, and invasive techniques like lung biopsy pose risks of exacerbating the disease and increasing mortality.

A research group at Nagoya University has developed an AI algorithm that swiftly and accurately diagnoses IPF using non-invasive data from lung images and routine medical information. This advancement represents a significant step toward

improving diagnostic precision and patient care in managing IPF.

AI-Powered Imaging Analysis

In pulmonary imaging, AI algorithms and machine learning techniques have shown promising results in automating image analysis, detecting abnormalities, and predicting disease prognosis.

Several firms have developed solutions utilising deep learning and AI to conduct real-time screening of medical images for radiologists and hospitals, with South Korea-based Lunit leading the way. Their Lunit FDA approved INSIGHT CXR is an AI-powered chest X-ray analysis solution capable of detecting 10 common lung abnormalities, including lung cancer and pneumonia. Lunit INSIGHT CXR has shown superior performance in multi-center studies, achieving the highest Area Under the Curve (AUC) and transforming global lung screening practices in markets such as Singapore, Saudi Arabia, Taiwan, and France.

Australian medical imaging AI company Annalise.ai has developed Annalise CXR, its flagship AI solution for interpreting chest x-ray studies. This comprehensive tool detects 124 findings, providing clinicians with additional diagnostic support and assurance. Annalise CXR is currently available for clinical use across Australia, New Zealand, the EU, the UK, India, ASEAN, the UAE, and expanding further. Meanwhile, 4DMedical, another Australian innovator, is pioneering non-invasive, quantitative analysis of lung function through their software and hardware products. Their technology sets a new standard in imaging and analysis for lung disorders such as unexplained dyspnea, asthma, COPD, cystic fibrosis, and cancer, advancing diagnostic capabilities and treatment outcomes.

India-based Qure.ai, which in June 2024 received investment from Merck Global Health Innovation Fund, provides FDA-approved solutions for diagnosing lung-related diseases. Their flagship product, qXR, employs AI to interpret chest X-rays, enabling the identification of lung cancer and other conditions with accuracy. Qure.ai also offers qTrack, an AI-powered platform designed for tuberculosis care management. This platform supports screening programmes and enhances case management through advanced technological solutions, contributing significantly to improved healthcare outcomes in respiratory health. Another Indian startup Dectrocel Healthcare has developed a platform in which digital and analogue chest X-Ray images and pictures of children are uploaded and, in a few minutes, the algorithm is able to diagnose respiratory abnormalities.

"AI and advanced technologies have immense potential to revolutionise lung-related health issues. These innovations analyse vast amounts of data with high precision, identifying patterns that streamline healthcare professionals' work, and extend their reach beyond the clinic, especially with remote patient monitors."

- Adrian Ang,
co-founder and CEO, Aevice Health, Singapore

"We've seen a lot of sensationalistic headlines about 'replacing doctors' or such things. On the other hand, sceptics see it all as snakeoil. The reality is somewhat different. AI is most valuable as a complement, as a tool completing tasks that add new value into the process."

- Dr Josh Reicher,
co-founder and CEO of IMVARIA, USA

"While AI shows great promise, it's important to note some challenges. The need for large, diverse datasets to train AI models effectively, ensuring AI algorithms work consistently across different populations and healthcare settings, and maintaining patient privacy and data security are some of the challenges."

- Brandon Suh,
CEO, Lunit, South Korea

"Very soon AI could identify individuals within populations who are at highest risk of developing chronic respiratory diseases, such as COPD, allowing for targeted preventive diagnosis. This could ensure faster access to appropriate treatments and medications, which is critical for improving outcomes in respiratory conditions."

- Dr Ameera Patel,
CEO, TidalSense, UK

"In lung disease we have lung function tests, CT scans, blood biomarkers, breathing monitors, all sorts of data to work with. And we have multi-year delays in diagnosis common in lung diseases! AI helps both with depth and breadth here, better analysing the tiny minutiae in these data elements, but also combining them in ways that are otherwise irrelevant. This means we can both do a better job diagnosing patients and doing it consistently and effectively," said Dr Josh Reicher, co-founder and CEO of IMVARIA, USA.

Diagnosis through sound

Cough is an early symptom associated with various pulmonary diseases and serves as a marker for tracking the progression of respiratory conditions and infections. Since COVID-19, there has been heightened interest in analysing cough patterns to differentiate between COVID-19 and other types of coughs. Machine Learning (ML) algorithms enable AI systems to learn and recognise distinctive patterns in lung sounds, aiding in the early detection and diagnosis of specific diseases.

The Australian company ResApp Health has been working on acoustic diagnosis of respiratory diseases since 2014, well before the pandemic. With the emergence of COVID-19, the company shifted its focus and developed an audio-based COVID-19 screening test. By 2022, the tool successfully identified 92 per cent of positive COVID-19 cases solely from the sound of a patient's cough. Shortly thereafter, Pfizer acquired the firm for $116 million.

Indian firm Salcit Technologies has developed Swaasa, an AI-powered software that analyses cough sounds for assessing lung health. Swaasa has received a no-objection certificate from the Central Drugs Standard Control Organisation (CDSCO) and holds patents in India, the US, Australia, and other countries. Korean researchers have also developed a new machine learning (ML) algorithm that detects pneumonia by analysing cough recordings and room acoustics. This algorithm can diagnose respiratory diseases both in hospitals and at home.

ML for predictive analytics

Researchers are working on developing tools capable of detecting early signs of diseases years before doctors can diagnose them. A researcher from the University of Texas at Dallas, along with international colleagues, has developed an algorithm that could potentially provide early medical alerts for the onset of asthma attacks or other respiratory problems in the future.

Researchers from the University of Canterbury, New Zealand have developed a tool known as Breath-to-Breath Observed Biometrics, or BOB, to help prevent respiratory illnesses. With BOB, more frequent monitoring can be as simple as breathing normally into the device each morning. They have developed research specialised software to interpret and transmit these results to GP, enabling data-driven care that exceeds the capabilities of appointments every one to three months. This software can automate diagnosis and frequent patient monitoring, reducing the strain on scarce clinician time.

Singapore-based Aevice Health, is partnering with London-based Jiva.ai, to develop a remote patient monitoring platform that will allow people living with asthma to track their condition and predict asthma attacks.

"In general the predictive capabilities of AI open up new possibilities in respiratory care," says Dr Ameera Patel, CEO, TidalSense, UK. TidalSense is developing AI-based diagnostic and monitoring solutions for COPD and asthma. These solutions utilise patented sensor technology to detect changes in the lungs, enabling automatic and more accurate diagnosis of respiratory conditions.

Dr Ameera Patel further said, "In the future we could forecast future disease development, guiding clinical decisions and enabling early interventions. Very soon AI could identify individuals within populations who are at highest risk of developing chronic respiratory diseases, such as COPD, allowing for targeted preventive diagnosis. This could ensure faster access to appropriate treatments and medications, which is critical for improving outcomes in respiratory conditions."

"While AI shows great promise, it's important to note some challenges," says Brandon Suh, CEO, Lunit, South Korea. He said, "The need for large, diverse datasets to train AI models effectively, ensuring AI algorithms work consistently across different populations and healthcare settings, and maintaining patient privacy and data security are some of the challenges."

In addition, there are also concerns that AI might replace specialists. Experts however foresee AI providing physicians with insights they couldn't previously obtain and becoming a vital tool for enhancing diagnoses.

"We've seen a lot of sensationalistic headlines about 'replacing doctors' or such things. On the other hand, sceptics see it all as snakeoil. The reality is somewhat different. AI is most valuable as a complement, as a tool completing tasks that add new value into the process," concludes Dr Reicher. BS

Ayesha Siddiqui

Can Biosimilars Repeat Success of Generics?

The combination of many biologics coming off patent plus high biosimilar adoption rates paints a bright future for biosimilars, and their ability to have a dramatic impact on healthcare and the pharmaceutical industry in broadening access to a new class of impactful affordable medicines. Can biosimilars transform the industry like generics did? Let's find out:

As more biologics lose patent protection—over $200 billion worth of innovator biologics are set to go off-patent by 2030—the influx of biosimilars is poised to expand, offering cost-effective alternatives and significantly impacting healthcare.

Billions of people lack access to the medicines and healthcare services they need and biosimilars play a crucial role in creating a more sustainable healthcare ecosystem by increasing access and affordability to essential biologic medicines.

"Before the adoption of biosimilars, a much smaller number of patients were able to access high-quality biologic medicines. With biosimilars, we are able to treat many more patients and at an earlier stage in their disease. This included many individuals who may not have had access previously. This is especially important for patients with rheumatoid arthritis (RA) or inflammatory bowel disease (IBD), who can develop long-term complications if not treated at an early stage of disease development. Testament to this, is that patient access to biologic therapies has already increased by as much as 100 per cent in Europe after biosimilars were introduced," said spokesperson from Samsung Bioepis, a leading biosimilar firm based in South Korea.

This is particularly true in Asia-Pacific, where non-communicable diseases (NCDs) cause nearly two thirds of all deaths and there is a significant disparity in access to medicines, as reported by The Lancet study. Biosimilars, priced typically 40-50 per cent lower than biologics, offer affordable alternatives for treating NCDs.

It is no wonder then that APAC is currently experiencing a boom in biosimilars, with many companies actively developing them. The region currently holds 30 per cent of the global biosimilars market. With 60 per cent of the global population residing in Asia, APAC leads in biosimilar development compared to other regions as reported by Generics and Biosimilars Initiative (GABI).

Governments in the region are actively supporting developments in biosimilars. South Korea, a leader in biosimilar manufacturing, provides capital, tax breaks, and regulatory guidance to local biosimilars companies. Samsung Bioepis and Celltrion, two major biosimilar companies, are based there. The country has approved 13 biosimilars, according to GABI.

In Japan, GABI observed that the government launched the Honebuto policy to develop biosimilars and promote National Health Insurance (NHI) schemes, high-cost medical care benefit programmes, and other reimbursements. To date, the Japanese regulator has approved 35 biosimilars.

China is a key market, having approved over 20 domestically developed biosimilars. In 2022, the oncology and immunology biosimilar market in China alone achieved sales of approximately $2 billion, as estimated by Clarivate. The Chinese government also offers various initiatives to support the development and adoption of biosimilars. Some of the leading names in the biosimilar market in China include Shanghai Henlius Biotech, Chia Tai Tianqing and Innovent Biologics.

India is the leading market with over 100 approved biosimilars and some of the top biosimilar companies include Biocon, Intas Pharmaceuticals, Dr. Reddy's Laboratories, Reliance Life Sciences, Gennova Biopharmaceuticals, Lupin, Gland Pharma, Zenotech Laboratories, Serum Institute of India, USV, Virchow Biotech and Wockhardt. It is estimated that over 100 biopharma companies in India are working on various platforms to produce biosimilars products to treat deadly diseases like cancer, diabetes, hepatitis, orphan and other autoimmune diseases.

In Taiwan, the government announced an incentive programme to promote biosimilars starting July 2024 until 2026. The aim there is to increase biosimilar usage from 7.8 per cent to 30 per cent by 2026, as well as to create substantial savings over the three-year pilot programme.

Repeating Generics' Success Story

Generics have contributed for nearly four decades and now represent 80-90 per cent of prescriptions filled around the world. Can biosimilars repeat history? Experts believe so.

"Biosimilars are the next wave of affordable medicines. As large molecules lose patents, biosimilars are expanding access to key biologic therapies by making them affordable and increasing supply for providers and patients. These are competitive markets with the number of players often determined by the complexity of the product – the more complex, the less competitors and vice versa. Pharmaceutical manufacturers must successfully navigate the landscape across development, manufacturing, and commercialisation for each molecule to be successful. In the US today, for example, over 90 per cent of total prescriptions are filled by generics – from oral solids to complex injectables. Similarly, for the early biosimilars launched in the US over the last several years, adoption rates for biosimilars are over 80 per cent for many molecules. This projects well that biosimilars are and will be adopted in a similar fashion as generics over time," said ***Anthony DiMeo, Vice President, Investor Relations & Media, Amneal Pharmaceuticals,*** a global, diversified pharmaceutical company that offers access to high-quality, affordable, and essential medicines, primarily in the US.

There are several challenges in replicating this success though. Unlike generics, biosimilars are derived from living organisms, making their development and manufacturing processes inherently more complex and costly.

"Biosimilars have a larger molecular size and more complex structure compared to small-molecule generics, adding cost and complexity to their development and manufacturing. Biosimilars development may take six to nine years and cost $100-300 million per candidate. A simple small molecule generic, by contrast, can cost as little as $1-2 million and take approximately two years to develop," said ***Simon Lee, Head, Asia Cluster, Sandoz, Switzerland.***

Sandoz is a pioneering company in the development of biosimilars, with ten marketed biosimilars and a robust pipeline comprising 24 molecules across various disease areas with high unmet needs. They lead the industry with biosimilar products reaching a wide patient base. Sandoz initiated the world's first biosimilar development programme in 1996 and was the first to receive approvals for biosimilars in Europe, Japan, Canada, and the US.

There are other numerous global challenges, from regulatory to commercial, that influence the adoption of biosimilars.

"Interventions such as pharmacy-level substitution and discount agreements for generics create cost pressures that are the root cause of supply shortages. To avoid the same fate for biosimilars and democratise access to biologic medicines, it's imperative to steer clear of implementing pharmacy-level substitution and discount agreements. These agreements can undercut the market for biosimilars by limiting their competitive edge and diminishing their availability. Similarly, automatic substitution and price-only tendering schemes should be avoided as they reduce competition between manufacturers and pose risks to ensuring a reliable and secure supply of biologic medicines. By prioritising policies that promote fair competition and robust market participation, we can safeguard the sustainable growth and accessibility of biosimilars, thereby enhancing patient access to crucial biologic treatments globally," said Simon.

A sustainable market environment must be created and balanced incentives will matter to keeping all the necessary contributors available over the longer term.

"The catastrophic price erosion of generics to unsustainable levels is having a severe effect on the healthcare sector in multiple markets around the world, and we must avoid that happening for biologics too. It has led to supply shortages for drugs, especially in the oncology sector, which can have severe consequences for patient care. It is important to have policies that not only drive broader patient access to cost-effective medicines, but also policies that ensure long-term biosimilar sustainability through multiple products remaining commercially viable in the market place over time. A sustainable market for biosimilars will further foster future biosimilars from being developed, and may help mitigate the current void in the biosimilar pipeline," added spokesperson from Samsung Bioepis.

Biosimilars not only expand patient access to potentially life-changing medicines but also enhance treatment options for healthcare providers and deliver substantial cost savings to healthcare systems. The use of biosimilars is projected to save up to $290 billion by 2027, concludes IQVIA's Global Use of Medicines Report 2023. BS

Ayesha Siddiqui

“We're seeing AI-powered diagnostic tools enhancing accuracy and efficiency, across multiple sectors”

In July 2024, Advanced MedTech Holdings (AMTH) appointed Wong Yau Chung as its new Group Chief Executive Officer, succeeding his role as Group Chief Operating Officer. With a core focus in urology devices and contract manufacturing services, the company serves millions of patients and physicians across 100 countries worldwide. Wong Yau Chung interacts with BioSpectrum Asia and shares his vision for Advanced MedTech Holdings' future and insights on key trends shaping the medtech industry. ***Edited excerpts:***

« **Wong Yau Chung,** Group Chief Executive Officer, Advanced MedTech Holdings, Singapore

As the new Group CEO, what is your strategic vision for Advanced MedTech Holdings?

My strategic vision is to build upon our strong foundation and continue our trajectory as a leading global urology company. Our focus is on maintaining sustainable innovation-driven growth through R&D investment, expanding our global footprint with a particular emphasis on the US, source of 60 per cent of our revenue.

Our ultimate goal is to fully leverage our integrated urology platform to serve the needs of our customers. In the immediate term, I will continue to work closely with the leadership team to ensure a smooth transition and embark on global visits to meet with customers and gain deeper insights into the challenges that they face.

What new advancements or innovations can we expect in urology devices?

There are 2 areas where innovation is growing in urology: (1) laser lithotripsy; (2) AI application in urology.

The entire field of laser lithotripsy over the past few years has seen major innovation breakthroughs in (a) disposable URS; and (b) shift from Holmium to Thulium. AMTH has been proud to launch several product innovations in the above areas and continues to do so.

Our Thulio laser is one such example of how we have innovated on existing laser technologies. Holmium:YAG technology has been the gold standard for laser lithotripsy for over 20 years, but right now, we are standing on the precipice of change with Thulium-based technology. The Thulio’s RealPulse technology is optimised for dusting, fragmenting and enucleation performance in a lightweight and compact footprint – the ideal one solution for many treatment needs. Our single-use Axis scope is also one of the best in the market, with 2.5 times more pixels than its leading competitor at launch. The scope provides users with uncompromised image quality and manoeuvrability without the costs or risks associated with reprocessing equipment.

We are also extremely proud of the recent launch of UroGPT, our groundbreaking Artificial Intelligence (AI) tool designed to support kidney stone patients.

Over the past few years, we've seen AI revolutionise the way we work - this trend will inevitably impact the MedTech industry. We're seeing AI-powered diagnostic tools enhancing accuracy and efficiency, across multiple sectors. Digital health platforms are facilitating remote patient monitoring and telemedicine, whilst generative AI applications are supporting R&D efforts and enabling better patient outcomes through tailored information and communications.

Developed by Dornier MedTech, UroGPT is the first of its kind in urological care, providing patients with on-demand advice and actionable insights about their condition. This innovation represents a significant step forward in patient-centric care and demonstrates our commitment to leveraging cutting-edge technology in urology. This has been adopted by leading academic teaching hospitals in the US, such as Stanford, with excellent results from initial studies at UCLA that will be showcased at the upcoming World Congress of Endourology & Uro-Technology.

AI in medical technology continues to revolutionise the area of imaging, and we are exploring the use of AI to better improve urological treatment. For example, we are doing research on AI to improve stone recognition during ESWL ultrasound treatments.

How does AMTH navigate the complex regulatory landscape, and what changes are you preparing for?

The main regulatory challenge facing medical devices companies in the past few years is the move to the CE MDR regulatory framework from the older CE MDD framework. We were prepared for this development, and I am glad that we were one of the first urological medical device companies to achieve MDR certification in 2021.

China has also been updating their regulation to align with international standards, and we are committed to ensure that our products developed in China meet these standards. We strive to exceed regulatory standards globally - this approach ensures we can continue to bring innovative products to market efficiently and safely, regardless of varying regional complexities.

Other key trends we're monitoring include increased focus on data and cybersecurity and emphasis on real-world evidence. Our dedicated regulatory affairs team monitors evolving regulations in each market we operate in, and we actively engage with regulatory bodies and collaborate with local partners to understand and prepare for any changes.

What do you see as the most significant trend currently shaping the medtech industry?

Over the past few years, we've seen AI revolutionise the way we work - this trend will inevitably impact the MedTech industry. We're seeing AI-powered diagnostic tools enhancing accuracy and efficiency, across multiple sectors. Digital health platforms are facilitating remote patient monitoring and telemedicine, whilst generative AI applications are supporting R&D efforts and enabling better patient outcomes through tailored information and communications.

Could you share some crucial future plans?

Looking forward, we shall continue to focus on executing our Integrated Urology Platform strategy, continuing to invest in R&D, expanding our market presence globally, and exploring strategic partnerships and acquisitions.

Our success stems from our dedicated employees, trusted customers, and supportive partners. We remain committed to improving patients' lives through innovative urology solutions, maintaining operational excellence, and prioritising customer satisfaction. With our strong foundation and clear strategic focus, we're well-positioned to drive sustainable growth and make a lasting impact in the field of urology and medical technology.

What initiatives does AMTH have to promote sustainability?

Sustainability is a growing focus for Advanced MedTech. We've initiated several programmes to address this important issue across the Group, including a pilot recycling programme for our Axis single-use scopes with a large health network customer in California, and a carbon neutrality programme in Germany to offset our carbon footprint. Our factory in Germany has also installed a groundwater heat pump air conditioning system to provide regulated temperatures all year round, making the factory less reliant on electricity or gas to run cooling or heating systems, thus reducing our carbon footprint. BS

Ayesha Siddiqui

How technology and AI are democratising healthcare

As Artificial Intelligence (AI) continues to shape the way we work and live, we must ensure that we are tapping into its full potential when it comes to the healthcare space. By leveraging its unique capabilities to address the accessibility barriers that we see in our healthcare centres in the APAC region and equip policymakers and industry leaders with the knowledge, tools and information to change and democratise our healthcare systems.

« **Adam Chee,**
Associate Professor,
Saw Swee Hock School
of Public Health, National
University of Singapore

The healthcare sector, like many others, has not been immune to the technological shift brought about by artificial intelligence (AI). Touted as a great tool to aid in streamlining operations, AI and generative AI are predicted to contribute to around $100 billion in savings for the already burdened healthcare sector.

Yet, the applications and potential of the technology expand beyond just enhancing efficiency for day-to-day workplace tasks: it has also shown great promise in reducing barriers to access for healthcare knowledge and for supporting the complex analysis of data in drug trials and research. AI's data processing capabilities, while not unexpected, are precisely what is needed when we look to democratise healthcare and focus on an equitable future in healthcare.

The Asian Context

Historically, in Asia, the healthcare sector is one where social and economic disparity is placed under a microscope. Around 1.6 billion people in Asia and the Pacific lack effective access to social health protection due to a variety of legal and systemic issues.

Infrastructure issues in less developed economies means that local healthcare centres and systems are simply unable to accommodate patients in need. Even if private healthcare options exist for some conditions, many patients may not have access to treatments or care.

According to OECD data , the number of health resources and personnel available to populations across the APAC region is highly dependent on the number of resources allocated to the sector as well as population growth rates and density.

In an average low- to middle-income country in Asia, a person in need of medical care would have to compete for the attention of 1.1 doctors and less than 2 nurses per 1000 people. Depending on which country they are in, they would be faced with either 1 hospital bed per 100 people or even less than 1. And if they were living in a rural part of the country, they would have to travel to an urban centre to access any health resources at all.

A study showed that up to 81 per cent of people living with non-communicable diseases, such as diabetes and cardiovascular diseases in South Asia have inadequate health literacy. While in China, about 28 per cent of adults in 2022 were able to do the same, with disparity among provinces and regions. As these regional differences and disparities stack on top of one another, we see a plethora of unmet needs in the region that must be addressed before they worsen further.

The AI solution

When it comes to issues around lack of manpower, AI and other automations provide some relief. Remote monitoring and telehealth tools are able to provide both patients and doctors with streamlined ways of attending consultations and accessing medical data that break down accessibility barriers. For instance, by reducing wait times and reducing accessibility barriers for patients who cannot travel to medical centres in person, these tools boost goal-centred patient engagement.

These tools that encourage goal-centred patient engagement and in the care delivery process can counterbalance the health disparities experienced by socially and economically disadvantaged populations.

They can also aid in the management of chronic conditions with data being readily available for review either by healthcare administrators or by the patients and their caretakers themselves.

AI will need to have access to a wealth of data to turn the visions into reality. Given this, it is critical to develop ethical guidelines on AI use in the medical space. The guidelines should ensure that patient and practitioner data are safe through appropriate data security protocols and anti-virus software. At the same time, we must also ensure that the information we are training our AI models on is bias-free.

The wealth of data that can be mapped out by AI through predictive analytics and data processing also encourages the development of holistic treatment plans that do not view a disease in isolation. Additional data about where a person lives or how they live can provide a great starting point for diagnoses but can also trigger subconscious biases in medical staff. For instance, external factors such as lifestyle habits, community infrastructure and access to clean drinking water can even impact the prevalence of certain diseases in communities.

While they can provide unique insights into medical history and complaints, they can also preemptively colour a doctor or nurse's opinion about a patient's condition and cause them to over or under diagnose them. Incorporating more representative data in AI development can minimise bias to ensure that patients, regardless of geography and socio-economic conditions, are treated equally and objectively.

Governments and policy makers can also leverage the technology's data processing capabilities to ensure that they are able to efficiently bridge the gaps that we currently see in health access from a legislative and health policy perspective. Such data can support the development of not just public health facilities and policies but also boost infrastructure development and environmental protection efforts that can undoubtedly become aggravating factors for chronic conditions in the long run.

Working together

AI developers and medical personnel must also look to working in tandem with patient groups, policy makers, and the wider healthcare industry as a whole to truly understand how best to serve the unmet needs in a community.

In a region as diverse as APAC, there is a need for providers to strive to be as hyper-local as they can be. The unmet needs of populations can change drastically within a 50-mile radius in the same province; there can be no one-size-fits-all approach to healthcare solutions. By partnering with health/patient organisations, providers across the ecosystem adapt to the changing landscape, as well as ensure that solutions are more accessible and create a stronger impact for more patients.

The Alliance & Partnerships for Patient Innovation & Solutions (APPIS) platform and its Innovator Program exemplify successful collaboration in improving healthcare access. This program supports patient organisations in the Asia Pacific, Middle East, and Africa regions, bringing them together with various stakeholders to foster collaboration and find solutions for patients' access to healthcare.

The Breast Health Foundation is a compelling example of an organisation that has benefited from this program, winning the APPIS Innovator Program in 2024. With the assistance of APPIS, the foundation is expanding its efforts to address health literacy gaps and early screening for breast cancer in South Africa, utilising its AI-based Health Awareness Assessment Tool.

Driving the discussion together with policymakers on the immediate or priority needs of a community would be largely beneficial in broadening access and advocating for health equity. For instance, are the patients who need the treatment the most able to have access to it? Are they able to receive it in a timely manner? What additional medical support or applications do they need to have access to in order to monitor the effectiveness of the treatment? All of these are essential questions that must be addressed through mutual dialogue and knowledge sharing between different stakeholders.

AI will need to have access to a wealth of data in order to turn these visions into reality. Given this, it is critical to develop ethical guidelines on AI use in the medical space. The guidelines should ensure that patient and practitioner data are safe through appropriate data security protocols and anti-virus software. At the same time, we must also ensure that the information we are training our AI models on is bias-free. Societal disparities that come about through human bias and stereotyping can very well be exacerbated if those same views are fed into our software. Therefore, we must review and cross-check the initial data sources to mitigate this risk and maintain objectivity. BS

Why global pharma companies choose India for GCCs

India's pharmaceutical industry is globally recognised for its capabilities in research and manufacturing and for its skilled labour. The country's attractiveness as a destination for Global Capability Centres (GCCs) is underpinned by several key factors, including cost-efficiency, a vast talent pool, robust infrastructure, and strong regulatory support.

« **Anil Matai,** Director General, Organisation of Pharmaceutical Producers of India (OPPI)

India serves as a key global hub for development, attracting investments of more than $7 billion. Global pharmaceutical companies have established GCCs in India which serve as centres of excellence for drug discovery, formulation development, and healthcare solutions, while also supporting a strong ecosystem by employing talent and increasing the knowledge base.

For instance, Novartis has had a significant footprint in India since 1947, and in the last two decades, it has evolved to be an integral part of the development journey of many breakthrough medicines in various therapeutic areas like cardiovascular, oncology, immunology, neurology, and ophthalmology, amongst others. Similarly, MSD is primed to support the Indian government in protecting every woman through HPV vaccination with nearly 85 per cent of their products being manufactured locally. In India, Novo Nordisk is conducting phase 2-4 clinical trials across major disease areas with over 3,000 enrolled patients. With 37 ongoing trials in various therapy areas, India accounts for 7-8 per cent of Novo Nordisk's global patient pool. As GCCs have evolved to become centres for innovation and research, India has transformed into a hub for new product development for global enterprises. Consequently, over 50 per cent of the world's GCCs are now located in India, driven by factors that provide a competitive edge for businesses aiming to optimise operations and drive innovation.

Cost-efficiency of conducting business

India offers a compelling cost-quality ratio, making it financially advantageous for companies to establish their GCCs in the country. Labour costs in India are significantly lower than those in countries like North America and Europe, enabling companies to reduce operational expenses while maintaining profitability. According to a NASSCOM report, companies setting up GCCs in India could achieve average cost savings of 40-50 per cent compared to their home countries. These savings extend beyond salaries to include operational costs such as real estate, utilities, and infrastructure. Bayer's Hyderabad centre has been selected as a key APAC hub as India has a significant talent pool to support global drug development and manufacturing initiatives. There are over 100 employees currently working here. The Novartis Corporate Centre serves as one of the key global hubs for development wherein scientists are providing support in the development of many chemical entities developed and commercialised by Novartis globally.

Extensive Talent Pool

India boasts a large pool of highly skilled professionals with the world's second-largest English-speaking youth population and the highest number of Science, Technology, Engineering, and Mathematics (STEM) graduates. The foundation of a thriving GCC model in India is the nation's abundant talent pool and expanding knowledge economy. The Indian talent is equipped to meet the demand because of its unique characteristics like generative artificial intelligence (GenAI) and cloud computing. GSK's GCC in Bengaluru employs over 2,500 people in global business operations and R&D, with more than 50 per cent focusing on R&D in areas like safety science, regulatory, biostatistics, clinical operations, and more. Pfizer's Global Drug Development Centre in Chennai has emerged as a powerhouse of innovation, propelling the company's quest for groundbreaking medical solutions. Bristol Myers Squibb's new facility in Hyderabad expands the company's global drug development and IT and

digital capabilities. It is expected to be home to over 1,500 employees, enhancing the company's workforce and impact on patients.

Robust infrastructure and regulatory support

The country has made substantial investments in modernising its infrastructure to support business operations. This includes state-of-the-art office spaces, reliable high-speed internet connectivity, and consistent power supply, which are crucial for the seamless functioning of the GCCs. Additionally, India's advanced transport systems and logistics networks facilitate the efficient movement of goods and personnel, ensuring that operations run smoothly and without interruption. For example, cities like Hyderabad, Bengaluru, and Pune have developed into major business hubs, offering world-class infrastructure that meets the demanding needs of global companies. Integrating advanced technologies such as AI, machine learning, and big data analytics into the infrastructure framework supports innovation and enhances operational efficiency. Digital infrastructure initiatives such as the creation of smart cities and tech parks provide an ecosystem conducive to cutting-edge research and development. Lilly's GCC in Bengaluru supports digital transformation and innovation by providing cloud automation, advanced analytics, AI, software engineering, and information security solutions. Leveraging expertise in data analytics and digital technologies, it enhances clinical trial processes and drives innovation in AI and machine learning for biopharmaceutical challenges.

Focus on Innovation and R&D

India is rapidly emerging as a global hub for pharmaceutical R&D, driven by a robust ecosystem that includes academic and research institutions, industry partnerships, and government support. This ecosystem fosters collaboration and innovation, making India an ideal location for GCCs in the pharmaceutical sector. These centres are at the forefront of cutting-edge research, clinical trials, and drug development, significantly contributing to the global R&D efforts of their parent companies.

Pfizer collaborated with the National Institute of Pharmaceutical Education & Research (NIPER), Ahmedabad to encourage startups in India and help early-stage innovators advance on their journey. This collaboration is an example of how healthcare startups are turning their innovative ideas into market-ready solutions. Sanofi's The Department of Scientific and Industrial Research (DSIR)-approved R&D centre in Goa has developed innovative products and technologies for the past 15 years, focusing on new product development, lifecycle management, new dosage forms, R&D support, technology transfer, site troubleshooting, product harmonisation, process improvements, and compliance. Ferring India R&D works on technology platforms like FDG's, SmaRTgel, and LBOL-IR/XR, investing over 60 million Euros in Indian R&D, with 1-2 million Euros spent annually on capital expenditure. Lilly Capability Centre India (LCCI) in Bengaluru and Merck's new Healthcare R&D Excellence Centre in Bengaluru leverage India's strengths in drug development and technology, driving global healthcare innovation.

Growing Technological Infrastructure

The rapidly expanding technological infrastructure provides a significant competitive advantage, enabling global pharma companies to enhance their operations, drive innovation, and achieve cost efficiencies. The country's robust IT infrastructure supports various aspects of operations, including R&D, data management, and digital health initiatives. For instance, Roche is harnessing India's robust technology ecosystem to forge ahead in the digital landscape, crafting innovative solutions that resonate on a global scale. Roche Services and Solutions (RSS) adds expertise around the technological advancements happening in the healthcare space through the utilisation of AI/ML concepts contributing towards significant improvement in the lives of patients. Similarly, AstraZeneca's Global Innovation & Technology Centre (GITC) in Chennai drives the company's digital journey and technology innovation, housing over 50 per cent of its global IT staff. GITC offers services in software engineering, cybersecurity, IT infrastructure, cloud, hyper-automation, AI/ML, extended reality, and IoT.

Way Forward

The future of these hubs in India's pharmaceutical sector appears promising. Factors such as continued investment and talent accessibility, contribute to their sustained growth. Additionally, a favourable regulatory environment and an expanding healthcare market attract global companies to establish their hubs, facilitating collaborations and technology-driven solutions. These hubs also have ample opportunities to explore emerging technologies and foster collaborations, leading to breakthrough discoveries. Furthermore, increasing government support for innovation and entrepreneurship through initiatives and policies enhances the growth potential of these hubs. As we move forward, it's crucial to leverage the opportunities these GCCs present and continue to solve the healthcare challenges of India. BS

Reviewing Global Biotech Investment

Pharmaceutical companies are strategically acquiring assets to reduce risk in anticipation of upcoming patent expirations. It is possible that certain M&A activity has been influenced by concerns regarding the potential impact on existing product portfolios. However, in today's challenging economic landscape, dealmakers are being driven to think outside the box and consider creative solutions to achieve growth amidst ongoing uncertainty.

« **Surbhi Gupta,** Industry Principal, Healthcare & Lifesciences, Frost & Sullivan

The investment outlook for the biotech industry returned to pre-COVID-19 levels in 2023, following a peak in 2021 and a decline in 2022. There is a strong likelihood that it will continue to gain momentum in 2024, as numerous deals were announced during the fourth quarter of 2023. The sourcing and commercialisation of novel biological development are complicated by deglobalisation and the confrontation between the US and China. The potential impact of the 2024 US presidential election on global and domestic policy is a concern within the industry. Geopolitical tensions have the effect of diminishing cooperation, causing disruptions in the initial public offerings (IPO) sector and imposing financial penalties. Consequently, these factors contribute to the unpredictability of economic forecasts. The future of public financing for biotech was uncertain in 2023 and is improving gradually. However, venture capitalists have consistently shown a strong interest in investing substantial amounts of money in innovative technologies that have the potential to revolutionise the industry. Most of the financing has been allocated to cutting-edge platform technologies, such as artificial intelligence (AI)-enabled drug development, cell and gene therapy (CGT), and messenger ribonucleic acid (mRNA).

Biotech M&A Trends

As a proportion of all acquisitions, M&A (mergers and acquisitions) for clinical-stage firms dropped to 15 per cent in 2023 from about 25 per cent in 2021-22, indicating a change in investors' preferences for riskier assets. The transaction value of acquisitions in the biopharmaceutical industry experienced a significant increase, while the overall deal value grew substantially during the second half of 2023. In the year 2023, there was a notable increase in M&A activity compared to the sluggish pace observed in 2022. During this period, there were more than 10 deals that exceeded a value of $1 billion, and two of these deals even surpassed the $10 billion mark. Biopharmaceutical companies that achieve positive results in clinical trials experience reduced vulnerability to a slow market due to their ability to attract significant investor attention and witness substantial increases in their stock prices. Many life science investors have a long-time horizon and use a wait-and-watch strategy, which contributes to the adhesive nature of the biopharmaceutical business.

Pharmaceutical companies are strategically acquiring assets to reduce risk in anticipation of upcoming patent expirations. It is possible that certain M&A activity has been influenced by concerns regarding the potential impact on existing product portfolios of Medicare prescription price negotiations under the Inflation Reduction Act (IRA). Large biopharma firms like Novartis, AbbVie, BMS, AstraZeneca PLC, Eli Lilly and Company, and Roche Holding AG are setting the standard. Several major pharmaceutical companies, such as Abbvie, BI, Bayer, and J&J, have not engaged in any significant (M&A) activities within the past two years. It is highly probable that they will do so in 2024.

Cardiometabolism has the potential to gain equal prominence among acquirers, like oncology and immunology. The success of Novo and Lilly's GLP-1 brands in the fields of diabetes and obesity is expected to have a positive impact on M&A, potentially paving the way for more companies to enter the market. In 2023, oncology accounted for 51.1 per cent of the deals. The field of oncology is expected to maintain its primary focus, as several M&A have been announced for 2023. BMS has announced its acquisition of Mirati Therapeutics for a total of $4.8 billion. Roche has

announced its acquisition of Carmot Therapeutics for a substantial sum of $3.1 billion. Carmot Therapeutics specialises in the development of drugs for oncology and metabolic diseases. AstraZeneca has announced its acquisition of Gracell Biotechnology, a company specialising in the development of innovative cellular therapies for cancer and autoimmune diseases. The deal is valued at $1.2 billion. In other areas outside of oncology, the central nervous system (CNS) and immunomodulators will continue to play a significant role. As an example, BMS, with a focus on the CNS, has agreed to acquire Karuna Therapeutics for a substantial sum of $14 billion. Karuna Therapeutics specialises in the development of groundbreaking drugs for mental and neurological disorders. AbbVie has announced its acquisition of Cerevel Therapeutics Holdings, a company specialising in the development of treatments for neurological illnesses. The deal is valued at $8.7 billion. AstraZeneca acquired CinCor, a pharmaceutical company specialising in cardiovascular, metabolic, and renal diseases, for a substantial sum of $1.8 billion.

Antibody-drug conjugates (ADCs) are older than advanced technologies like CGT. Major pharmaceutical corporations favour lower-risk ventures. Despite fewer agreements than in 2022, ADC's transaction value increased. CGT contains the largest deals, although 2023 saw fewer and lower prices. AbbVie purchased ImmunoGen for $10.1 billion on February 12, 2024, to develop and market next-generation ADCs, expanding its cancer portfolio. On December 14, 2023, Pfizer purchased Seagen for $43 billion. Monoclonal antibodies target cancer cells and deliver cell-killing chemicals in Seagen's antibody-drug combo treatment.

Tmunity was acquired by Gilead Sciences' Kite Pharma for $1.3 billion on February 22, 2023. Tmunity creates novel cell receptors and T-cell platforms to control T-cell activation and direction. Orchard Therapeutics, a pioneer of revolutionary gene therapeutics for severe orphan illnesses, was bought by Kyowa Kirin for $477.6 million.

Outlook for 2024 and beyond

Strategic partnerships, licensing arrangements, joint ventures, and other low-risk collaborations have, to some extent, replaced traditional acquisitions. Nevertheless, M&A will continue to be an attractive strategy for biopharmaceutical companies to quickly establish a presence and bridge revenue shortfalls.

Big biopharma companies are efficiently filling gaps in their pipelines by acquiring promising biotech startups through a series of smaller transactions rather than relying on the large deals of the past. These companies continue to make a limited number of significant acquisitions to address gaps in their portfolio. Our focus is on obesity, rare diseases, the central nervous system (CNS), oncology, and immunology. RNA-based therapies, the glucagon-like peptide 1 (GLP-1) class, and ADCs will receive increased investment.

If companies don't have access to their preferred funding options, they may need to explore alternative sources of investment such as public shares, debt finance, or royalty monetisation. High interest rates can make debt financing seem less attractive. Therefore, biopharma companies will engage in bolt-on acquisitions to achieve significantly better value. In 2024, acquirers will continue to have a cautious approach towards risk, prioritising transactions involving targets that have been de-risked. These targets will typically include assets that are in Phase III or were marketed in 2023. Except for biotech companies that have late-stage assets, the current market favours buyers. Small/emerging biotech companies are poised to maintain their stronghold on innovation. Given the nature of these pre-commercial biotech enterprises, it is likely that many of them will pursue M&A exits. This is because it will take some time for the market's financial situation to fully recover. Commercial and late-stage enterprises are often viewed more favourably by buyers due to their predictable future, which can result in higher prices. Pre-clinical enterprises do not have enough information to support a potential purchase, so acquirers will not further complicate an already risky situation.

Buyers are likely to be drawn to the precision medicine sectors, given the incorporation of comprehensive omics data sets, the pursuit of regenerative treatments, and the discovery of significant genetic alterations on a large scale. Platform companies should explore opportunities to broaden their focus beyond rare illnesses and oncology to tackle other important areas where there is a lack of medical alternatives. In today's challenging economic landscape, dealmakers are being driven to think outside the box and consider creative solutions to achieve growth amidst ongoing uncertainty. Dealmakers will consider different approaches to drive growth in 2024, including licensing and partnership agreements, joint ventures, structured deals for R&D financing arrangements, and spin offs and divestitures. BS

University of Sydney launches institute in Vietnam to focus on public health & sustainability

The University of Sydney Vietnam Institute has been officially launched and will build on a network of leading researchers and educators to benefit communities in Vietnam and beyond through impactful research and engagement. From a strong foundation of health and human clinical trials, the institute will be the site of multidisciplinary research in health, agriculture, arts, social sciences, business, and Net Zero initiatives. Australian researchers will work alongside Vietnamese collaborators and the community on projects such as supporting public health efforts and combating tuberculosis in Vietnam, developing emerging technologies for breast cancer diagnosis in the country and examining Vietnam's future as a media innovation hub. One of the Vietnam Institute's goals is to improve in-country scientific capacity and contribute to the region's economic and social development. The institute is supported by up to 40-45 million (AUD) in non-profit funding from the Australian government and international donors. All revenue generated by the institute will be reinvested into research activities in Vietnam.

ADU and Burjeel sign MoU to advance health sciences research

Abu Dhabi University (ADU) and Burjeel Holdings have signed a Memorandum of Understanding (MoU) to enhance clinical research and academic programmes in the UAE. The MoU signed between the two entities focuses on advancing health sciences studies and aligns with the national goal to establish the UAE as a global healthcare hub. The collaboration will provide ADU students and faculty members with increased access to national and international grants. It is expected to contribute significantly to academic excellence by integrating industry insights into the university's curriculum. Joint initiatives between ADU and Burjeel will include the development of innovative labs and fostering a culture of innovation through collaborative research projects. This move is set to reinforce ADU's position as a centre for advanced discoveries in the healthcare sector.

StudyMEDIC & OC Academy launch clinical fellowship programme for global medical careers

StudyMEDIC, the leading International Medical Education Training Provider based in Qatar, and Bengaluru-based OC Academy, India's leading online healthcare education and medical upskilling firm, have introduced the transformative Clinical Fellowship Programmes integrated with Royal College Memberships and Fellowships Examination Training. This programme aims to empower medical professionals with the knowledge, hands-on experience, skills, and global recognition necessary to propel their careers to new heights. The two-year programme offers a unique combination of comprehensive foundational online learning, hands-on clinical training at leading multi-specialty and super-specialty across India, and expert coaching to prepare candidates for the prestigious Royal College Memberships and Fellowships Clinical Fellowship Programmes integrated with Royal College Memberships and Fellowships Examination. Successfully completing these exams will confer esteemed Royal College Memberships and Fellowships. This presents an alternative path for MBBS graduates for a specialist career.

Wong Yau Chung steps in as Group CEO of Advanced MedTech

Singapore-based Advanced MedTech Holdings (AMTH or the Group), innovative global leader in urology, has announced that Abel Ang will retire as Group Chief Executive Officer (CEO) as part of a planned leadership transition. Wong Yau Chung, previously Group Chief Operating Officer (COO),

has assumed the role of Group CEO-designate from July 1, 2024 and will take over as Group CEO on October 1, 2024. Yau Chung will also be appointed to the Board of Directors as Group CEO, and Abel will continue to remain on the Board of Directors of AMTH. Yau Chung thrives in working in a global business environment, having spent significant time in all three continents of Americas, Europe and Asia-Pacific. One of his key focuses is on leading change management across different cultures and global organisations. He was earlier working as the Managing Director / Chief Operating Officer at Dornier MedTech where he was responsible for the development of three new medical devices during the pandemic years- Thulio (the Advanced Thulium Laser), Nautilus (Dornier's new flagship urology table) that received FDA clearance and CE mark approval in first half of 2022, and Delta 3 Pro that received CE mark approval.

Medit appoints Han Ryu as CEO

South Korea-based Medit, a leading provider of dental 3D scanners and digital dentistry solutions, has appointed Han Ryu as its new Chief Executive Officer (CEO). Ryu brings with him over three decades of senior management experience in global medical device and healthcare companies, including prominent roles at Siemens Healthineers, Qorvo Biotechnologies, Accelerate Diagnostics, and Bain & Company. Since 2023, he has successfully led Medit North America, driving significant growth in the region through strategic oversight of sales and marketing initiatives. Under Ryu's leadership, Medit is enhancing support initiatives such as educational programmes and customer communications. Specifically, Medit has launched a Medit Users Group Chat in India to facilitate direct inquiries and support interactions. This initiative involves participation of the Medit local education team and Indian Key Opinion Leaders (KOLs), to deepen users' understanding of Medit products and applications.

Siemens Healthineers India names Kalavathi GV as Executive Director and Head of Development Center

Kalavathi GV has been appointed as the Head of Development Center (DC) and executive director at Siemens Healthineers India, starting July 1, 2024. In her new role, she will lead over 3,500 DC employees in India and Slovakia, driving the development of precision healthcare solutions using artificial intelligence, automation, and digital transformation for all business lines of Siemens Healthineers. Kala has an extensive track record of driving global digital transformation at large multi-national organisations. She has previously held leadership positions at Philips Healthcare and GE Healthcare, and is a strong advocate of representation of senior female leaders in the Indian IT ecosystem. Kala has taken office from Dileep Mangsuli, who will now lead global corporate activities in the fight against tuberculosis at Siemens Healthineers.

Ravindra Boratkar, Publisher, MM Activ Media, receives Exemplary Leadership Award of Exhibition Industry

Ravindra Boratkar receiving Exemplary Leadership Award from dignitaries at the Exhibition Excellence Award ceremony.

Jagdish Patankar, Executive Chairman, Ravindra Boratkar, Managing Director and the team of MM Activ Sci Tech Communications Pvt Ltd receiving the award presented to Bengaluru Tech Summit in Grand Conference category.

Ravindra Boratkar, Publisher & Managing Editor, BioSpectrum (India and Asia), NUFFOODS Spectrum (India and Asia) and AgroSpectrum (India and Asia) was presented the Exemplary Leadership Award in the Exhibition Excellence Awards in the Editor's Choice category in his capacity as the Managing Director of MM Activ Sci-Tech Communications Pvt Ltd., the parent company of all the media brands.

Exhibition Excellence Awards are presented annually for various events, exhibitions, conferences seminars, venues and personalities to recognise their contribution and felicitate the distinguished achievers of the sector. The awards are Asia's iconic, only recognition initiative for the exhibition and convention industry.

The awards are given by the Exhibition Showcase, Asia's most comprehensive media platform for exhibitions. This was the 8th edition of the Exhibition Excellence Awards and Summit 2024, held at the CIDCO exhibition and convention centre in Navi Mumbai.

The award citation said, "Boratkar's remarkable contributions and visionary leadership has left an indelible mark on the industry, shaping its trajectory for the better. Boratkar is a driving force in the organisational consulting, marketing, management and event organisation."

MM Activ gets awards for BTS 2023, Startup Mahakumbh

MM Activ Sci Tech Communications, received other three awards for two of its shows at the Exhibition Excellence Awards 2024. Bengaluru Tech Summit (BTS) 2023, encapsulating Bio Technology, bagged the award as the Grand Conference, while the Start Up Mahakumbh 2024, organised in Delhi received award as Top Start-Up India Promotion Show and 1st runner up in the category Top New Show (B2C). Jagdish Patankar, Executive Chairman and Ravindra Boratkar, Managing Director and the team of MM Activ Sci Tech Communications Pvt Ltd received the awards.

Boratkar also moderated the panel discussion on CEO's Forum titled "Future outlook for India's Exhibition Industry" prior to the award ceremony. Panellists in the discussion, were Sanjeev Bolia, Founder Afairs Exhibitions & Media Pvt Ltd, Phil Chung, CEO KINEXIN – IICC, Milind Dixit, Managing Director, KOELNMESSE Pvt Ltd, Nabjeet Ganguli, Chief Marketing Officer, Informa Markets, Pradeep Padekar, Chief Financial Officer, Messe Muenchen India, Vinay Mittal, Managing Director Deepali Design & Exhibits Pvt Ltd.

In his remarks during moderating the session, Boratkar said that the future of India's exhibition industry appears exceedingly bright. India's rapidly expanding economy and its strategic geographical location make it an attractive destination for global exhibitions. India's rich cultural heritage and diverse industrial base provide a fertile ground for specialised exhibitions across various sectors—from automotive and healthcare to information technology and agriculture. Each exhibition serves as a platform for knowledge-sharing, networking, and exploring new business opportunities.

MM Activ Sci-Tech Communications has won these awards consecutively for the third time. BS

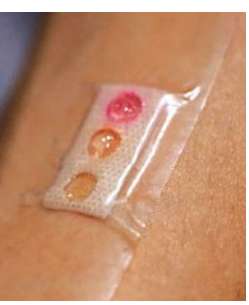
Hong Kong identifies novel gut microbiome biomarkers to facilitate diagnosis of autism spectrum disorders

The Chinese University of Hong Kong (CUHK)'s Faculty of Medicine (CU Medicine) has conducted a large cohort study among 1,627 children with and without autism spectrum disorder (ASD) and found alterations in four kingdoms of the gut microbial species in children with ASD. Using machine learning, they developed a panel of 31 multi-kingdom and functional markers that showed high diagnostic performance for ASD and has great potential as a clinical diagnostic tool. In a

pilot study, the researchers also found that modulation of the gut microbiome helped alleviate symptoms of anxiety in children with ASD, introducing the possibility of a new therapeutic paradigm for the condition. The CU Medicine research team has recently completed a pilot clinical study to investigate the use of a gut microbiome modulator that aims to boost the abundance of γ-Aminobutyric acid (GABA) in children with ASD. GABA is a neurotransmitter that, when depleted, can be associated with sensory hypersensitivity and anxiety. 30 children aged 4- 11 years old with ASD were recruited to receive the novel synbiotic formula SCM06 for 12 weeks.

Singapore develops 'band-aid' with microlaser technology for detecting glucose levels in sweat

Researchers at Nanyang Technological University (NTU), Singapore have developed a 'band-aid' or plaster that measures body 'biomarkers' that can indicate health or disease through sweat, paving the way for a new non-invasive and effective way for patients to monitor their health. By encapsulating a microlaser in liquid crystal droplets and embedding the liquid within a soft hydrogel film, NTU team created a compact and flexible light-based sensing device, like a plaster which can provide highly accurate biomarker readings within minutes. When sweat interacts with the plaster, the amount of light emitted by the microlasers fluctuates based on the concentration of biomarkers present. To read the biomarker levels, users shine a light source on the plaster, and the light emitted from the microlaser sensors is analysed and translated using a mobile application. The in vitro results detected fluctuations of glucose, lactate and urea levels in sweat down to 0.001 millimetre. The NTU team believes their innovation to be the first reported wearable sensing device that is capable of measuring multiple biomarkers in sweat with ultra-high sensitivity and dynamic range.

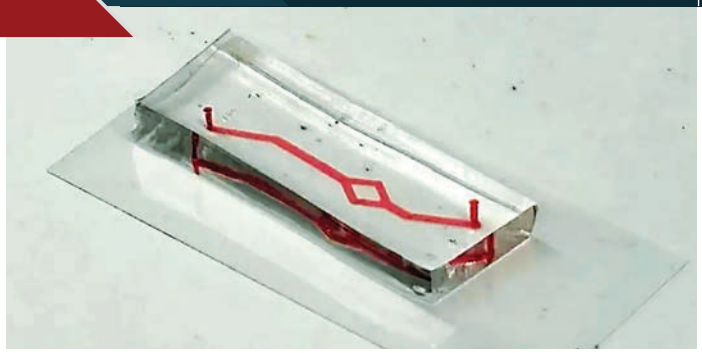


Researchers discover new enzyme with promising antibacterial activity in Japan

Acute graft-versus-host disease (aGVHD) is a medical condition that occurs when donor immune cells attack the recipient's tissues after an allogeneic hematopoietic stem cell transplantation (allo-HCT). The pathogenesis of aGVHD is influenced by gut dysbiosis and Enterococcus domination. A multidisciplinary team led by Associate Professor Kosuke Fujimoto from Osaka Metropolitan University and the University of Tokyo, alongside Professor Seiya Imoto from the University of Tokyo, and Satoshi Uematsu from Osaka Metropolitan University and the University of Tokyo, Japan recently identified a bacteriophage-derived enzyme called endolysin capable of targeting biofilms formed by Enterococcus faecalis. Their findings offer hope for tailored interventions in allo-HCT. The team initiated their investigation by examining the intestinal microbiome of allo-HCT patients, where they noted a predominance of Enterococcus species, particularly E. faecalis. This was notably associated with acute leukaemia. Despite being sensitive to several antibiotics, E. faecalis strains possessed cytolysin-associated genes, indicating high virulence.

Scientists get promising results in pre-clinical trials for brain cancer treatment in India

Glioblastoma, the most common and aggressive type of cancerous brain tumour in adults, poses significant treatment challenges despite available options like surgery, radiation, and chemotherapy. Patients diagnosed with glioblastoma typically have a life expectancy of only 12–18 months post-diagnosis. Researchers at the Indian Institute of Technology (IIT) Delhi have given such patients a ray of hope with their new study. Working under the guidance of Dr Jayanta Bhattacharyya, Associate Professor, Centre for Biomedical Engineering, IIT Delhi; a PhD student named Vidit Gaur primarily conducted the study. Vidit Gaur has developed a novel nanoformulation, namely Immunosomes, that combines a CD40 agonist antibody with the small molecule inhibitor RRX-001. This innovative approach aims to enhance treatment efficacy for brain tumours, potentially offering new hope for improving outcomes in glioblastoma patients.

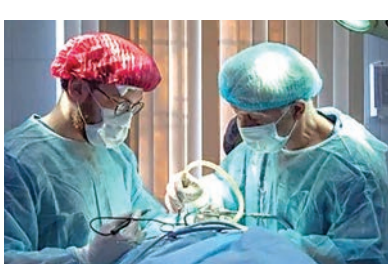


Australia creates new transparent blood vessel-on-a-chip

A University of Sydney team has successfully created a transparent microchip with the potential to reduce the testing of new drugs to treat heart disease on animals before proceeding to clinical trials. The innovative device mimics blood vessel damage due to high blood flow and inflammation, the first stage that leads to development of heart disease. The design offers a more accurate and detailed understanding of how and why blockages occur in specific locations in blood vessels. A blood vessel-on-a-chip is a small device that has tiny channels etched into it where human cells can grow, mimicking the structure and function of human blood vessels which helps scientists and doctors do tests quickly and with very little liquid. Although mice and other animals have similarities to human biology, the vessel-on-a-chip utilises real human cells and offers more manageable and cost-effective control in the lab. The Australian researchers have also developed a new more effective surface modification approach that improves the materials current microchips are made from, making them better for protein and cells to attach to compared to the traditional materials.

Researchers in Korea develop ultrasound-assisted photothermal therapy technology

Professor Jin-ho Chang's research team from the Department of Electrical Engineering and Computer Science at Daegu Gyeongbuk Institute of Science and Technology (DGIST), South Korea has developed 'Ultrasound-assisted photothermal therapy (ULTRA-PTT)' technology that significantly enhances the performance of conventional photothermal therapy. This technology was developed in collaboration with Senior



Researcher Hye-min Kim from the Advanced Photonics Research Institute at Gwangju Institute of Science and Technology (GIST) using the team's proprietary 'ultrasound-induced optical clearing' technology. Phototherapy, using light, is widely used in clinical settings for skin tightening, laser tattoo removal, and laser cancer therapy, since it can selectively improve or destroy targeted lesions. However, as light travels through biological tissues, optical scattering occurs, causing distortion of the light path and limiting the depth of light penetration.

Shimadzu partners with Tescan Group to launch Scanning Electron Microscopes in Japan

Shimadzu Corporation has concluded a business partnership agreement with Tescan Group, a leading manufacturer of scanning electron microscopes (SEM) in the Czech Republic. Tescan's SEM will be added to Shimadzu's core analytical measurement product lineup, and the product will be launched in Japan this fall, creating synergies with existing analytical and measurement instruments. Tescan products are renowned for their robustness and ease of operation, with more than 4,000 units sold in 80 countries. The Japanese SEM market was worth 17 billion yen in fiscal 2022 and has grown by more than 10 per cent in recent years. Although commonly used optical microscopes cannot observe objects smaller than the wavelength of light, SEM

enables high-resolution surface observation in nanometers (1 nm = 1/1 billion m) by using electron beams with a wavelength shorter than that of light. SEM is an essential and basic observation and analysis device for all kinds of scientific and technological research.

BD announces commercial launch of new single-cell research tool for scientists

American firm BD (Becton, Dickinson and Company), a leading global medical technology company, has announced the commercial launch of a new single-cell research tool to help scientists better understand how the molecular machinery within a cell function and how it regulates changes in a cell that can lead to cancer and other diseases. Researchers worldwide are currently using innovative approaches to study multiple aspects of health and disease at a single-cell level. In the ever-evolving field of biological research, the newly launched BD Rhapsody Single Cell ATAC-Seq (assay for transposase-accessible chromatin using next-generation sequencing) Assay enables scientists to perform single-cell analysis of the epigenome, the set of chemical marks, or epigenetic changes, on the DNA in a single cell that holds critical clues about mechanisms of disease. Commercially available globally now, the BD Rhapsody ATAC-Seq Assay, BD Rhapsody TCR/BCR Next Multiomic Assay and BD Rhapsody Intracellular CITE-seq Assay are designed to be used on the BD Rhapsody Single-Cell Analysis System – a gentle, microwell-based instrument for conducting single cell research.

Eurofins Scientific acquires Labormar, expanding presence in Latin America

The Eurofins network of companies has announced the completion of the acquisition of Labormar. The acquisition is expected to further strengthen the Eurofins network's food and feed, cosmetics, pharmacological and environmental testing offering, in addition to its presence in Latin America. Going forward, known as Eurofins Labormar, the lab represents the second Eurofins lab in Colombia. Headquartered in Barranquilla, Labormar is nationally recognised as a reference laboratory in the provision of high-quality safety and quality control tests for food and feed products, cosmetics and pharmacological products, as well as environmental management and customised consulting solutions. Labormar's 90 employees established in 10 locations, consisting of a laboratory and 9 logistics and sampling centres with nationwide coverage, support government agencies, private companies, and industrial bodies and organisations with the highest standards of quality and delivery times.

Thermo Fisher unveils fully automated plasmid purification system

US-based Thermo Fisher Scientific Inc. has introduced the Thermo Scientific KingFisher PlasmidPro Maxi Processor, the only fully automated maxi-scale plasmid DNA (pDNA) purification system. PlasmidPro enables innovation at scale, providing complete automation across mini and maxi scale purification and delivering high-purity plasmid without manual column preparation and intervention. This is the latest addition to the Thermo Scientific KingFisher instrument portfolio which offers a wide range of plasmid DNA extraction products to help drive efficiency and consistency. The PlasmidPro purification system requires no set-up, centrifugation or pipetting and completely automates the purification process from culture to plasmid. The product uses a self-contained cartridge pre-filled with all necessary reagents to perform the purification, eliminating the need for additional instrumentation and plastics while minimising set-up time and contamination risks.

Beckman Coulter brings new integrated chemistry and immunoassay analyser

Beckman Coulter Diagnostics, a clinical diagnostics leader, has introduced the new DxC 500i Clinical Analyser, an integrated clinical chemistry & immunoassay analyser. Utilising Beckman Coulter's common reagents &consumables across its scalable clinical chemistry & immunoassay portfolio, the DxC 500i Analyser enables commutable patient results, offering hospitals & healthcare networks strategic benefits in patient care & inventory management. The DxC 500i Clinical Analyser features FlexMode operations, prioritising immunoassay & chemistry testing according to each sample's urgency. The new dynamic sample handler manages repeats and re-runs without operator intervention and pulls in a new sample rack as soon as the previous rack is offloaded, optimising rapid throughput in a compact footprint.

Nikon introduces new imaging technology to accelerate biotech research

Nikon Instruments Inc., the US microscopy arm of Nikon Healthcare, is expanding its AX series lineup with the introduction of the AX R with NSPARC 2K software. This solution provides maximum resolution performance across four times the field of view. The expanded capabilities of the AX R with NSPARC Super-Resolution Confocal Microscope contribute to accelerated speed and efficiency of experiments across fundamental biology, disease research, and drug development. The Nikon Spatial Array Confocal (NSPARC) detector, combined with the AX R Confocal Microscope system, enables more precise observations with extremely low noise and exceptionally sharp image contrast. The newly updated software expands the observation range by about four times at the same magnification compared with previous products. In addition, the image acquisition speed at the same magnification is improved six-fold compared to a traditional galvano scanner. Equipped with the NSPARC detector, which provides high-speed, large field of view, high-resolution imaging capability, researchers can clearly observe even the smallest parts of cells and tissues. This enables higher-quality data analysis, deeper scientific understanding, and valuable insights into understanding the root causes of disease.

Early Detection key to Combat HCV

Globally, an estimated 50 million people have chronic hepatitis C virus (HCV) infection, with about 1.0 million new infections occurring per year. The World Health Organization (WHO) estimated that approximately 242,000 people died from hepatitis C, mostly from cirrhosis and hepatocellular carcinoma (primary liver cancer), in 2022, indicating that every day 3500 lives are lost to viral hepatitis.

With no effective vaccine against hepatitis C currently available, Direct-acting antiviral medicines (DAAs) can cure over 95 per cent of persons with hepatitis C infection, but access to diagnosis and treatment is low. A few people are diagnosed when the infection is fresh, because new HCV infections are usually asymptomatic. In people who develop chronic HCV infection, the infection is often undiagnosed because it remains asymptomatic until decades after infection when symptoms develop secondary to serious liver damage. Hence, early diagnosis can prevent health problems that may result from infection and prevent transmission of the virus. WHO recommends testing people who may be at increased risk of infection.

The WHO noted that acute HCV infections are usually asymptomatic and most do not lead to a life-threatening disease. Around 30 per cent of infected persons spontaneously clear the virus within six months of infection without any treatment. The remaining 70 per cent of persons will develop chronic HCV infection. Of those with chronic HCV infection, the risk of cirrhosis ranges from 15 to 30 per cent within 20 years.

The WHO recommends all adults have access to and be offered HCV testing with linkage to prevention, care and treatment services. The WHO noted that about 2.3 million people of the estimated 39 million living with HIV globally have serological evidence of past or present HCV infection. Chronic liver disease represents a major cause of morbidity and mortality among persons living with HIV globally.

Of the 50 million people living with HCV infection globally in 2022, an estimated 36 per cent people knew their diagnosis, and of those diagnosed with chronic HCV infection, around 20 per cent (12.5 million) people had been treated with DAAs by the end of 2022. Hepatitis C virus infection is seen in all WHO regions with South-East Asia Region (9 million) and the Western Pacific Region (7 million) people are chronically infected. Access to HCV treatment is improving but remains limited.

To provide critical support in expanding access to testing and diagnosis, accelerating global efforts to eliminate hepatitis C, the WHO has prequalified the first hepatitis C virus (HCV) self-test on July 10. The self-test version, specifically designed for use by lay users, provides individuals with a single kit containing the components that are needed to perform the self-test. The addition of this product to the WHO prequalification list provides a safe and effective way to expand HCV testing and treatment services, ensuring more people receive the diagnosis and treatment they need, and ultimately contributing to the global goal of HCV elimination.

The WHO had recommended HCV self-testing (HCVST) back in 2021, to complement existing HCV testing services in countries. The recommendation was based on evidence demonstrating its ability to increase access to and uptake of services, particularly among people who may not otherwise test. National-level HCVST implementation projects, largely supported by Unitaid, have shown high levels of acceptability and feasibility, as well as empowering people through personal choice, autonomy and access to stigma-free self-care services.

The availability of a WHO prequalified HCV self-test enables low- and middle-income countries to have access to safe and affordable self-testing options which is essential to achieving the goal of 90 per cent of all people with HCV to be diagnosed. This contributes to improving access to quality-assured health products for more people living in low-income countries.

The WHO organises annual World Hepatitis Day, which falls on July 28, campaigns to increase awareness and understanding of viral hepatitis. For World Hepatitis Day 2024, WHO focuses on the theme "It's time for action." Last year the focus was on “One life, one liver” to illustrate the importance of the liver for a healthy life and the need to scale up viral hepatitis prevention, testing and treatment to prevent liver diseases and achieve the 2030 hepatitis elimination target. BS

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