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2025 Trends

APAC's Buoying Boom Phase

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Acknowledgement/ Feedback

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- Verity, Australia

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- Julian, Australia

Thanks much for the opportunity for Orange Biomed in Diabetes Care story. We would be happy to contribute in the future.

- Shanno, US

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- Christine, Australia

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Letter from Publisher

Dear Readers,

The biological sciences, like many other industries, were in rough weather in 2024, including geopolitical crises and a declining economy. The industry has shown remarkable resilience in the face of these challenges, and there are promising opportunities for both recovery and expansion. Research and development in important fields like antibody drug conjugates (ADCs), cell and gene therapies, artificial intelligence (AI), contract development and manufacturing organisations (CDMOs), and many more are receiving large expenditures. These sectors have contributed significantly to growth this year and are anticipated to present encouraging prospects in the Asia Pacific region in the upcoming year. In our lead story, we have examined how these life sciences trends could impact the industry in 2025.

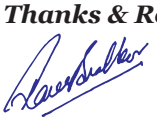
Vietnam has recognised AI's enormous potential and deemed it a crucial technology for the country's economic advancement. In order to establish itself as one of the top AI countries in ASEAN and the world by 2030, the nation has started the National Strategy on Research, Development, and Application of AI. The strategy has lofty goals, including creating three national centres for big data and high-performance computing that will be connected by a dedicated network and establishing ten well-known AI brands in the area. To facilitate AI research, development, and application across a range of economic sectors, Vietnam is poised to create about 50 publicly available datasets. As the nation takes lead in advancing AI, we have covered an article that talks about Vietnam's efforts to become an AI powerhouse and how that's transforming its healthcare sector.

Although there have been significant national and worldwide efforts to provide financial incentives for antibiotic research and development, it is still unclear how best to fortify the existing programmes to further spur antibiotic innovation. However, our correspondent in an article says that it seems like there isn't enough global coordination among all the programmes, which could lead to duplication of effort, funding gaps in the value chain, and the failure to include crucial Antimicrobial resistance (AMR) objectives.

The US Biosecure Act is expected to have positive effects on Indian pharma Contract Development and Manufacturing Organizations (CDMOs) as a result of geopolitical changes that resulted in a significant legislative shift in September 2024. This will increase demand for Indian CDMOs and CROs from US pharma companies in the coming year. Indian CDMOs can take advantage of this by improving infrastructure and regulatory procedures and lowering their reliance on China to enhance the resilience of their supply chains. Besides, in an article, an expert talks about the growth that was primarily driven by advancements made in biotechnology, personalised medicine innovations, and an expanding market for biosimilars in 2024.

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

Thanks & Regards,



Ravindra Boratkar
Publisher & Managing Editor

COVER 20

2025 Trends
Buoying Boom Phase in APAC

Like many industries, life sciences, too, faced numerous challenges in 2024, such as a slowing economy, and geopolitical conflicts. Despite these headwinds, the sector has shown remarkable resilience, with strong prospects for recovery and growth. Significant investments are being directed toward research and development in key areas such as Antibody Drug Conjugates (ADCs), Cell and Gene Therapies, Artificial Intelligence (AI) and Contract Development and Manufacturing Organisations (CDMOs) and many more. These fields have been major drivers of growth this year and offer promising opportunities. It's that time of year again when we interact with leaders from major market segments of the industry. These leaders provide their insights into what the coming year is likely to hold for their respective fields. Lets look into a few trends from life sciences that are expected to make a significant splash in 2025.

COVER

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VIETNAM

SPEAKING WITH

REGULARS

JAPAN'S PHARMA REVAMP

Dr Milind Kokje
Chief Editor
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Japan appears to be gearing up to face the problem of drug lag or drug loss. Its Ministry of Health, Labour and Welfare (MHLW) is planning to amend the Pharmaceuticals and Medical Devices Act (PMD Act) and establish a safe and rapid approval system, while implementing legal compliance and quality assurance systems to respond to new pharma technologies.

MHLW wants to address the issue of 'drug loss' that has emerged in Japan. The development of a drug approved in other countries has not been initiated in Japan causing drug lag or drug loss. Between 2010 and 2020, 265 new drugs were approved in the US or Europe. However, development of only 31 per cent of them had commenced in Japan by December 31, 2020,

Japan's share in the global market has come down sharply from 25 per cent in the 1980s to a mere 4.4 per cent in 2023. The industry attributes the decrease to Japan's drug pricing policy not justifying the development and regulatory efforts required for approvals. Thus, price reductions led to disincentive and further market stagnation.

As per the MHLW report of March 2023, among the unidentified unapproved drugs, 86 had not initiated the development process in Japan. It came down to just 82 by March 2024, the Japan Pharmaceuticals Manufacturers' Association (JPMA) has pointed out. During the same year from 2023 to 2024, the number of drug lag category products reduced from 57 to just 53. The experts attribute Japan's significant share in the pharma global market in the 1980s to the pricing system which was supportive of new products along with strong discovery capabilities.

However, the current non-availability of drugs in Japan that are approved overseas is attributed to the disincentive pricing system and more so to the country's complicated drug approval system. The researchers have identified that the necessity of Japanese data may be contributing to this drug lag since as per the drug development guidelines clinical trial data of Japanese participants is required. However, the drug development is shifting to biopharma companies based out of Japan. Hence the data of Japanese participants is not available or local trials have to be conducted to make it available.

The MHLW wants to establish a rapid but safe approval system through the amendment to the concerned act. The committee also discussed the issues of patient access to drugs with high medical necessity and improving access to pharma products when there is a lack of supply of approved drugs.

South Korea too has presented an 'innovation plan for drug approval' for similar reasons that Japan is facing. The plan aims at expediting the approval of new drugs, conducting joint reviews with foreign countries and increasing new drug approval fees from $65,220 to $297,148.

Like Japan, South Korea too is facing the problem of non-availability of new drugs. Of the new medicines launched globally since 2012, 85 per cent are available in the US. However, only 33 per cent are available in South Korea with the average waiting period for patients being 28 months. Hence, the innovation approval plan aims to shorten the review period for new drug approval to 295 days to support the rapid development of new drugs, establish a number of reviewers from the current 30 per cent to 70 per cent and establish international review standards through joint reviews with overseas regulatory authorities.

The industry feels that a 50-fold increase in fees for new drug approval will adversely affect drug development in the country as the companies will be less inclined to prioritise South Korea for new drug launches. Global companies in Korea have also demanded a moratorium on the government's innovation plan for drug approval, which is to be implemented in January next year.

The fate of such plans of countries like Japan or Korea hangs in the balance just as precariously, hinging on effective implementations of proactive policies. BS

Singapore contributes additional $10 M to pandemic fund

Minister for Health Ong Ye Kung has announced Singapore's contribution of an additional $10 million to The Pandemic Fund. The additional contribution will match Singapore's initial contribution in 2022, bringing the total to $20 million. It reflects Singapore's continued commitment to strengthen the global health architecture in preparation for the next pandemic.

The Pandemic Fund was established in 2022 to provide dedicated long-term financing to strengthen pandemic prevention, preparedness and response capabilities globally, in particular in low- and middle-income countries, so as to build a stronger global health system. Ong suggested an increased focus in two areas to maximise the impact of The Pandemic Fund. These are global surveillance, and enhancing the abilities of less developed countries to prepare for and respond to future pandemics, especially in upgrading manpower capabilities.

India launches scheme for strengthening medical device industry

To provide a big boost to the medical devices industry, the Union Minister of Chemicals & Fertilizers and Health & Family Welfare, Jagat Prakash Nadda, has launched the Scheme for Strengthening the Medical Device Industry in India. The scheme is a comprehensive one which targets critical areas of the medical device industry, covering manufacturing of key components and accessories, skill development, support for clinical studies, development of common infrastructure and industry promotion. The new scheme has a total outlay of Rs 500 crore. It consists of five sub-schemes which are as follows- Common Facilities for Medical Devices Clusters (Rs 110 crore); Marginal Investment Scheme for Reducing Import Dependence (Rs 180 crore); Capacity Building and Skill Development for Medical Devices (Rs 100 crore); Medical Device Clinical Studies Support Scheme (Rs 100 crore); and Medical Device Promotion Scheme (Rs 10 crore).

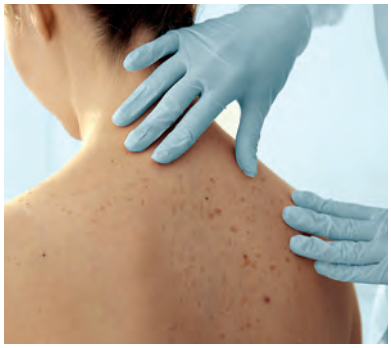
UAE partners with AstraZeneca to drive early lung cancer detection

The Ministry of Health and Prevention (MoHAP), United Arab Emirates (UAE) has signed a strategic agreement with AstraZeneca, the multinational pharmaceutical and biotechnology company, to enhance lung cancer early detection programmes across the country utilising the latest global technologies and practices. As part of the agreement, a digital lung health assessment platform will be launched, targeting high-risk groups, particularly individuals aged 50 and older who are current or former smokers. The Ministry has also

announced that a national guide for the early detection of lung cancer is being developed in collaboration with the National Committee for the Prevention and Control of Cancer. This move is in line with the Ministry's end goal of promoting non-communicable disease prevention and creating a sustainable health infrastructure in the country. Under the agreement, an integrated system for early lung cancer detection using artificial intelligence will be developed, alongside training medical staff on international best practices and implementing innovative awareness programmes targeting high-risk groups. The agreement also includes updating initiatives aimed at reducing the incidence of the disease.

Australia enhances national skin cancer screening with $10.3 M investment

The Albanese Government is investing $10.3 million to tackle the most common cancer in the sunburnt country, skin cancer. Australia has the highest rate of skin cancer in the world, with 2 in 3 people diagnosed with some form of the disease in their lifetime. It is the most commonly diagnosed cancer in Australia. More than 18,000 people last year were diagnosed with the most lethal form of skin cancer, melanoma. Early detection is essential to give Australians the best chance to treat their



skin cancer. This funding will bring together the expertise of the cancer sector and accelerate the development of a national targeted skin cancer screening roadmap. The programme will be led by Professor Georgina Long and Professor Richard Scolyer at the Melanoma Institute Australia. Melanoma Institute Australia will work in collaboration with other cancer stakeholders to research risk-based and cost-effective national screening approaches. This includes improving skin cancer data collection for the Australian Cancer Database in close collaboration with the Australian Institute of Health and Welfare.

Hong Kong approves 2 new drugs submitted under 1+ mechanism

Two new drugs submitted under the "1+" mechanism have been approved for registration in Hong Kong. These new oral drugs in two different dosages are used to treat patients with anaemia caused by chronic kidney disease, bringing more treatment options for patients and facilitating good drugs for use in Hong Kong. The Hong Kong Special Administrative Region (HKSAR) government has implemented the "1+" mechanism since November 1, 2023. New drugs used for the treatment of life-threatening or severely debilitating diseases that are supported by local clinical data and recognised by local experts are required to submit approval from one reference drug regulatory authority for application for registration in Hong Kong. According to "The Chief Executive's 2024 Policy Address", the "1+" mechanism has been extended to all new drugs, including all new chemical or biological entities and new indications, and vaccines and advanced therapy products with effect from November 1, 2024.

Korea holds training programme for vaccine and biopharma manufacturing

The Ministry of Health and Welfare in South Korea has organised four-week Vaccine and Biopharmaceutical Manufacturing Training through the Global Training Hub for Biomanufacturing in partnership with the World Health Organization (WHO) from November 11. This programme was aimed to enhance vaccine production capacity in low- and middle-income countries. While the Global Training Hub for Biomanufacturing has previously conducted regional training in partnership with organisations such as the Asian Development Bank (ADB) and Inter-American Development Bank (IDB), this session marked a significant milestone as it expands for the first time, in collaboration with WHO, providing practical training for vaccine manufacturing on a global scale. Fifty-nine participants from 27 low- and middle-income countries worldwide took part in this training, where they learnt to manufacture high-demand vaccines, such as mRNA and viral vector vaccines, in compliance with Good Manufacturing Practice (GMP) standards.

Insilico Medicine enters into revolving loan facility of up to $100 M with HSBC

Hong Kong-based Insilico Medicine, a global leading generative artificial intelligence (AI)-driven biotechnology company, has signed a Revolving Loan Facility of up to $100 million with HSBC, one of the world's largest banks and financial services institutions. The credit line, provided from HSBC New Economy Fund, will support the expansion of Insilico's proprietary novel drug discovery pipeline and the upgrade of its end-to-end diversified artificial intelligence (AI) platform, Pharma.AI. In early 2024, Insilico published a Nature Biotechnology paper presenting the entire R&D journey from AI algorithms to Phase II clinical trials of ISM001_055, the company's lead drug pipeline with AI-discovered target and AI-designed structure. Following that, Insilico has recently announced positive preliminary results from a Phase IIa trial (NCT05938920), where ISM001_055 showed favourable safety and tolerability across all dose levels, as well as dose-dependent response in forced vital capacity (FVC), after only 12 weeks of dosage.

AstraZeneca injects $1.5 B into ADC manufacturing facility in Singapore

AstraZeneca plans to hire over 800 employees in Singapore for highly skilled roles ranging from engineering, quality, technical services to global supply chain, as it begins construction of its manufacturing facility for antibody drug conjugates (ADCs), treatments that deliver highly potent cancer-killing agents directly to cancer cells through targeted antibodies. The $1.5 billion facility is targeted to be operationally ready by 2029. The new site is set to produce ADCs that can precisely target cancers, providing supply of the next-generation medicines to patients globally. AstraZeneca has a broad portfolio of in-house ADCs, with six wholly owned ADCs in the clinic and many more in preclinical development. The planned greenfield facility is AstraZeneca's first end-to-end ADC production site globally, fully incorporating all steps of the manufacturing process at a commercial scale. Manufacturing of ADCs is a multi-step process that comprises antibody production, synthesis of chemotherapy drug and linker, conjugation of drug-linker to the antibody, and filling of the completed ADC substance into vials.

GHIT Fund invests $4 M to advance diagnostics and treatments for NTDs and malaria

Japan-based Global Health Innovative Technology (GHIT) Fund has announced a total investment of approximately JPY 578 million ($4 million) in four projects for the development of new diagnostics and drugs for neglected tropical diseases (NTDs) and malaria. Trachoma remains a public health issue in 39 countries, with over 103 million people at risk of infection. In order to overcome this situation, the GHIT Fund has decided to invest approximately

JPY 280 million ($2 million) in a project led by US-based non-profit organisation Drugs & Diagnostics for Tropical Diseases (DDTD), in collaboration with Medical & Biological Laboratories (MBL) in Japan, The Carter Center (TCC, USA), and Big Eye Diagnostics, Inc. (BEDx, USA), with active support from the Centers for Disease Control and Prevention (CDC), to develop a Rapid Diagnostic Test (RDT) kit for trachoma. This is the first time for the GHIT Fund to support product development targeting trachoma. In addition, the GHIT Fund has decided to invest in three product development projects targeting malaria and Chagas disease.

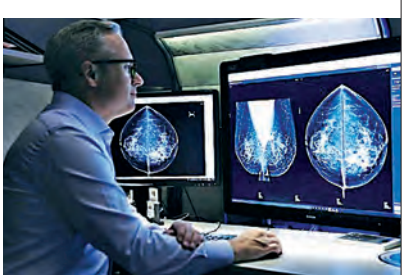
OneSource Specialty Pharma receives equity commitments of Rs 801 Cr from marquee investors

Strides Pharma Science has announced that its associate company, OneSource Specialty Pharma (formerly known as Stelis Biopharma), Group's Specialty Pharma CDMO (contract development and manufacturing organisation), has received confirmed commitments for fundraising of Rs 801 crore (~$95 million) from marquee domestic and foreign institutional investors and family offices, in the pre-listing round. The share

subscription agreements are being executed at a pre-money equity value of $1.65 billion, delivering to Strides' shareholders an embedded value of Rs 663 per share of Strides' holding in OneSource representing an ~82 per cent premium over the previous embedded value of Rs 364 per share as per the Scheme of Arrangement announced earlier in September 2023. The strong interest from leading investors reflects growing confidence in its capabilities and the immense potential of the CDMO sector emerging out of India.

Lunit company announces $7.3 M contract with US Defense Health Agency

Volpara Health, a South Korea-based Lunit company and a global leader in software for the early detection of cancer, has announced a significant contract with the US Defense Health Agency (DHA) valued at $7.3 million over five years. The contract will see Volpara's Patient Hub, an advanced mammography reporting, cancer risk assessment and patient tracking system, deployed across DHA's military health system. The goal is to modernise breast cancer screening and patient management for military personnel and their families. The DHA is part of the US Department of Defense and is responsible for healthcare services for approximately 9.6 million active-duty military members, retirees, and their families across the Army, Navy, Air Force, and Marines. Volpara's Patient Hub integrates critical aspects of breast health management, including scheduling data collection, risk assessment and mammogram tracking. These features ensure that healthcare providers can deliver personalised, timely care through automated follow-ups, reminders, and patient communications.



Samsung Biologics inks largest ever manufacturing deal of $1.24 B with Asia-based pharma

South Korea-based Samsung Biologics, a global contract development and manufacturing organisation (CDMO), has announced a contract manufacturing deal with an Asia-based pharmaceutical company. The disclosed deal, worth $1.24 billion, is the largest contract signed by a single client. Production will take place at Samsung Biologics' biomanufacturing site in Songdo, South Korea and the contract runs through December 2037. With the latest agreement, the company's accumulated contract for 2024 surpasses $3.3 billion. Samsung Biologics has now to date partnered with 17 of the world's top 20 pharmaceutical companies, and continues to expand its customer base to key regions, including Japan. In addition to sales offices in the US, the company is planning to open a regional office in Tokyo to further enhance relationships with clients. Samsung Biologics is on track to complete the construction of a dedicated ADC facility by the end of this year. A fifth plant is set to be operational in April 2025, adding a fresh capacity of 180 kL, for a total of 784 kL across Plants 1 to 5.

Takeda and Boston Medical Center to decarbonise healthcare value chain

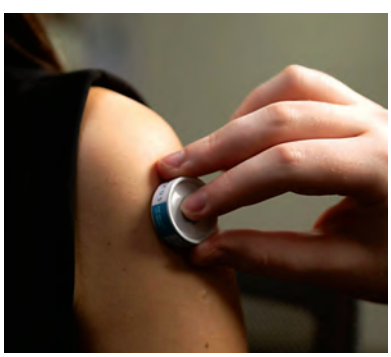
Japan-based pharmaceutical firm Takeda and Boston Medical Center (BMC) in the US have announced a new collaboration focused on identifying innovative solutions that can reduce hard-to-abate greenhouse gas (GHG) emissions in the healthcare sector. The collaboration between Takeda and BMC aims to reduce the GHG emissions caused by disposal of regulated medical waste, such as pharmaceutical packaging and single-use plastics, which are among the most difficult environmental challenges facing the industry. The effort will also seek to scale the interventions developed through the collaboration by sharing best practices to help other organisations adopt and learn new ways to decarbonise in their operations to drive wider healthcare ecosystem impact. As a part of this collaboration, BMC will conduct waste audits across key clinical areas to identify emission hotspots and pilot new technologies aimed at reducing emissions from the disposal of regulated medical waste, including pharmaceutical packaging.

Formosa Pharma marks first entry into EU market for ophthalmic therapies

Taiwan-based Formosa Pharmaceuticals has entered into an exclusive licensing agreement with DÁVI Farmacêutica in Portugal, for exclusive rights to the commercialisation of clobetasol propionate ophthalmic suspension, 0.05% (APP13007), a marketed innovative medicine for the treatment of inflammation and pain following ocular surgery. DÁVI is a trusted partner of Pharmathen Global Holding B.v., AZAD Pharma AG, NTC S.r.l. and Pfizer through marketing and promotion of Xalacom (Latanoprost + Timolol) and Xalatan (Latanoprost) for more than 12 years. DÁVI is one of the key players in the Portuguese market, with over 100 years' history in the distribution and promotion of branded ophthalmology products. Clobetasol propionate ophthalmic suspension, 0.05% (APP13007), approved by the US Food and Drug Administration (FDA) in March, 2024, was launched in the United States in September, 2024. The DÁVI licensing agreement includes upfront, commercialisation milestones, and sales milestones, with additional considerations throughout the term of the agreement.

Vaxxas licences next-gen vaccine for RSV from NIH

Australia-based Vaxxas, a clinical-stage biotechnology company commercialising a novel high-density microarray patch (HD-MAP) vaccination platform, has announced that the United States National Institutes of Health (NIH) has granted the company a licence to a next-generation vaccine antigen (DS2), designed for use in prophylactic vaccines against Respiratory Syncytial Virus (RSV). Vaxxas' worldwide licence from the NIH enables the company to create the first needle-free, room-temperature stable RSV vaccine to enter clinical studies. The next-generation DS2 RSV vaccine antigen licensed by Vaxxas was developed by scientists at the NIH's Vaccine Research Centre and the National Institute of Allergy and Infectious Diseases to prompt a more robust and durable immune response against RSV compared to the antigen used in currently approved vaccines (DS-Cav1). Vaxxas' HD-MAP vaccine delivery platform is advancing toward commercialisation, with five successful Phase I clinical trials involving more than 500 participants completed, including a second-generation COVID-19 vaccine candidate, a HD-MAP delivered flu vaccine showing greater immunogenicity than the approved injectable vaccine comparator, and a measles and rubella vaccine.

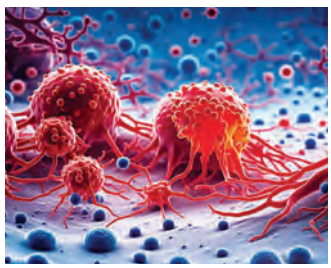


ZEISS India expands Global Capability Centre in Bengaluru

ZEISS, a globally leading player in optics and optoelectronics, has inaugurated its Global Capability Centre (GCC) in Bengaluru, India, marking a pivotal expansion to further bolster digital transformation, research and innovation efforts in India. ZEISS India GCC is a strategic hub that will tap into Bengaluru's deep IT talent pool to drive technology solutions and further expand ZEISS's global R&D capabilities. The premise spans across 43,000 sq.ft. and will accommodate 600+ employees with deep domain expertise in the field of application research for Medical Technologies, Vision care, Cyber Security, Artificial Intelligence (AI), Cloud Excellence and Digital Transformation. The company aims to double this current workforce by 2028. ZEISS India has also collaborated with the Karnataka Government to enhance the region's Research and Development (R&D) ecosystem for emerging technologies. This joint R&D initiative will support Karnataka's vibrant startup ecosystem by establishing a collaborative centre where ZEISS will contribute with its infrastructure and expertise while startups bring along the agility and disruptive innovation.

J INTS BIO launches AI-Supercomputing alliance to transform cancer therapy in Korea

J INTS BIO has signed a Memorandum of Understanding (MoU) at Baekyangnuri Plaza, Yonsei University, unveiling a groundbreaking artificial intelligence (AI)-driven collaboration to revolutionise cancer treatment. This alliance unites leading institutions, including Yonsei University College of Medicine's DAAN Cancer Research Institute, Daegu Gyeongbuk Institute of Science and Technology (DGIST), Korea Research Institute of Chemical Technology (KRICT), and Korea Advanced Institute of Science & Technology (KAIST). Using AI and national supercomputing infrastructure, the project aims to enhance drug efficacy prediction and minimise toxicity, addressing the critical challenges that plague conventional oncology drug development. The collaboration is structured around a comprehensive, four-phase research strategy-meticulous patient sample collection and preparation, AI-driven protein analysis using supercomputers, synthesis of drug candidates informed by AI insights, and rigorous clinical trials for validation.



Ring Therapeutics to establish gene therapy R&D efforts in Singapore

Ring Therapeutics, a life sciences company founded by Flagship Pioneering to revolutionise gene therapy with its commensal virome platform, has announced new strategic partnerships with the Agency for Science, Technology, and Research (A*STAR), Singapore's lead public sector R&D agency; and the Singapore Eye Research Institute (SERI) to advance innovative R&D efforts and support the continued development of the biomedical science ecosystem in the region. The A*STAR and SERI partnership will accelerate the creation of new potential treatments for eye diseases (ophthalmology) and cancer (oncology), while also improving the methods and technologies needed to produce these treatments. The collaboration will bring together synergistic expertise in scale-up manufacturing and capabilities for continued advancements of scientific breakthroughs and technological development in the region. Ring Therapeutics is revolutionising the genetic medicines and nucleic acid medicine space by harnessing the most abundant and diverse member of the human commensal virome, anelloviruses.

Seaport secures $225 M to develop neuropsychiatric medicines

The clinical-stage biopharmaceutical startup, Seaport Therapeutics, which uses a unique drug delivery platform originally developed by Australia's Monash University, has announced the closing of an oversubscribed $225 million Series B financing round. The funding syndicate was led by General Atlantic with participation from funds and accounts advised by T. Rowe Price Associates, Inc., Foresite Capital, Invus, Goldman Sachs Alternatives, CPP Investments, and other new investors. Founding investors ARCH Venture Partners, Sofinnova Investments, Third Rock Ventures, and co-founder PureTech Health also participated. The announcement comes just six months after launching with $100 million in April 2024, bringing the total capital raised by the Boston-based Seaport to $325 million. Seaport will use the proceeds to advance its clinical-stage pipeline of first and best-in-class neuropsychiatric medicines through important clinical milestones as well as further advance the capabilities of the Glyph technology platform, which has already demonstrated clinical proof-of-concept.

Neurophet secures significant foothold to accelerate entry into China market

South Korea-based startup Neurophet, an artificial intelligence (AI) solution company for brain disease, has secured a significant foothold to accelerate entry into the Chinese market. Neurophet has announced the exclusive sales agreement with Beijing LADO Technology, a leading Chinese software medical device manufacturer, for its brain PET image analysis (PET tracer deposition) software 'Neurophet SCALE PET' and confirmed the establishment of a joint venture in China. Neurophet plans to expedite Chinese market entry and obtain essential regulatory approvals through the sales agreement of Neurophet SCALE PET with LADO and the joint venture. Neurophet SCALE PET quantitatively analyses biomarkers labelled with radioactive tracers using PET (positron emission tomography) images.

Eisai Innovation to strengthen programme for pharma startup ecosystem

Eisai Co. and Eisai's corporate venture capital subsidiary, Eisai Innovation, Inc. have announced that Eisai Innovation, Inc. has been selected as a registered venture capital of the Strengthening Programme for Pharmaceutical Startup Ecosystem implemented by the Japan Agency for Medical Research and Development (AMED). To address the shortage of large-scale funding necessary for new drug development, this programme provides subsidies to pharmaceutical startups for development and commercialisation. This support is contingent upon startups securing funding from AMED-registered venture capital firms, which specialise in drug development and offer hands-on business management and commercialisation support. The Eisai global network of affiliated companies (the Eisai Group) launched its venture investment business in May 2019, aiming to support the acceleration of drug discovery innovation and the establishment of an ecosystem platform in areas including dementia. This involves supporting the discovery of innovative technologies and services by supporting venture businesses with such capabilities and exploring possible future collaborations with these businesses.

MicrobioTx unveils first fingerprick-based test to profile gut microbiome

India-based startup MicrobioTx, a new-age gut microbiome company, has announced the commercial availability of Gut Function Test (GFT) that profiles gut microbiome with just a few blood drops. With this test, gut microbiome profiling, which was earlier only possible by stool sample, will now be possible with a finger-prick without the need of collecting stool sample. MicrobioTx's GFT is clinically validated in trials at leading Indian research institutes and has been recently approved by the Indian regulator. The commercial launch of the MicrobioTx's GFT is supported by a grant from DPIIT through the Institute of Life Science, Bhubaneshwar. Scientific evidence has established that a good gut microbiome could set the foundation for good health, such as better weight management, stronger immunity, and other physiological functions. This breakthrough test solution, developed after three years of intense research, allows users to gain valuable insights into their gut health at a fraction of the cost, making it a smart and affordable choice for everyone.

NTU launches S$50M Nanyang Frontier Fund to support deep tech spin-offs

Nanyang Technological University, Singapore (NTU Singapore) and leading global venture capital (VC) firm Walden International are launching a new VC fund to support deep tech spin-offs from the university. Known as the Nanyang Frontier Fund, it has an initial target sum of S$50 million. The Nanyang Frontier Fund is Singapore's first venture capital fund dedicated to a university. Tan Lip-Bu, Chairman of Walden International, and his associates are committing an investment of S$5 million to kickstart the fund, with NTU co-investing another S$5 million. Tan Lip-Bu is a globally renowned venture capitalist with almost four decades of experience in the tech industry. Dubbed the "pioneer of Asian VC" by Forbes for pioneering the US venture capital concept in Asia, he has been instrumental in the success of numerous global tech startups. The Nanyang Frontier Fund will fuel innovation and enterprise building and increase investor confidence in NTU's spin-offs, contributing to Singapore's reputation as a hub for technology-driven entrepreneurship.

Merck announces winners of Emerging Biotech programme in APAC

Merck, a leading science and technology company, has announced the winners of its Emerging Biotech (EB) Grant Programme in Asia Pacific (APAC). The award is designed to support biotech startups with resources to enable emerging companies to discover, develop, optimise, and commercialise therapeutics faster and more efficiently. Southern RNA for enabling the manufacturing of mRNA for personalised medicines emerged as the winner in Australia & New Zealand; Other winners include- Institute for Drug Technology for enabling the manufacturing of antibody-drug conjugates; Psaio for developing bispecific antibodies targeting prostate-specific antigen to treat prostate cancer; and Kimer Med for developing a family of broad-spectrum antiviral biologics to treat infectious diseases, and for pandemic protection. In Taiwan, HanchorBio emerged as the winner for developing clinical-stage and next-generation immuno-oncology therapies through innovation in cutting-edge designer biologics with novel, multi-functional modalities; Other winners include- Pell Biomed Technology for developing more efficient and cost-effective gene-modified cell therapies; Glyconex for glycan-directed cancer therapies including antibody-drug conjugates to treat a range of solid tumors such as gastrointestinal cancers; and Shine-On BioMedical for developing targeted exosomes as a platform for drug delivery as well as tri-specific antibody for cancer treatment.

WHO lists additional mpox diagnostic tests for emergency use

As part of ongoing efforts to enhance quality-assured testing options, the World Health Organisation (WHO) has listed two additional mpox in vitro diagnostics under its Emergency Use Listing (EUL) procedure. WHO's EUL is based on the review of quality, safety and performance data in compliance with international standards while addressing the specific needs of low- and middle-income countries (LMICs). Polymerase Chain Reaction (PCR) testing, which detects viral DNA, is considered the gold standard for diagnosing mpox infection. WHO listed the Xpert Mpox, a real-time PCR test manufactured by Cepheid under its EUL procedure, on October 25, 2024 Another PCR-based option, the cobas MPXV assay, developed by Roche Molecular Systems, Inc., was listed on October 14, 2024. It is intended for use on the cobas 6800/8800 Systems. This tool is a real-time PCR test capable of detecting both mpox clades and delivering results in under 2 hours. WHO previously listed Alinity m MPXV assay, manufactured by Abbott Molecular Inc. under EUL on October 3. WHO is working with manufacturers of the EUL-listed products and national regulatory authorities in affected countries to facilitate domestic registration or emergency listing.

WHO study lists top endemic pathogens for which new vaccines urgently in need

A new World Health Organisation (WHO) study names 17 pathogens that regularly cause diseases in communities as top priorities for new vaccine development. The WHO study is the first global effort to systematically prioritise endemic pathogens based on criteria that included regional disease burden, antimicrobial resistance risk and socioeconomic impact. The study reconfirms longstanding priorities for vaccine research and development (R&D), including for HIV, malaria, & tuberculosis – three diseases that collectively take nearly 2.5 million lives each year. The study also identifies pathogens such as Group A streptococcus & Klebsiella pneumoniae as top disease control priorities in all regions, highlighting the urgency to develop new vaccines for pathogens increasingly resistant to antimicrobials. Pathogens where vaccine research is needed include- Group A streptococcus, Hepatitis C virus, HIV-1, Klebsiella pneumoniae; Pathogens where vaccines need to be further developed include- Cytomegalovirus, Influenza virus (broadly protective vaccine), Leishmania species, Non-typhoidal Salmonella, Norovirus, Plasmodium falciparum (malaria), Shigella species, Staphylococcus aureus; & Pathogens where vaccines are approaching regulatory approval, policy recommendation or introduction include- Dengue virus, Group B streptococcus, Extra-intestinal pathogenic E. coli, Mycobacterium tuberculosis, & Respiratory syncytial virus (RSV).

Egypt receives malaria-free certification by WHO

The World Health Organisation (WHO) has certified Egypt as malaria-free, marking a significant public health milestone for a country with more than 100 million inhabitants. The achievement follows a nearly 100-year effort by the Egyptian government and people to end a disease that has been present in the country since ancient times. Egypt is the third country to be awarded a malaria-free

certification in the WHO Eastern Mediterranean Region following the United Arab Emirates and Morocco, and the first since 2010. Globally, a total of 44 countries and 1 territory have reached this milestone. Certification of malaria elimination is granted by WHO when a country has proven, beyond reasonable doubt, that the chain of indigenous malaria transmission by Anopheles mosquitoes has been interrupted nationwide for at least the previous three consecutive years. A country must also demonstrate the capacity to prevent the re-establishment of transmission.

Sudan rolls out first malaria vaccines

Sudan's Federal Ministry of Health, in partnership with the United Nations Children's Fund (UNICEF), the World Health Organization (WHO) and Gavi, the Vaccine Alliance, has rolled out malaria vaccines for the first time in the country to bolster efforts to protect children from the deadly disease. The launch followed the arrival of the first consignment of 186,000 doses of malaria vaccines to Sudan in October. The vaccinations began in health facilities in 15 localities in the Gedaref and the Blue Nile states, benefitting more than 148,000 children under the age of 12 months. In 2025 and 2026, the vaccine will be introduced in 129 localities across Sudan. Sudan is among the first African countries, and the first in the WHO Eastern Mediterranean Region, to introduce the malaria vaccine, a remarkable accomplishment in a country grappling with an ongoing conflict. Recommended for children aged 5 to 12 months, the vaccine is expected to reduce child hospital admission & mortality from the disease.

Pandemic Fund allocates second round of grants to boost preparedness in 50 countries

Concluding its second funding round, the Pandemic Fund's Governing Board has approved $418 million in new grants designed to bolster pandemic prevention, preparedness, and response (PPR) capacities in 40 countries across six geographical regions. These grants will provide much-needed investments to strengthen disease surveillance and early warning systems, upgrading laboratories, and building health workforce. This latest allocation is in addition to the $128.89 million approved in September for five fast-tracked projects to support 10 countries impacted by the mpox Public Health Emergency of International Concern (PHEIC), bringing the total funding awarded under the second round to $547 million, which will mobilise an additional $4 billion for investments in PPR in benefiting countries. Over 50 per cent of the funds awarded under the second round are for countries in sub-Saharan Africa – the region with the highest demand for Pandemic Fund grants. Over 74 per cent of the funded projects will benefit low- and lower-middle income countries.

Immune-boosting bacterial platform to aid nasal vaccines

Researchers at Swedish biotech company Abera Bioscience are set to test whether their bacterial-based platform could strengthen intranasal vaccines being developed to protect against epidemic and pandemic threats. Supported by a new grant of up to $1 million by Norway-based Coalition for Epidemic Preparedness Innovations (CEPI), Abera Bioscience will investigate the role of bacterial outer membrane vesicles (OMVs) in boosting a special type of protection, known as mucosal immunity, which scientists believe could be key to stopping the

onward transmission of viruses. Unlike traditional vaccines, which are commonly injected into muscle, vaccines inhaled into the lungs or sprayed into the nose (the mucosal route) could induce this special type of protection. Abera Bioscience researchers will use the new CEPI funding to decorate OMVs, developed on its proprietary vaccine platform, BERA, with antigens produced by cell-free-production methods, resulting in new immune-boosted nasal vaccine sprays and powders. The BERA platform enables decoration of OMVs with antigens into one particle, by contrast with existing OMV vaccines consisting of a mix of OMVs and antigens. In this project, flu vaccines will be tested for proof-of-concept in preclinical models and the level of immunogenicity induced during the testing will be benchmarked against currently approved flu vaccines.

PAHO to facilitate access to maternal vaccines to protect babies from respiratory syncytial virus

Starting in the first quarter of 2025, the Pan American Health Organisation (PAHO), through its Regional Revolving Funds, will provide countries of the Americas with affordable access to the vaccine against respiratory syncytial virus (RSV), a leading cause of paediatric hospitalisation and death from respiratory infections during the first six months of life. Each year, around 13 million children are born in the region who could benefit from this measure if the vaccine is offered to pregnant women. In November 2023, the PAHO Technical Advisory Group (TAG) recommended administering the vaccine to pregnant women between 32 and 36 weeks of gestation. This strategy ensures effective protection for the newborn and reduces the risk of preterm birth. Maternal antibodies provide protection against RSV for approximately six months after birth, when the risk of severe disease is highest. Currently, only one vaccine has been approved by the World Health Organization (WHO) to prevent RSV-related diseases in infants. Countries in the region that request it will be able to access it through PAHO next year.

African CDC unveils new digital health platform for Africa

As the use of digital tools for effective healthcare delivery gradually takes foothold in Africa, the Africa Centres for Disease Control and Prevention (CDC) has unveiled a new platform that caters for differing needs in technology, including access, cost and infrastructure to member states. The digital exchange platform named 'The Africa HealthTech Marketplace' which showcases targeted, accessible digital health solutions is a collaborative effort between African CDC and the Digital Impact Alliance (DIAL). The platform provides an opportunity for government technologists, policymakers, and health professionals to navigate, evaluate and implement the right solutions for their respective communities. It simplifies digital transformation by cataloguing online tools, products and resources from trusted sources. These resources are used by governments, development actors and policy decision-makers to improve health outcomes.

UK to create world-first 'early warning system' for pandemics

The United Kingdom (UK) will create the world's first real-time surveillance system to monitor the threat of future pandemics, prevent disease and protect the public. Plans have been announced to form a new partnership between the government, Genomics England, UK Biobank, NHS England and Oxford Nanopore - a UK-headquartered, world-leading life sciences company. Oxford Nanopore uses long read sequencing technology to analyse genes and pathogens to rapidly diagnose a range of cancers, along with rare and infectious diseases. The technology can sequence long strands of DNA or RNA in one go, without breaking it up into smaller fragments. In infectious diseases, Oxford Nanopore's technology will help to create an early warning system for future pandemics and potential biological threats, both preventing disease and protecting the public. It will be used in the expansion of NHS England's Respiratory Metagenomics programme, being led by Guy's and St Thomas' NHS Foundation Trust. It uses samples from patients with severe respiratory infections and rapid genetic testing to match those patients with the right treatments within 6 hours.

2025 Trends
Buoying Boom Phase in APAC

Like many industries, life sciences, too, faced numerous challenges in 2024, such as a slowing economy, and geopolitical conflicts. Despite these headwinds, the sector has shown remarkable resilience, with strong prospects for recovery and growth. Significant investments are being directed toward research and development in key areas such as Antibody Drug Conjugates (ADCs), Cell and Gene Therapies, Artificial Intelligence (AI) and Contract Development and Manufacturing Organisations (CDMOs) and many more. These fields have been major drivers of growth this year and offer promising opportunities. It's that time of year again when we interact with leaders from major market segments of the industry. These leaders provide their insights into what the coming year is likely to hold for their respective fields. Lets look into a few trends from life sciences that are expected to make a significant splash in 2025.

Antibody Drug Conjugates (ADCs) in Stoplight

ADCs, touted as 'magic bullets' for targeted cancer therapies, are having a moment. All the major biopharma firms have announced acquisitions, investments, or partnerships in this space, with new deals emerging practically every day. In 2024, the Asia-Pacific region (APAC) witnessed significant activity in this space. The year began with Swiss giant Roche signing a billion-dollar licensing agreement with Chinese startup MediLink Therapeutics for its lead candidate YL211, which targets c-Mesenchymal epithelial transition factor (c-Met) to combat solid tumours. More recently, on November 7, 2024, AstraZeneca held a groundbreaking ceremony in Singapore to commemorate the expansion of its new ADC manufacturing facility, the largest in the Asia-Pacific region.

Chinese companies are leading the ADC trend, accounting for half of the top ten developers, as they seek to capitalise on potential returns, according to Global Data. All the big pharma companies have inked a deal in this space with Chinese biotech companies. Some of the important deals include Bristol Myers Squibb, in collaboration with SystImmune, entered an exclusive agreement to jointly develop and commercialise BL-B01D1, an innovative EGFRxHER3 bispecific antibody-drug conjugate. SystImmune is spearheading efforts in Mainland China, while Bristol Myers Squibb oversees developments elsewhere. GSK strategically fortified its oncology portfolio by acquiring Hansoh Pharma's gynaecologic cancer candidate (HS-20089), showcasing a commitment to addressing specific cancer types. In a clinical trial collaboration agreement, Eisai and China-based Bliss Biopharmaceutical partnered for BlissBio's ADC candidate targeting Human Epidermal Growth Factor Receptor 2 (HER2) in cancer treatment. AstraZeneca joined the ADC surge with the acquisition of China-based LaNova Medicines, gaining access to LaNova Medicines' preclinical candidate LM-305, focused on relapsed and refractory multiple myeloma.

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

ADCs have offered a stronger hope that the elusive cure for cancer will finally be on the horizon and biotech firms will continue to bet big on this in the coming year.

Cell and Gene Therapies (CGT) Remains Hot

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

Yescarta, developed by Fosun Kite, and relma-cel, from JW Therapeutics, stand as China's first regulatory-approved CAR-T cell therapies, heralding a new era for the industry. A notable achievement is cilta-cel, developed by Legend Biotech, which has successfully gained US FDA approval, marking its global recognition. While India lags behind China in the production of cell and gene therapies, a wave of new biotech startups is emerging to address this challenge. Organisations like Immuneel Therapeutics and ImmunoACT are currently developing CAR-T cell therapies. ImmunoACT's NexCAR19 therapy received approval from India's Central Drug Standards Control Organisation (CDSCO) for treating relapsed or refractory B-cell lymphomas and leukaemia. This approval positions

3 trends to gain traction in 2025

« **Zhao Lijian,**
CEO,
BGI Genomics,
China

1. AI's Future Integration into Clinical Practice: In the coming years, AI will become seamlessly integrated into healthcare, transforming both disease detection and patient care. Advanced neural network models trained on multi-omics data will enhance our ability to predict diseases with unprecedented accuracy, making diagnostics faster and more reliable. The rise of human-machine interactions through telehealth will revolutionise medical consultations. Imagine a future where Large Language Models, like ChatGPT, provide instant, accurate medical advice, easing the burden on healthcare professionals and drastically reducing patient wait times from weeks to mere moments.

2. AI-Integrated Multi-omics-Based Disease Risk Prediction Models: AI-powered models are increasingly being used for the early prediction and prevention of major diseases, such as malignant tumours and severe cardiovascular conditions. By integrating multi-omics data—spanning across genomics, proteomics, transcriptomics, epigenomics, metabolomics, and microbiomes—these models recreate digital representations of biological processes. This digitalisation allows for the simulation of disease progression and the effects of various interventions, using machine learning to tailor personalised treatment solutions. This approach gives clinicians critical insights for selecting the most effective treatment strategies while minimising unnecessary side effects and reducing patient suffering.

3. Proactive Health Monitoring model: The future of healthcare is moving beyond treatment and diagnostics to proactive health management. Our vision involves creating a comprehensive health model for continuous individual monitoring, integrating imaging data, multi-omics diagnostics, and lifestyle information to establish a "life index." BGI Genomics has developed such a proactive health system model, which represents a groundbreaking approach to disease prevention and personalised health management. This holistic index provides a detailed view of an individual's health risks and outcomes, empowering proactive and informed health management. BS

ImmunoACT to lead India's indigenous CAR-T cell therapy efforts, with NexCAR19 undergoing Phase II trials for other lymphomas and leukaemia types.

In 2025, we anticipate a surge in approvals for cell and gene therapies. Oncology is expected to remain the dominant area, driving significant advancements and accounting for 44 per cent of the CGT market by 2029. Other therapeutic areas, including neurodegenerative, autoimmune, and cardiovascular diseases, are poised to benefit from the continued growth of CGT.

Indispensable Artificial Intelligence (AI)

Artificial Intelligence (AI) has touched every industry, and the pharmaceutical sector is no exception. Companies in APAC are embracing AI for tasks like hypothesis generation from literature and biological data, target identification for various diseases, novel molecule design, clinical pharmacology, trial enrollment and analysis, personalised medicine etc.

AI has become an indispensable part of drug discovery and AI-driven drugs are already in the clinic. Recently, Insilico Medicine received US FDA approval for its Investigational New Drug (IND) application for ISM3412, a small molecule inhibitor targeting MAT2A to treat MTAP-deleted cancers. This drug was designed using Insilico's generative AI platform, marking a significant milestone in AI-conceived drug development. As 2025 approaches, AI's role in drug discovery will continue to grow, bringing us closer to the reality of AI-designed drugs receiving regulatory approval and entering the market.

"Multimodal generative reinforcement learning will continue to be the main trend in life sciences in 2025 dramatically improving productivity in drug discovery and development. I hope to see the previous record of 9 months from the start of a new preclinical programme to preclinical candidate nomination broken. This may coincide with the trend toward deregulation across the board with

Sustainability continues to gain significant attention in 2025

From the emergence of recombinant DNA technology in the 1970s to advancements in monoclonal antibodies and large-scale screening methods in the 1990s, the biotech and life sciences industries have continually evolved. Since the 2000s, the focus has shifted toward genetic testing techniques, alongside advancements in automation and miniaturisation, such as microarrays and sensors.

Today's prominent trends include the rise of gene and cell therapies, which enable individualised (personalised) medicine and Companion Diagnostics, as well as RNA therapeutics. The intelligent use of digital data and information in a globalised world is also key, leveraging AI-powered data analysis, cloud-based storage, and the Internet of Things (IoT). Sustainability has also gained significant attention, with "green" packaging and manufacturing attempting to lower energy and resource consumption for a lower carbon footprint.

It will be interesting to see how the scientific innovations and technology applications today will transform medical devices or pharmaceutical products in the future. However, with each innovation comes the need for regulatory oversight. For instance, the EU Artificial Intelligence (AI) Act, approved by the EU Parliament in March 2024, seeks to safeguard fundamental rights, democracy, the rule of law, and environmental sustainability against high-risk AI applications.

« **Dr Oliver Eikenberg,** Global QA/RA Manager, Pure Global, Germany

Now, more than ever, qualified regulatory experts are essential to guide manufacturers through the complex landscape of emerging regulations. Smart solutions are also crucial for streamlining processes in manufacturing, enhancing efficiency in operations and documentation, and ensuring compliance with regulatory standards. We have taken steps on this journey by incorporating tools like the Pure Global Resource Center into our daily regulatory processes, improving efficiency, and ensuring alignment with evolving standards. BS

regulators recognising the opportunity to provide a larger number of high-quality drugs to patients in need faster and advancing the most promising programmes developed using AI to boost industry performance," said Dr Alex Zhavoronkov, Founder and CEO of Insilico Medicine, China.

Apart from this, experts are especially bullish on the role of AI in improving clinical trials. "By the end of 2025, artificial intelligence will transform clinical operations, dramatically improving efficiency and productivity. Already, generative AI enables the automation of labour-intensive tasks but there is also promise in predictive analytics, which can leverage historical and real-time clinical operations data to forecast outcomes, optimise resource allocation, and streamline timelines. AI will also soon be used more to extract key information from protocol documents to populate downstream systems, reducing manual entry errors and increasing speed. This same data will also start to be used to auto-generate study calendars based on the schedule of assessments, streamlining trial planning," said Dr Jeff Sidell, Chief Technology Officer, Advarra, USA. Advarra provides integrated solutions that safeguard trial participants, empower clinical sites, ensure compliance, and optimise research performance.

Additional use cases that will become more common this year include using AI to analyse past trials and recommend improvements based on data patterns. Site selection will also benefit from AI by identifying optimal sites with the greatest likelihood for patient recruitment success, considering factors like demographics, past performance, and patient availability.

"In 2025, the life sciences industry will finally witness the realisation of AI's promise in clinical trials, moving beyond years of hype to tangible, industry-wide transformation. This is the year AI converges with SaaS tools to redefine the clinical trial process entirely, shifting from a service-heavy, project-based model to a scalable, technology-first

Japan to witness shift in Innovation, Leadership and Talent

Elsie Zhang,
Senior Client Partner, Korn Ferry, Tokyo and a member of Global Life Sciences Practice & Global Industrial Practice

The life sciences and healthcare industry has undergone significant evolution over the past three to four years. A clear trend has emerged: companies are divesting non-core businesses while heavily investing in innovative technologies and scientific advancements to strengthen their core operations. This shift aims to address unmet market needs and focus on specialised treatments.

In response, organisations are driving transformations to become more productive, efficient, and dynamic. Companies and hiring managers are increasingly seeking talent that is dynamic, multifunctional, and creative in their approach. Business acumen and people leadership have become essential competencies for new leaders in this evolving landscape. Previously, scientific and technical leaders were primarily valued for their expertise in their fields. Now, there is a growing demand for leaders who can bridge the gap between science and business, driving both innovation and commercial growth. Leadership styles are also shifting from traditional top-down approaches to more coaching-oriented and empathetic management that prioritises care and collaboration.

In Japan, a highly talent-driven market, attracting and retaining top-tier bilingual candidates is crucial. Companies must provide attractive career paths, a psychologically safe work environment, and competitive compensation packages. Strong technology and innovative products remain critical. Additionally, some organisations are hiring professionals from outside the healthcare and life sciences industries to introduce fresh perspectives and dynamic thinking. Bilingual, non-Japanese talent is also increasingly welcomed in the market. BS

paradigm. Key innovations, like fully automated and error-free protocol builds, will enable therapy sponsors to embrace hyper-adaptive trial designs that evolve in real time. This is not just about efficiency—it's about reimagining the critical path in ways never seen before. Trials that once took years to plan and execute will be built and optimised in weeks, driven by AI tools that offer unprecedented speed, precision, and scalability," said Dr Michelle Longmire, CEO & Co-Founder, Medable, USA.

Medable is a platform technology company committed to accelerating drug development by improving evidence generation in clinical trials. It serves the biopharmaceutical industry and is utilised by leading drug developers worldwide.

Ruling the Roost in Clinical Trials

The APAC region continues to rule the roost in clinical trials, experiencing dramatic growth rates surpassing those in the US and Europe. Various reports highlight APAC's emergence as a pivotal hub for clinical trials, with almost half of the world's trials now conducted in the region. The area's abundant patient population makes it a prime choice to start cutting-edge trials across a range of diseases, and since 2021 it has surpassed the rest of the world in the number of clinical trials that it annually hosts.

"From 2019 to 2023, the percentage of clinical trials in APAC countries (including Australia/Oceania) rose from 44 to 55 per cent and 2025 will continue to see APAC come out on top. The most impactful life sciences trend in 2025 will be the Asia-Pacific region's normalisation as a leader in advanced clinical trials on the world stage," said Dr Annie Siu, Director of APAC Content, Citeline, Hong Kong.

China will be the major driver of this growth story. "China will continue to drive the growth of clinical trials in the APAC region, attracting trials for innovative therapies and numerous domestic industry sponsors. From 2019 to 2023, the percentage of global Phase I-IV trials starting in China jumped from 25 to 39 per cent, making it the top trial location globally in 2020. Innovative therapies and domestic industry sponsors are the key drivers for China taking an increasingly large

Resurgence of blood-based treatments as essential medicine

Blood-based treatments are experiencing a resurgence as foundational therapies in medicine. Historically, blood transfusions and plasma therapies have been used to treat a wide range of conditions, from trauma-related blood loss to autoimmune diseases. Today, these treatments are seeing renewed importance as medical research highlights the complex interactions of circulating blood components and their impact on immune modulation, inflammation, and chronic disease management.

Therapies like plasma exchange (TPE) and convalescent plasma transfusions are gaining prominence for their ability to reduce disease severity in complex, multifactorial conditions. TPE, for instance, removes a spectrum of harmful molecules, including cytokines, antibodies, and inflammatory proteins, which can be particularly beneficial in autoimmune diseases, where standard drugs may not fully control immune responses. Similarly, in infectious disease management, convalescent plasma—rich in antibodies from recovered patients—has been used to aid patients with severe infections by providing immediate, passive immunity.

In the realm of cell and gene therapy, blood-derived products are also essential as carriers of engineered cells and vectors, further reinforcing their role in advanced therapeutic approaches. With innovations in blood purification, such as selective pathogen and toxin removal, blood-based treatments are expanding beyond traditional uses and showing potential in managing both chronic and emergent diseases. Moreover, these therapies will further shift away from traditional, advanced care centres to centres in proximity to patients. Almost in their backyard. These advances underscore the central role of blood-based therapies in modern healthcare, not only as standalone treatments but as integral components of personalised medicine and immune modulation, solidifying their place as a cornerstone of essential medicine. BS

« **Koenraad Dierick,** Vice President Patient Access, Terumo Blood and Cell Technologies, Japan

share of global clinical trial activity, with recent regulatory reforms and listing rule changes acting as 'rocket propellant' for this growth," said Dr Annie Siu.

Within the APAC region, the most impactful trend for 2025 will be its growing dominance in oncology trials. Even though oncology continues to be the therapeutic area with the most drugs under development worldwide, 30 per cent of trials initiated in the APAC region from 2019 to 2023 were oncology trials, while only 19 per cent of trials were focused on oncology in the rest of the world.

"In 2025, APAC is expected to maintain its lead in oncology trials because of its large treatment-naïve patient pool. From 2019 to 2023, approximately 63 per cent of oncology trials with treatment-naïve patients were carried out in the APAC region and, despite worldwide decreases in trials for this segment as it becomes increasingly competitive, APAC is still slated to have an advantage in oncology because of the number of treatment-naïve patients it still has to offer. Pharmaceutical companies may also choose to conduct clinical trials for less common types of cancer in APAC due to the high rates of occurrence and death associated with these diseases in comparison to Western countries, making it a lucrative market to study treatments for emerging forms of cancer and fast-track new treatments for common cancers," said Saakshi Gupta, Senior Analyst, Oncology, Citeline, USA.

It's not just the increasing number of trials held in this region that will cement it as a world leader in clinical trials; APAC has surpassed Western countries in the scale and scope of clinical trials, thus solidifying its appeal to both local and global pharmaceutical firms seeking strategic advantages.

China's Biopharma Boom

Over the past decade, Mainland China's biopharmaceutical sector has rapidly advanced to become a global leader in innovation, ranking

"Biopharma industry executives are going to have to figure out how to minimise any risks associated with the heightened geopolitical tensions that may be triggered by the proposed BIOSECURE Act. A reduction in US-Mainland China biopharma collaborations could be a boon for European pharma and biotech companies."

- Michael Ward,
Global Head of Thought Leadership, Life Sciences & Healthcare, Clarivate, England

"In 2025, the life sciences industry will finally witness the realisation of AI's promise in clinical trials, moving beyond years of hype to tangible, industry-wide transformation. This is the year AI converges with SaaS tools to redefine the clinical trial process entirely, shifting from a service-heavy, project-based model to a scalable, technology-first paradigm."

- Dr Michelle Longmire,
CEO & Co-Founder, Medable, USA

"The BIOSECURE Act and less reliance on China's supply chain is expected to especially benefit Indian CDMO companies. India pharma is well recognised globally for quality generics. In the future, we will see massive growth of Indian CDMO companies due to evolving opportunities amid the BIOSECURE Act and less reliance on China's supply chain by the US and Europe-based pharma companies."

- Prashant Khadayate,
Director – Lifesciences Consulting & Research, GlobalData, India

"In 2025, global drug shortages and limited patient access to advanced therapies will remain critical challenges in the life sciences industry. Addressing these issues requires a shift towards decentralised manufacturing models, where therapies like CAR-T can be produced closer to the point of care to provide higher quality and better economics."

- Kevin Kyle,
Chief Executive Officer, Germfree, USA

among the top three for initial drug launches. Driven by reforms, increased investment, and progressive policies, the industry has reduced approval timelines, raised regulatory standards, and improved patient access to advanced therapies.

Insights from the Institute for Scientific Information show that China's Gross Expenditure on Research and Development has grown 3.5 times over the past decade, outpacing growth rates in the UK and the U.S. These developments, combined with an evolving healthcare reimbursement system, have enabled both domestic and multinational companies to bring new therapies to market, benefiting millions of patients, according to the Clarivate report.

China has approved 113 innovative drugs since the start of its 14th Five-Year Plan in 2021, according to data presented at a forum in Shanghai on the development of the domestic pharmaceutical industry, as reported by the South China Morning Post. In 2024 alone, 37 innovative drugs and 51 medical devices were approved for sale, according to data from the Ministry of Industry and Information Technology shared at the forum.

The growing importance of China in the global biotech sector is clear, as major pharmaceutical companies increasingly invest in the country. For example, in November 2024, Pfizer announced plans to invest $1 billion in China by 2030, focusing on accelerating innovation, improving diagnostics, and supporting the local biotech ecosystem.

In October 2024, Eli Lilly China committed approximately RMB 1.5 billion to upgrade its Suzhou plant, expanding the production of innovative drugs for type 2 diabetes and obesity. This investment is part of Eli Lilly's largest global capacity expansion in history. Since 2022, the

"By the end of 2025, AI will transform clinical operations, dramatically improving efficiency and productivity. Already, generative AI enables the automation of labour-intensive tasks but there is also promise in predictive analytics, which can leverage historical and real-time clinical operations data to forecast outcomes, optimise resource allocation, and streamline timelines."

- Dr Jeff Sidell,
Chief Technology Officer, Advarra, USA

company has doubled its global production capacity for incretin injection drugs. The investment will further accelerate capacity growth and ensure a steady supply of these critical drugs. Additionally, Eli Lilly is expanding its innovation presence in Beijing, opening two new research centres: the China Medical Innovation Center and Lilly Gateway Labs. The newest Gateway Lab is the second outside the U.S., following a recently announced European branch in the UK These innovation incubators offer flexible partnerships, allowing researchers to leverage Lilly's resources and expertise during drug development.

In September 2024, Bayer opened a life sciences incubator in Shanghai, citing China's innovation capabilities as 'among the world's top two.' In August 2024 Roche Diagnostics announced a $420 million investment to expand its manufacturing site in Suzhou, marking its largest single investment to date.

CDMO Digital Revolution

As the pharma industry shifts from generic to personalised medicines, traditional manufacturing systems, designed for large-scale, standardised production, struggle to keep pace. To address this, the industry is embracing AI and machine learning to create smarter, more agile manufacturing solutions.

"In 2025 and beyond, we expect to see a step-change in the re-examination of business models to build a culture of standardisation, leveraging AI, digital systems and new workplace processes to reduce the time it takes to move from research to development, to clinical manufacturing, to full-scale commercial manufacturing and distribution. We are already seeing industry innovators coming

"China will continue to drive the growth of clinical trials in the APAC region, attracting trials for innovative therapies and numerous domestic industry sponsors. From 2019 to 2023, the percentage of global Phase I-IV trials starting in China jumped from 25 to 39 per cent, making it the top trial location globally in 2020."

- Dr Annie Siu,
Director of APAC Content, Citeline, Hong Kong

"Pharmaceutical companies may also choose to conduct clinical trials for less common types of cancer in APAC due to the high rates of occurrence and death associated with these diseases in comparison to Western countries, making it a lucrative market to study treatments for emerging forms of cancer and fast-track new treatments for common cancers."

- Saakshi Gupta,
Senior Analyst, Oncology, Citeline, USA

"In 2025 and beyond, we expect to see a step-change in the re-examination of business models to build a culture of standardisation, leveraging AI, digital systems and new workplace processes to reduce the time it takes to move from research to development, to clinical manufacturing, to full-scale commercial manufacturing and distribution. We are already seeing industry innovators coming together in Singapore to lay the foundation for new automation standards to reduce bottlenecks and speed technology transfer."

- Kristel Biehler,
Vice President of Life Sciences, Emerson, USA

"Multimodal generative reinforcement learning will continue to be the main trend in life sciences in 2025 dramatically improving productivity in drug discovery and development. I hope to see the previous record of 9 months from the start of a new preclinical programme to preclinical candidate nomination broken."

- Dr Alex Zhavoronkov,
Founder and CEO of Insilico Medicine, China

together in Singapore to lay the foundation for new automation standards to reduce bottlenecks and speed technology transfer. Those efforts will only increase as life sciences innovators take advantage of new technologies like AI to break down barriers to a faster development pipeline-bringing treatments to patients with unprecedented speed and efficiency," said Kristel Biehler, vice president of Life Sciences, Emerson, USA. Emerson is a leading global technology, software, and engineering company providing innovative solutions for customers in industrial and commercial markets.

Pharma and Contract Development and Manufacturing Organisations (CDMOs) organisations are bringing clinical trials, manufacturing and distribution closer to patients in high-demand markets to maximise speed and agility while minimising cost and supply chain risk.

"In 2025, global drug shortages and limited patient access to advanced therapies will remain critical challenges in the life sciences industry. Addressing these issues requires a shift towards decentralised manufacturing models, where therapies like CAR-T can be produced closer to the point of care to provide higher quality and better economics. Innovations such as mobile and modular cleanrooms are anticipated to play a transformative role, enabling localised production of personalised medicines and sterile drugs in short supply. These solutions reduce logistical barriers, accelerate delivery timelines, and improve resilience against supply chain disruptions, expanding access in underserved regions," said Kevin Kyle, Chief Executive Officer, Germfree, USA. Germfree is a pioneering laboratory & cleanroom manufacturing company.

BIOSECURE Act Boosting Indian CDMOs

On September 9, 2024, the US House of

Representatives passed the BIOSECURE Act. The Act restricts US Federal agencies from contracting with or procuring services and equipment from Chinese 'biotechnology companies of concern', and will extend to companies that source or utilise equipment or services from five Chinese companies, namely WuXi Apptec, MGI, BGI, Complete Genomics, and WuXi Biologics. According to a report from LEK Consulting, international demand accounts for a large portion of revenue for these companies (e.g., WuXi Apptec derived 65 per cent of its 2023 revenue from the US). This Act could potentially result in a remarkable decrease in upstream demand for the services provided by the named companies.

"Biopharma industry executives are going to have to figure out how to minimise any risks associated with the heightened geopolitical tensions that may be triggered by the proposed BIOSECURE Act. Companies in Mainland China are the premier source of Active Pharmaceutical Ingredients (API) to the global pharma industry

The APAC region continues to rule the roost in clinical trials, experiencing dramatic growth rates surpassing those in the US and Europe. Various reports highlight APAC's emergence as a pivotal hub for clinical trials, with almost half of the world's trials now conducted in the region. The area's abundant patient population makes it a prime choice to start cutting-edge trials across a range of diseases, and since 2021 it has surpassed the rest of the world in the number of clinical trials that it annually hosts. Within the APAC region, the most impactful trend for 2025 will be its growing dominance in oncology trials. APAC has surpassed Western countries in the scale and scope of clinical trials, thus solidifying its appeal to both local and global pharmaceutical firms seeking strategic advantages.

which will find it difficult to replace with enough high-quality production from other sources. Moreover, after a decade of policy decisions focused on boosting the Chinese biopharma sector, Mainland China is already leading the world in life sciences research publications and patents and is now looking to global markets for its innovative products. A reduction in US-Mainland China biopharma collaborations could be a boon for European pharma and biotech companies," said Michael Ward, Global Head of Thought Leadership, Life Sciences & Healthcare, Clarivate, England.

Both US and non-US biopharmaceutical companies have begun to explore mitigation plans and seek backup supplies. Contract organisations such as Evotec and Fujifilm Diosynth have been receiving increasing engagement and exploratory inquiries, as per LEK Consulting. This is opening opportunities for India to dominate the landscape and could potentially benefit from the Bill as pharmaceutical companies seek to diversify their production from the mentioned companies, or even from China. "The BIOSECURE Act and less reliance on China's supply chain is expected to especially benefit Indian CDMO companies. India pharma is well recognised globally for quality generics. In the future, we will see massive growth of Indian CDMO companies due to evolving opportunities amid the BIOSECURE Act and less reliance on China's supply chain by the US and Europe-based pharma companies," said Prashant Khadayate, Director – Lifesciences Consulting & Research, GlobalData, India.

Michael agrees, "Some industry estimates suggest that the Act is projected to create a multi-billion-dollar opportunity for India's biotech industry over the next five years. Indeed, Indian CDMOs like Divis Labs, Syngene, Piramal Pharma, Suven, and Laurus are expecting to see a surge in demand, with some reporting a year-on-year increase in requests for proposals (RFPs) for Indian CDMOs during 2024."

While the BIOSECURE Act presents significant opportunities for Asian CDMOs outside of China, they will need to adapt their strategies, invest in capabilities, and navigate complex market dynamics to fully capitalise on this shift in the global biopharma ecosystem. BS

Ayesha Siddiqui

Indian Lifesciences Industry Going Ahead in its Innovation Journey While Navigating Challenges

« **Ruplekha Choudhurie,** Research Manager, Advanced SciTech, Everest Group

While India is a hub for biosimilar manufacturing and continues to build its capabilities to manufacture these complex therapeutics, Indian biopharma companies are building R&D capabilities and establishing public-private collaborations and Centre of Excellences (CoEs) to develop innovative biologics and advanced therapeutic modalities like cell and gene therapy (CGT) and mRNA vaccines and therapies, biopharma sector remained robust in 2023, accounting for $53.8 billion (35 per cent of the BioEconomy). The growth was primarily driven by advances in biotechnology, personalised medicine innovations, and an expanding market for biosimilars in 2024.

India is a major supplier of vaccines, with more than 50 per cent of the world's vaccines coming from India. According to the WHO Global Vaccine Market Report, the vaccine major Serum Institute of India (SII) accounted for 24 per cent of the global vaccine market. SII joined the CEPI, (the Coalition for Epidemic Preparedness Innovations), network of vaccine producers, which will support rapid, agile responses to possible future infectious disease outbreaks. In addition to conventional vaccines, India has also emerged strong with two mRNA vaccines approved for the omicron variant. Innovations have also increased, with Indian Immunologicals Ltd (IIL), launching India's 'first' indigenously developed Hepatitis A vaccine, Havisure in February 2024.

Many Indian startups and academic organisations have been relentlessly working to advance affordable cell and gene therapies for oncology, rare diseases, and other indications. The push to develop more efficacious and accessible CAR-T therapies to millions of patients finally saw fruition, with the first indigenous CAR-T cell therapy receiving approval in 2023, making it the most affordable CAR-T therapy. The commercial launch of NexCAR19 in 2024 has helped India firmly establish its position in the advanced cell and gene therapy space. This launch has also sparked interest in investors and companies investing in cell and gene therapy developers. Other players like Cellogen Therapeutics are developing advanced CAR-T therapies by developing bi-specific CARs and adding immunostimulatory molecules. They received a $2 million investment from Natco Pharma in 2024 to support the R&D programmes. Immuneel Therapeutics also received $12 million in funding in 2024, which will help propel its CAR-T therapy manufacturing and development platform. Other notable developments included approving the country's first gene therapy clinical trial for Hemophilia A in February 2024.

Growing Focus on Precision Health

Globally, there is a notable push for value-based precision medicine approaches, and India has also embarked on the precision medicine journey with several federal and corporate initiatives and projects. Council of Scientific and Industrial Research (CSIR) launched the Phenome India project in December 2023, which aims to develop country specific prediction models for cardio-metabolic diseases targeted at the Indian population. Phenome India project exemplifies CSIR's commitment to advancing precision medicine through Predictive, Personalised, Participatory, and Preventive healthcare.

Pharma and biopharma companies have focused on utilising digitalisation and AI to accelerate precision medicine efforts with flagship projects and collaborative initiatives. Notable collaborations, such as the one between Siemens Healthineers and the Indian Institute of Science (IISc) with the launch of the Siemens Healthineers-Computational Data Sciences (CDS) Collaborative Laboratory for AI in Precision Medicine in January 2024 will develop open-source AI-based tools to automate digital pathology results in neuroimaging, will help in accurate diagnosis and population health analytics. As healthcare becomes more patient-centric, Indian hospitals strive to provide personalised offerings. Apollo Hospitals launched India's first AI-Precision Oncology Centre at Apollo Cancer Centres in Bengaluru in 2024. This, along with many other examples of how pharma companies, hospitals, diagnostics developers, and other stakeholders

across the healthcare and life sciences value chain are adopting AI and digitalisation, is also indicative of the progress India is making to keep itself abreast in terms of tech-enabled innovations.

Partnerships Play a Pivotal Role in Sustaining Momentum

Building a strong and sustainable infrastructure for biomanufacturing will keep India ahead in its global position, and the recent BioE3 (Biotechnology for Economy, Environment, and Employment) Policy approved in August 2024 will help position India as a global leader.

While the 2024 Indian budget did not particularly have special provisions or policy announcements to foster pharma and biopharma R&D, specific announcements, such as the government setting up a mechanism for private sector-driven research and innovation, the pool of Rs 1 lakh crore and more than Rs 2000 crore of The Production Linked Incentive (PLI) allocation for the pharmaceutical industry for this fiscal year.

Expediting access to advanced therapies is also critical for improved accessibility, and the Central Drugs Standard Control Organisation (CDSCO) recently waived off the requirement for local trials for drugs that already have approval in certain foreign markets. Advanced therapies such as cell and gene therapies, drugs for orphan diseases, and other advanced therapeutic modalities that have been approved by the US, Japan, Europe, and other major countries would be eligible for waiver of the local clinical trials.

The life sciences sector has witnessed strategic partnerships to expand capabilities and market access. In May 2024, Merck inked a partnership with Aurobindo Pharma-owned TheraNym Biologics to expand its biologics manufacturing facilities and advance contract manufacturing. In July 2024, Miltenyi Biotec, a global biomedical solutions company, partnered with the Translational Health Science and Technology Institute (THSTI), an autonomous institute under the Department of Biotechnology, collaboratively developed innovative cell and gene therapies for oncology and haematological indications.

Facing Flaks over Quality and Compliance

Despite the advances and the strong position of the Indian Contract Development and Manufacturing Organisation (CDMO) industry, many of the Indian companies have been under scanner due to significant quality control and regulatory lapses in the last two years. The CDSCO inspected 400 drug manufacturing units over the past year and a half, ordering the closure of more than 36 per cent due to non-compliance leading to quality concerns.

The CDSCO has intensified its monitoring and enforcement if such lapses are found and flagged several drugs in 2023 and 2024 due to quality or efficacy issues from many renowned pharma companies.

With pharma exports accounting for a substantial share of the global market, India is taking solid measures to regain its reputation and re-emerge as a reliable supplier of generic, high-quality, affordable medicines. Since August 2024, more than 200 fixed-dose drug combinations have been banned, citing potential risks to human health.

Many companies, such as Astra Zeneca and Novartis, are re-evaluating their India business strategy, trimming down portfolios and refraining from making new investments. Facing regulatory hurdles, IPR challenges, and pressure to generate revenue and net profit, most multinational corporations are reevaluating their strategies for the Indian market.

What is on the horizon?

The innovation ecosystem is expected to strengthen further in 2025 and the years ahead, with more advanced therapies like cell and gene therapies, mRNA therapies, and advanced antibodies entering clinical development. With stringent monitoring and streamlining regulatory measures, pharma companies are expected to collaborate with regulatory bodies to make quality control and production processes more airtight and transparent.

Stakeholders eagerly await specific policies and initiatives to drive biopharma R&D in the next annual budget, not a mere reduction in taxes and regimes. Incentivisation of high-value, high-risk projects for innovative therapeutics must be in place for India to make a mark in the biotech race.

Geopolitical changes resulting in a significant legislative shift with the U.S. Biosecure Act coming into force in September 2024 are likely to have positive implications for the Indian pharma CDMOs. This Bill aims to reduce US dependence on Chinese pharmaceutical supply chains by restricting collaborations with certain Chinese biotech firms, which would directly increase demand from US pharma companies for Indian Contract Research Organisations (CROs) and CDMOs in the next year. However, Indian CDMOs can seize the opportunity by levelling up in terms of infrastructural investments and regulatory protocols, and reducing dependence on China to make its supply chain more resilient. BS

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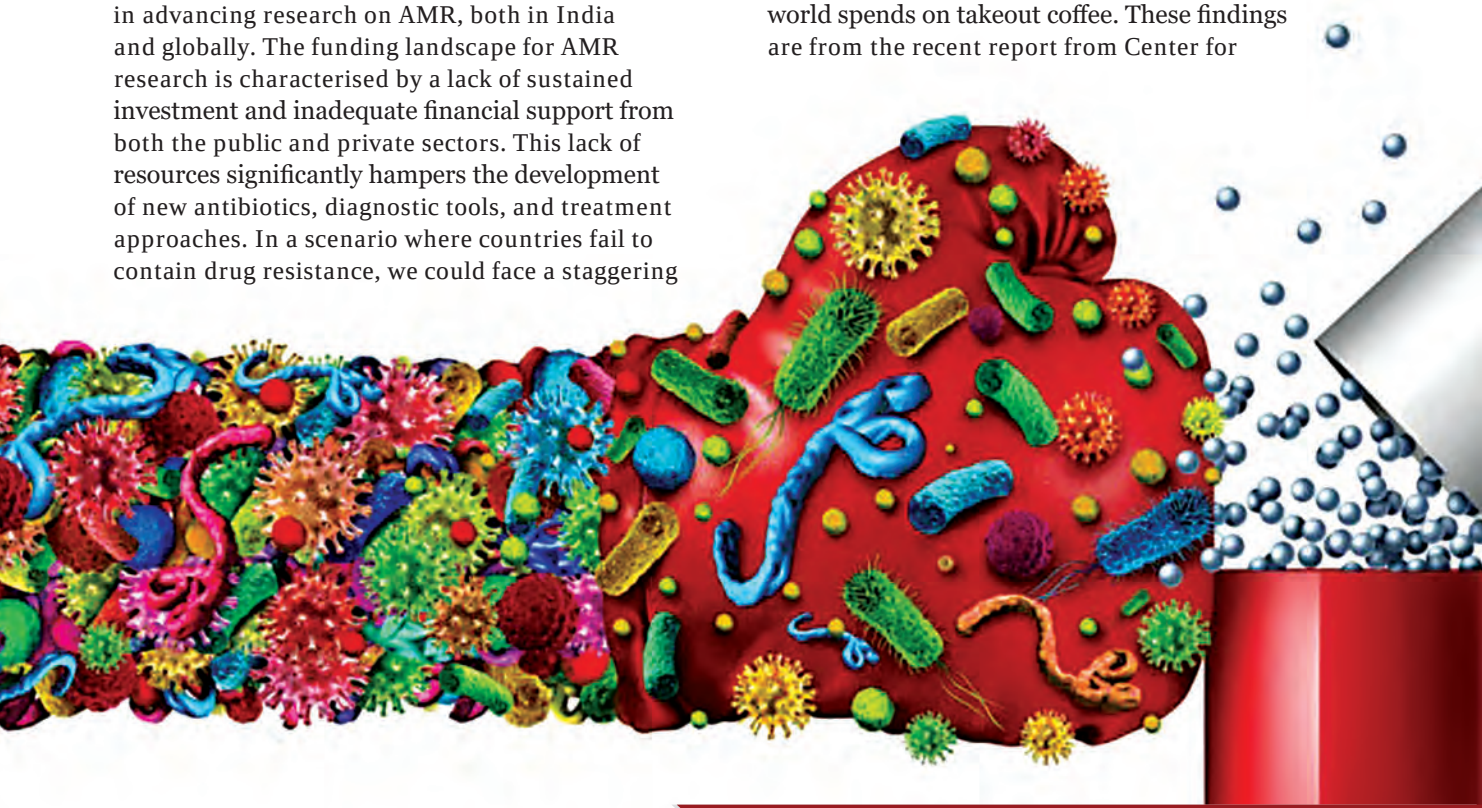
What's dampening the GLOBAL AMR BATTLE?

Although there have been significant national and worldwide efforts to provide financial incentives for antibiotic research and development, it is still unclear how best to fortify the existing programmes to further spur antibiotic innovation. The incentive programmes in place now are a crucial first step in enhancing the economic viability of antibiotic development. However, it seems like there isn't enough global coordination among all the programmes, which could lead to duplication of effort, funding gaps in the value chain, and the failure to include crucial AMR objectives. Let's dig deeper.

Antimicrobial resistance (AMR) is a growing global concern, with the situation worsening year by year. The speed of developing resistance is at par or, in fact, more than the speed of novel antibiotic development. Most of the big pharmaceutical companies have left antibiotic research due to the high risk of failure and poor return on investment. Antibiotic research is mostly carried out by academic institutes and small- and medium-sized enterprises. However, they lack sufficient funds to take the compounds from early and mid-stage to clinical trials and market.

Insufficient funding remains a major challenge in advancing research on AMR, both in India and globally. The funding landscape for AMR research is characterised by a lack of sustained investment and inadequate financial support from both the public and private sectors. This lack of resources significantly hampers the development of new antibiotics, diagnostic tools, and treatment approaches. In a scenario where countries fail to contain drug resistance, we could face a staggering $1.7 trillion annual reduction in global economic output by 2050, amounting to a 0.88 per cent decrease in GDP. This would not only escalate hospital treatment costs but also adversely affect tourism and domestic hospitality.

An annual investment of $63 billion spent improving access to, and developing new antimicrobials, could generate more than $1.7 trillion in benefits a year by 2050. While $63 billion may sound like a lot of money—in reality, it's less than the world spends on cosmetic surgery, less than video gamers spend on in-game purchases, each year—and it's about an eighth of what the world spends on takeout coffee. These findings are from the recent report from Center for



Global Development, based at Washington DC and London, a think tank that uses economic research to reduce global poverty and inequality.

"Scenario that promotes increased access to high-quality treatment for bacterial infections, coupled with funding that spurs the development of new gram-negative antibiotics, presents a more hopeful future. Such initiatives could boost the global economy by an estimated $960 billion by 2050, while simultaneously reducing health care costs by $100 billion. This is in addition to the benefits of simply improving people's lives and the insurance value of reducing the risk of an AMR outbreak. Inaction on AMR carries a significant economic burden. However, the potential economic gains from measures that stem the rise of AMR are substantial," said Mark Plant, Chief Operating Officer and Senior Policy Fellow, the Center for Global Development, USA.

In India, funding for AMR research and initiatives has been relatively limited compared to the need. Public and private sector investments in AMR research have been insufficient, with most resources directed towards modifying existing antimicrobial compounds rather than discovering new therapeutic agents.

Misalignment of incentives

Only a handful of countries have addressed the AMR issue by implementing or proposing financial incentive models to promote antibiotic innovation. In India, many initiatives towards financial incentives have been made which include the UK-India Fleming Fund (a partnership between the Fleming Fund and India's Ministry of Health and Family Welfare. The fund's goal is to accelerate collaboration on AMR surveillance across One Health sectors), a partnership between C-CAMP and CARB-X that provides funding opportunities for Indian medical innovators working on AMR, Grand Challenges India, etc. However, the misalignment of these incentives is not allowing the achievement of desirable AMR goals in India.

"One important hurdle is misalignment of incentives. While governments and health services are incentivised to promote prudent use of this common good, pharmaceutical companies are incentivised to increase the volume of sales to

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"One important hurdle is misalignment of incentives. While governments and health services are incentivised to promote prudent use of this common good, pharmaceutical companies are incentivised to increase the volume of sales to maximise profits."

- Olof Lindahl,
Project Coordinator, Uppsala Antibiotic Center, Uppsala University, Sweden

"Equal attention to market sustainability through pull incentives is needed after antibiotic approval to mitigate the market failure challenges, as evidenced by the bankruptcy of Achaogen, an SME that developed plazomicin."

- Dr Reeta KH,
Professor, All India Institute of Medical Sciences, Delhi

"We need new weapons in our arsenal, and we need them now. While the development of new antibiotics is crucial, we cannot neglect the importance of antibiotic stewardship."

- Prof. Dr Rahul Pandit,
Chair Critical Care, Sir HN Reliance Foundation Hospital, Mumbai

"Tackling the sheer scale and pace of drug resistance is a complex global health issue that will require action from pharmaceutical companies across several areas."

- Marijn Verhoef,
Director of Operations and Research,
Access to Medicine Foundation, Netherlands

maximise profits. This problem must be addressed or else the major efforts going into developing new antibiotics will be in vain," opined Olof Lindahl, Project Coordinator at Uppsala Antibiotic Center, Uppsala University, Sweden.

The disconnect between costly antibiotic development and low net present value (NPV, a value calculated based on ultimate costs and revenue) stresses the need for financial incentives that can either decrease the cost of R&D or increase the market revenues. Therefore, several global organisations have put forward funding strategies to lower the cost of developing an antibiotic, directly or indirectly, by cutting down the risk of failures, as they cover both successful and unsuccessful projects. Of the major financial incentives in the field of antibiotic R&D, 71 per cent are strictly push incentives funding the development of novel antibiotics. For instance, the flourishing preclinical antibiotic pipeline in Europe (52 per cent) and America (35 per cent) can be attributed to the proactive approach of government and non-government philanthropic organisations in these continents.

Although these strategies showed a positive impact on NPV, they are insufficient as they do not cover the revenue generation after antibiotic approval and are inadequate alone to recuperate the dried antibiotic arena. Dr Reeta KH, Professor at All India Institute of Medical Sciences (AIIMS), Delhi said, "Equal attention to market sustainability through pull incentives is needed after antibiotic approval to mitigate the market failure challenges, as evidenced by the bankruptcy of Achaogen, an SME that developed plazomicin. Achaogen was unable to sustain the market of plazomicin despite being push-funded from initial stages to clinical trials by Wellcome Trust, the National Institute of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA)."

Revitalising the antibiotic pipeline through financial assistance in the form of push funding and uniting the scientific community can bring back the lost art of discovery. Various push funding mechanisms in the last decade have tried to narrow the discovery void that occurred after the lucrative 1980s era of antibiotic development. However, despite numerous funding mechanisms, the pace of development is still slow, and the antibiotic market is unattractive for the big pharmaceuticals. Along with push funding, there is a need to incentivise antibiotic developers through pull funding after regulatory approval to sustain the market.

Pharma's apathy towards AMR R&D

Indian pharmaceutical companies have significantly reduced investments in AMR research due to several interconnected factors. Developing new antibiotics is less profitable compared to other therapeutic areas like chronic diseases or lifestyle drugs. Antibiotics are usually prescribed for short durations, making their market potential smaller than drugs for chronic conditions, which have long-term usage and higher sales volumes. Moreover, the Indian pharmaceutical industry is highly competitive, with a focus on producing generic drugs at lower costs. Investing in new antibiotic research is seen as less lucrative because generic drugs dominate the antibiotic market, making it difficult for new, more expensive antibiotics to gain traction.

Even if a new antibiotic is successfully developed, it is often reserved for severe cases to prevent the development of resistance, leading to limited usage. This controlled application reduces sales potential, discouraging companies from investing in AMR research. Furthermore, Global efforts to limit the overuse of antibiotics further decrease the potential returns on investment for pharmaceutical companies. Policies that encourage the prudent use of antibiotics make it difficult to recoup the significant costs associated with research and development.

While commenting on the need for action from pharmaceutical companies, Marijn Verhoef, Director of Operations and Research, Access to Medicine Foundation, Netherlands said, "Tackling the sheer scale and pace of drug resistance is a complex global health issue that will require action from pharmaceutical companies across several areas. This includes providing appropriate access and implementing stewardship measures to safeguard the effectiveness of innovative antimicrobials. Failure to do this will limit efforts to tackle drug resistance."

The hesitance in investments by Indian pharmaceutical companies in AMR research is largely driven by economic considerations, scientific challenges, lack of robust incentive structures, and a focus on more profitable therapeutic areas with few approval processes and no need for extensive clinical trials. To reverse this trend, there needs to be stronger government support, global collaboration, and innovative funding models that can make AMR research a financially viable venture for these companies.

Why the urgency?

According to the United Nations Environment Programme (UNEP), up to 10 million deaths per year could occur by 2050 due to AMR. "The threat of AMR is not just theoretical; it's something we're seeing every day in our ICUs. Patients who would have had a fighting chance just a few years ago are now facing infections we struggle to treat. We need new weapons in our arsenal, and we need them now. While the development of new antibiotics is crucial, we cannot neglect the importance of antibiotic stewardship. By using these life-saving drugs responsibly and implementing effective infection control measures, we can help slow the spread of resistance." shared Prof. Dr Rahul Pandit, Chair Critical Care, Sir HN Reliance Foundation Hospital, Mumbai

Although major international and national initiatives are aimed at financially incentivising the research and development of antibiotics, it remains unclear how to effectively strengthen the current set of incentive programmes to further accelerate antibiotic innovation. The current set of incentive programmes is an important initial step to improving the economic feasibility of antibiotic development. However, there appears to be a lack of global coordination across all initiatives, which risks duplicating efforts, leaving funding gaps in the value chain and overlooking important AMR goals.

In conclusion, we can say that there are significant holes in the global incentive scheme that will impede progress towards bringing novel antibiotics to the market. Firstly, the majority of R&D funding focuses on early-stage push incentives aimed at basic research and preclinical trials, while late-stage push incentives for clinical development remain limited. Secondly, there is a significant lack of large-scale pull incentives that effectively stimulate private investment in clinical trials and the commercialisation of antibiotic products. Thirdly, key public health policies, which outline target product profiles, sustainability goals, and patient access considerations, are not well-integrated into existing R&D incentive frameworks.

Lastly, there is a lack of comprehensive guidance and coordination among the various initiatives currently in place. This fragmented approach could be a major factor contributing to gaps in the incentive structure and unmet public health needs. Establishing an international coordination and governing body to support national implementation could be a crucial step toward addressing these policy issues. At the national level, countries must reassess their funding strategies to better drive antibiotic innovation in response to the urgent global threat of AMR. High-level commitments need to be transformed into concrete actions across all sectors. BS

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Recent developments in Indian AMR space

- Innominds, a US-based digital transformation and product engineering company, partnered with Hyderabad-based startup SCIINV Biosciences to introduce AMRx, an advanced AI/ML-driven digital diagnostic tool designed to combat the growing threat of AMR (June 2024).
- The Indian Medical Association (IMA) formed the National Alliance of Medical Professionals on Antimicrobial Resistance (NAMP-AMR) (July 2024).
- Hyderabad-based Bharat Biotech collaborated with US-based Alopexx, Inc., for the co-development and commercialisation of Alopexx's proprietary broad-spectrum anti-microbial vaccine, AV0328, in India and other low-income and lower-middle-income countries (September 2024).
- Orchid Pharma, a Chennai-based company, formed Orchid AMS (Antimicrobial Solutions), a dedicated division focused on helping address the critical challenge of AMR in India (September 2024).
- Telangana launched the AMR Action Plan (October 2024).
- The International Centre for Antimicrobial Resistance Solutions (ICARS) signed a partnership with the Centre for Cellular and Molecular Platforms (C-CAMP), under the aegis of the India AMR Innovation Hub (IAIH), to tackle the growing threat of AMR across the One Health domain (October 2024)

How Vietnam is Leveraging AI to Reshape Healthcare

Vietnam has identified Artificial Intelligence (AI) as a key technology to boost its economy and has announced a series of partnerships, investments, and initiatives in this space. The country's focus on AI is having a ripple effect on healthcare and driving significant growth in the sector. According to a report by DealStreetAsia's Data Vantage, healthtech startups in Southeast Asia raised a total of $580 million through 60 deals in 2023. While Singapore and Indonesia led the region in attracting investments, Vietnam ranked third, securing 3.9 per cent of the total funding. Let's explore Vietnam's efforts to become an AI powerhouse and how that's transforming its healthcare sector.

Access Partnership, the world's leading tech advisory firm, recently presented an economic impact report titled 'Driving Digital Growth in Vietnam.' The report highlights the immense economic potential of Artificial Intelligence (AI) for the country. According to the findings, AI could contribute an estimated VNĐ 1.89 trillion ($79.3 billion) to Vietnam's economy by 2030, representing nearly 12 per cent of its GDP.

Recognising the immense potential of AI, Vietnam has identified it as a key technology for national development. The country has launched the National Strategy on Research, Development, and Application of AI to position Vietnam among the leading nations in AI within ASEAN and globally by 2030. The strategy includes ambitious objectives, such as establishing 10 high-profile AI brands in the region and developing three national centres for big data and high-performance computing, which will be interconnected through a dedicated network. Additionally, Vietnam plans to create approximately 50 open datasets to support AI research, development, and application across various economic sectors.

The Vietnamese government has launched a human resources development programme aimed at strengthening the country's AI capabilities. The goal is to train 5,000 AI engineers by 2030 as part of a broader initiative to integrate AI into various industries. The National Innovation Center (NIC) is collaborating with both domestic and international partners to create a centre for AI research, training, and application. This centre will focus on supporting AI startups, advancing research, and providing specialised training to meet global standards. By 2030, the NIC plans to train 7,000 AI experts and nurture around 500 AI startups.

The Vietnamese government is collaborating with industry leaders like Google to help the country achieve its AI ambitions. Google is focusing on human resource development and enabling Vietnam's growing startup ecosystem to fully embrace AI. Through its partnership with the Vietnam National Innovation Center (NIC), an agency under the Ministry of Planning and Investment, Google has offered 40,000 Google Career Certificates scholarships across 80 universities and launched a local AI-focused Google for Startups Accelerator program.

The Google for Startups Accelerator Southeast Asia – Vietnam is a three-month, equity-free initiative supported by the NIC. This programme is designed to accelerate high-potential AI startups in Vietnam by providing access to Google's AI products, expert guidance, and infrastructure. Startups selected for the programme will benefit from AI tools on Google Cloud, including Vertex AI and Gemini Pro, through the Google Startup AI Space, an online sandbox that facilitates the rapid development and prototyping of AI applications.

AI Innovations in Healthcare

"The Vietnamese healthcare system is increasingly integrating AI technologies, such as machine learning and data analytics, to optimise clinical practices and decision-making processes. For instance, AI applications are being utilised to analyse medical data to aid diagnosis and inform choice of treatment, thereby facilitating better patient outcomes and more efficient healthcare services. This particularly relates to the well-resourced and equipped private sector, with the public healthcare system lagging some way behind. This is exemplified by the internationally accredited Vinmec healthcare system, which is owned

by Vingroup, the largest conglomerate in Vietnam," said Dr Andrew Taylor-Robinson, Professor of Microbiology & Immunology, VinUniversity.

One of the major companies in this space in Vietnam is VinBrain, a health technology firm under the country's largest conglomerate, Vingroup. VinBrain develops a suite of pathology AI solutions called DrAid, which supports early disease detection across the country. Similarly, South Korean medical AI company AITRICS has received clearance from Vietnam's Ministry of Health for its AI software, designed to predict patient deterioration. Japan's Fujifilm launched AI-based health screenings, focusing on cancer in Vietnam. In a related effort, the Vietnam Young Physicians' Association (VYPA) has proposed a volunteer programme aimed at screening one million people for diseases using an AI platform, further advancing the country's healthcare capabilities.

Companies are combining AI and genomics to drive more personalised, efficient, and accessible healthcare solutions throughout the region. One prominent example is Gene Solutions, a pioneering genetic testing company that has become a leader in Asia's precision medicine space. With a focus on reproductive health, clinical oncology, and advanced genomics, Gene Solutions offers services such as Non-invasive Prenatal Testing (NIPT), Multi-cancer Early Detection (MCED), and Comprehensive Genomic Profiling (CGP). The company uses cutting-edge technologies, including circulating tumour DNA (ctDNA) tracking, to provide personalised, data-driven care. With over 1.5 million tests conducted, Gene Solutions is expanding beyond Vietnam, relocating its headquarters to Singapore and forming partnerships with leading hospital groups and cancer institutes across Southeast Asia, including in Indonesia, Thailand, the Philippines, and Malaysia.

Another key player is GeneStory, a startup backed by the Vingroup Corporation, which is pioneering the use of genetic data for personalised healthcare in Vietnam. Drawing on research from the 1,000 Vietnamese Genome Sequencing Project, GeneStory offers genetic reports that cover a wide range of health indicators, such as disease risk, drug response, and nutrition. The company aims to build a proactive healthcare roadmap for individuals, with a strong focus on promoting preventive medicine and national health initiatives.

Genetica Company is another example. In partnership with global leaders like Illumina and Thermo Fisher Scientific, Genetica has developed a proprietary gene-decoding chip tailored specifically to the Asian population. By analysing hundreds of genes, Genetica provides reports that give comprehensive insights into an individual's health risks, genetic potential, and behaviour. The company has recently launched a product that uses AI to detect genetic risks related to respiratory virus infections, further broadening the scope of personalised healthcare.

> "The Vietnamese healthcare system is increasingly integrating AI technologies, such as machine learning and data analytics, to optimise clinical practices and decision-making processes. For instance, AI applications are being utilised to analyse medical data to aid diagnosis and inform choice of treatment, thereby facilitating better patient outcomes and more efficient healthcare services. This particularly relates to the well-resourced and equipped private sector, with the public healthcare system lagging some way behind. This is exemplified by the internationally accredited Vinmec healthcare system, which is owned by Vingroup, the largest conglomerate in Vietnam."
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> **- Dr Andrew Taylor-Robinson,**
> Professor of Microbiology & Immunology,
> VinUniversity, Vietnam

Vietnam's Thabis, a leader in healthcare innovation, has partnered with U.S.-based Genomate Health Inc. to bring personalised, data-driven cancer treatments to Vietnam. Digosys will distribute Genomate through the Genous service, combining next-gen sequencing and molecular tumour board interpretation to deliver tailored cancer therapies across Southeast Asia. N2TP offers a unique approach to precision medicine through its SmartDoseAI clinical decision support software. Designed to assist healthcare providers in individualising drug dosing for patients with narrow therapeutic ranges, SmartDoseAI helps optimise treatment outcomes and improve patient safety.

Challenges and Solutions

Despite promising advances, the integration of

AI Targets Towards 2030

a) Bringing AI to be an important technology of Vietnam
- Vietnam is among the top 4 countries in ASEAN and in the group of world's top 50 countries in research, development and application of AI;
- Setting up 10 renowned AI centres in the region;
- Developing 3 national centres for big data storage and high-performance computing; connecting domestic data centres and high-performance computing centres to create a shared network for big data and computing for AI;
- Developing 50 open, linked and connected data sets in different economic sectors, socio-economic fields serving the research, development and application of AI.

b) Vietnam is a centre for innovation, developing solutions and vigorously applying AI
- Establishing 3 national innovation centres for AI;
- Building up a contingent of high-quality human resources working on AI, including a team of experts and engineers in applying AI applications. Rapidly increasing the number of scientific projects and patent applications for AI in Vietnam;
- At least 1 representative ranked in the top 20 AI research and training institutions in ASEAN.

c) Promoting a creative society, effective government to protect the national security and maintain social order and safety and promote sustainable economic growth
- Universalising the basic skills of AI application to direct workers, to promote innovation, reduce costs, boost labour productivity and improve the living standard of the people;
- Applying AI in national defence and security, rescue operations, prevention of natural disasters, and in incidents and epidemics responses;
- Along with digital transformation, the application of AI contributes to promoting growth in a number of economic sectors.

Source: en.baochinhphu.vn

AI in Vietnam's healthcare sector as a whole faces several challenges. Talking about the problems, Dr Taylor-Robinson said "Although the situation is fast moving, a few years ago it was highlighted that successful AI implementation requires a combination of technical expertise, financial sustainability, and socio-political commitment. Each of these factors is crucial to fostering an environment conducive to AI adoption. For the ambitious private healthcare sector, all these criteria are now met but this cannot be said of the public system that is antiquated and overstretched by comparison. While there is a degree of interest, entrenched culturally conservative attitudes that are frequently reticent to embrace change impede faster uptake at this time. Moreover, the depth of expertise and research in AI applications remains limited compared to high income nations."

For Vietnam to become a top AI destination, there is a pressing need for a comprehensive legal framework to support AI initiatives. "The framework is essential for addressing ethical concerns, data privacy, and the overall governance of AI technologies in healthcare, which are critical for building public trust and ensuring the safe deployment of AI systems. From a patient perspective, currently there is significant apprehension, justified or not, regarding data security, accuracy of robotic surgery and other safety issues. These concerns highlight the necessity for transparent communication and physician oversight to alleviate fears and foster acceptance among patients," said Dr Taylor-Robinson.

Of course, anything associated with technology raises concerns regarding the quality and safety of patients' data. Sharing details on this, Dr Taylor-Robinson said "The effectiveness of AI algorithms is heavily dependent on the quality of the data used for training, which can lead to potential biases and inaccuracies in clinical settings. The healthcare professionals within the Vinmec system are highly trained, often with experience gained in and professional accreditation from western countries, so this is less of a concern in the private sector. As there is no referral system in the Vietnamese healthcare system, the public tertiary care centres in the major cities are heavily oversubscribed and thus record keeping is typically still manual. In this context, transitioning to electronic systems is a long-term aspiration rather than an urgent priority and thus is a process still in its infancy."

To that effect, Vietnam has announced the nationwide expansion of its electronic health record (EHR) system. The government is extending the implementation of the digital health record system, which was initially piloted in Hanoi and Thua Thien-Hue Province, to the entire country.

As the nation takes lead in advancing AI, we can expect to witness groundbreaking innovations that will not only benefit its citizens but also contribute to the progress of healthcare technology in the Southeast Asia region. BS

Ayesha Siddiqui

“Kidney failure was the third fastest growing cause of death in 2023 exacerbated by the lack of treatments for kidney disease”

Dimerix, a clinical-stage biopharmaceutical company, is at the forefront of developing innovative treatments for inflammatory diseases, including kidney and respiratory conditions. With its lead candidate, DMX-200, currently in a pivotal Phase 3 clinical trial for FSGS, the company is making significant strides in advancing therapies for rare and complex diseases. The drug has already earned Orphan Drug Designation from both the US FDA and EMA, and Dimerix has secured strategic licensing deals in Europe, Canada, Australia, New Zealand, and the Middle East—valued at A$350 million in upfront and potential milestone payments, plus royalties. In this interview, Dr Nina Webster, CEO and Managing Director of Dimerix, Australia shares the company's journey, key trends shaping the future of biopharmaceuticals, and Dimerix’s next steps in its mission to transform the treatment landscape for rare patients worldwide. ***Edited excerpts:***

« **Dr Nina Webster,** CEO and Managing Director, Dimerix, Australia

How has the company evolved since its incorporation in 2004 to develop innovative treatments for inflammatory diseases?

Dimerix is a publicly listed, Australian clinical stage biopharmaceutical company originally founded on a scalable, proprietary platform technology - Receptor-HIT. We are focused on developing products for inflammatory disease, particularly unmet needs in kidney and respiratory disease.

Dimerix was initially set up as a fee-for-service company, using its proprietary technology to screen drug candidates for large pharmaceutical companies. However, using Receptor-HIT, we identified our own pipeline opportunities.

Over the last 12 years, Dimerix has focused on developing its promising candidate, DMX-200, to treat kidney disease. Specifically, Dimerix is currently undertaking a randomised, double-blind, multi-centre, placebo-controlled global phase 3 trial of DMX-200 to treat a rare and progressive type of kidney disease called Focal Segmental Glomerulosclerosis (FSGS), for which there are no approved products anywhere in the world.

Can you explain how your proprietary Receptor-HIT technology works and what makes it scalable and adaptable for different drug discovery needs?

Our Receptor-Heteromer Investigation Technology (HIT) platform uses cell-based assays to identify promising drug candidate activity at the receptor level. Receptor-HIT can be applied at a number of stages of drug development across different and joint receptors.

While Dimerix has identified a promising pipeline of potential candidates through Receptor-HIT, we are currently focused on our DMX-200 phase 3 trial aimed at addressing the global unmet need for FSGS treatment.

DMX-200 (QYTOVRA) is in Phase 3 trials for FSGS kidney disease. Could you explain how it works as an adjunct therapy and how it differs from the current standard of care?

FSGS is a rare, progressive and aggressive kidney disease with no current treatment. FSGS has a number of underlying causes and occurs globally across all age groups, including children as young as two years old.

FSGS patients typically present with high blood pressure. This causes a build-up of pressure in the kidney vessels that causes inflammation. This persistent and on-going inflammation in turn leads to sclerosis or fibrosis in the kidney, and ultimately the death of kidney cells. The remaining kidney cells come under increasing stress, accelerating the disease and as such, FSGS usually leads to kidney failure in 5-8 years.

FSGS patients typically progress to renal failure, requiring dialysis, and in some cases, where available, kidney transplants. Unfortunately, 60 per cent of such transplants are in turn affected by FSGS.

The current standard of care for FSGS is to treat high blood pressure. Dimerix's DMX-200 candidate is aimed at reducing the inflammation in the kidney and thus preventing scarring and fibrosis. As such, DMX-200 works as an adjunct therapy, given to patients already on the blood pressure medication.

The DMX-200 phase 3 trial is currently recruiting FSGS patients across 19 countries and approximately 170 clinical trial sites. It has a truly global reach. This also means we are engaged with regulators across 19 countries, including key markets in Europe, Asia and North America.

As FSGS is a rare disease, DMX-200 successfully received orphan drug designation in the US, Europe and UK, and has the potential for breakthrough designation in other territories. As such, while the full trial is a two year study, we have built in two different interim analysis points. The first interim trial analysis occurred in March 2024 which confirmed the study was on track for its final endpoints. The next interim analysis is planned when the 144th patient reaches week 35, which we expect to occur around mid-2025 based on current recruitment.

What are the company's plans for bringing DMX-200 and other pipeline candidates to global markets? Do you foresee launching these therapies in APAC, and what hurdles do you anticipate?

Given the high unmet need, Dimerix's aim is to get a safe, effective treatment to as many FSGS patients as possible, as soon as possible, wherever they live.

For this reason, we are working with regulatory authorities across 19 countries to ensure our phase 3 DMX-200 trial efficiently and effectively meets varied regulatory requirements to support both recruitment and ultimate marketing approval. We have opened trial sites across Latin America, Europe, Asia, and Australasia.

We anticipate launching DMX-200 across multiple territories including the Asia-Pacific. In Asia we are currently recruiting patients in Taiwan, Hong Kong, Mainland China and Malaysia. Critically, we have worked with the National Medical Products Administration (NMPA), the Chinese regulatory agency, to enable recruitment directly into our multi-region phase 3 trial.

Our orphan drug status aids our potential for a faster pathway to markets, extended exclusivity periods, as well as enabling orphan drug pricing which recognises the need for commercial incentives to tackle rare diseases.

We have already licensed DMX-200 in Europe, Canada, Australia, New Zealand and the Middle East. Collectively, those deals are valued at around A$350 million in upfront and potential milestone payments plus royalties. However, this is only a part of the global opportunity we are actively pursuing, with a focus on other key markets such as US and Chinese markets.

While FSGS is a rare disease, approximately 220,000 people across the seven major markets are diagnosed with FSGS each year, through biopsies. Since biopsy is a surgical procedure, this suggests that these patients have access to health care and thus any treatment. While there is nothing on the market for FSGS at this time, a different type of rare kidney disease product launched in 2021 is priced at approximately $10,000 per month per patient, or $120,000 per annum per patient, providing a reference point for rare kidney disease pricing expectations. These costs are typically met by insurers in jurisdictions like the US or public health systems in countries like the UK or Australia.

In terms of hurdles, one of the biggest challenges in rare disease clinical trials is patient recruitment due to the uncommon nature of such diseases. This is why we have opened 170 clinical sites across 19 countries worldwide to recruit for this study.

Beyond DMX-200, are there any new drug candidates or applications for the Receptor-HIT platform that you are particularly excited about?

Dimerix sees its near term focus and significant

opportunity in completing the phase 3 DMX-200 trial and bringing the first specific treatment for FSGS to global markets.

Dimerix is in a strong cash position to continue its global phase 3 trial. Further we have the near-term potential of the interim analysis outcomes and further potential licensing deals on the horizon. We believe 2025 will be a transformational year for Dimerix.

Our Receptor-HIT platform has identified a raft of potential longer term opportunities that we will bring into our candidate pipeline at the appropriate time. Dimerix will accelerate promising drug candidates at the right time, including to address kidney and respiratory inflammation.

What are the key trends in biopharma innovation that Dimerix is closely watching?

There are some interesting trends in biopharma relevant to Dimerix. One is the decline in the number of licensing deals globally for the last seven to eight years. The upside is while fewer deals are being done, they are typically being done at a far later stage, for higher value. This presents a significant opportunity for Dimerix to secure higher valuations for our late-stage phase 3 trial.

Kidney disease is an exciting space to be in at the moment. Historically, there was little or no innovation in addressing kidney disease over the last 20 years. This was largely due to the 'hard' renal endpoints required for clinical trials, i.e. renal failure or death, which could take decades to materialise. Around the year 2018-19 a number of key regulators and industry bodies worked together to establish surrogate endpoints for kidney disease clinical trials. These surrogate endpoints enable companies like Dimerix to complete studies in months or years versus decades.

This is critical to meet the growing prevalence of kidney disease. Between 2001 and 2021 kidney failure in the US alone has doubled. In 2023 kidney failure was the third fastest growing cause of death exacerbated by the lack of treatments for kidney disease. As a result of the growing need for treatments, and the change in the regulatory environment, Dimerix is at the forefront of innovation in kidney disease.

How is Dimerix addressing kidney disease?

People aren't always aware that kidney disease can affect people at any age – from anywhere from two years old to the elderly. That's why our DMX-200 phase 3 clinical trial sites include paediatric urology units, and we're recruiting patients as young as 12 years old in the current study.

Historically, there was little or no innovation in addressing kidney disease over the last 20 years. This was largely due to the 'hard' renal endpoints required for clinical trials, i.e. renal failure or death, which could take decades to materialise. Around the year 2018-19 a number of key regulators and industry bodies worked together to establish surrogate endpoints for kidney disease clinical trials. Between 2001 and 2021 kidney failure in the US alone has doubled. In 2023 kidney failure was the third fastest growing cause of death exacerbated by the lack of treatments for kidney disease. People aren't always aware that kidney disease can affect people at any age – from anywhere from two years old to the elderly.

Many serious kidney disease patients, including FSGS patients, end up on dialysis, which is not a long-term solution. Even fewer patients have access to kidney transplants, and sadly in FSGS patients, given the incidence of re-occurrence in the transplanted kidney, transplant is also not a solution.

Demand for innovative, effective, accessible and affordable treatments for aggressive kidney disease like FSGS is growing. Dimerix is laser focused on bringing hope and health to FSGS patients around the world. BS

Ayesha Siddiqui

"Our new partnerships in Korea will give our biotech clients access to top-tier research facilities and skilled investigators"

« **Yvonne Lungershausen,** Chief Executive Officer, Avance Clinical, Australia

With newly signed Memorandums of Understanding (MoUs) in South Korea, Australia-based contract research organisation (CRO) Avance Clinical aims to enhance its site relationships and leverage the country's advanced healthcare infrastructure to support high-quality, expedited clinical trials. In an exclusive chat with BioSpectrum Asia, Yvonne Lungershausen, Chief Executive Officer of Avance Clinical, Australia discusses the significance of these partnerships, the benefits for early-phase biotech clients, and how Avance Clinical plans to navigate the evolving regulatory landscape while prioritising key therapeutic areas like oncology and rare diseases. ***Edited excerpts:***

What are the strategic goals that have driven Avance Clinical's expansion in Asia-Pacific through recent MoUs in South Korea?

Our strategic goal is to continually grow our best-in-class site relationships to support clinical development across our key therapeutic areas for regional biotechs, as well as bring our global clients to Korea for their later phase studies. Korea, with its population of over 50 million, offers world-class medical research facilities, and vast patient populations, and is consistently ranked as a global leader for quality and number of trials conducted.

Signing these important MoUs with three key sites- CHA University Bundang Medical Center, Korea University Medicine, and Dong-A University Hospital, strengthens our clinical relationships in the region so we can further support biotech clients with our trademark agile, high-quality and streamlined approach to clinical trial delivery. Following these MoUs, we are seeing increasing interest from other prominent hospitals eager to join us on this growth journey. These partnerships not only give our biotech clients access to top-tier research facilities and skilled investigators but also strengthen our patient recruitment capabilities. This collaborative approach, supported by leading clinical sites, allows us to generate high-quality data more rapidly, particularly in high-need therapeutic areas, and further positions Avance Clinical as a trusted partner for biotech companies looking to achieve clinical milestones efficiently in the Asia-Pacific region.

How do these partnerships benefit early-phase biotech clients?

These established partnerships in South Korea allow faster access to advanced medical technology and experienced clinicians. Having these MoUs in place expedites feasibility and contracting activities, all supporting faster startup and trial completion. Our partnerships also provide early-phase biotech clients with access to diverse patient populations and faster patient recruitment which is critical for meeting trial timelines.

What challenges do you face in APAC regulatory landscape, particularly in South Korea?

We have an experienced in-house global scientific and regulatory team with key experts on the ground in the region. While we recognise the nuances of the regulatory environment in the different countries across Asia, we also have the expertise and experience to manage the processes successfully in a streamlined and time-effective manner. In the case of South Korea, Avance Clinical has consistently delivered regulatory approval timelines that are comparable to Australia and the United States.

What therapeutic areas or innovations are prioritised as Avance Clinical expands in Asia?

As we expand in Asia, we are prioritising therapeutic areas where there is both high unmet need and significant research demand, such as oncology, central nervous system (CNS) disorders, rare diseases, and infectious diseases. Our established relationships allow us to match innovative biotechs with innovative site partners. Our partnerships in the region also support innovations in trial design, including adaptive and decentralised trials when suitable, enabling us to offer flexible solutions to our biotech clients. BS

Ankit Kankar
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Singapore introduces new robotics and advanced pharma manufacturing degrees

Nanyang Technological University, Singapore (NTU Singapore) is introducing two new undergraduate degree programmes in robotics and advanced chemical and pharmaceutical manufacturing in August 2025. The two programmes are designed to meet an anticipated global demand for roboticists as industries continue to automate and cultivate a pipeline of talent with a unique skill set spanning chemistry and chemical engineering for

Singapore's advancing high-tech economy. The Bachelor of Engineering in Robotics focuses on acquiring practical and future ready robotics skills that are relevant to industry needs and is in line with Singapore's vision to become a Smart Nation. The Double Major Bachelor of Engineering Science in Process Engineering and Synthetic Chemistry (PESC) aims to nurture a new breed of graduates who can navigate the intricacies of chemistry and chemical engineering, a unique skillset that is currently lacking, and boost Singapore's efforts to become a hub for advanced manufacturing and innovation.

Dubai Health Authority launches diploma programme for health facility inspectors

The Dubai Health Authority (DHA) has announced the launch of a Professional Diploma Programme for Health Facility Inspectors in Dubai, in collaboration with Sharjah University. This initiative is part of the DHA's ongoing efforts to enhance education, training, and scientific knowledge among its staff, enabling them to carry out their duties in line with global best practices in the health sector. The programme, which spans ten months, aims to strengthen the professional competencies of DHA employees in the fields of inspection and regulation of health facilities. It will equip participants with the necessary scientific knowledge, skills, and experience to perform their job functions with high efficiency, professionalism, and ethics, ultimately contributing to the enhancement of healthcare service quality provided to the community.

IIT Madras partners with French University to offer sustainable biomanufacturing course

Indian Institute of Technology Madras (IIT-M) is partnering with University of Tours, France, to offer a course on 'Sustainable Bio-Manufacturing of high-value Phytochemicals'. This course is being offered through the 'Global Initiative of Academic Networks' (GIAN) programme to promote collaboration with international universities. The course is in line with the vision of the Government of India's recently-announced 'BioE3' Policy, which aims to promote and facilitate large-scale manufacturing of bio-products for sustainable development with high-performance biomanufacturing. The course deals with sustainable biomanufacturing of high-value plant-derived natural products using plant and microbial bio-factories, which can also conserve nature while fulfilling the increasing market demand for phytochemicals for various commercial applications. This course is also open for those outside IIT Madras. Researchers, industry professionals, students (BTech, MTech, MSc, PhD) in plant biotechnology/bioprocess engineering/ biotechnology and faculty from recognised institutions can apply. Applicants are expected to have a basic knowledge of plant cell and microbial technology and fermentation.

Shyamakant Giri to join as CEO of Gland Pharma

Gland Pharma's Board has approved the appointment of Shyamakant Giri, as the new Chief Executive Officer (CEO) of the company. Giri is expected to join the company with effect from January 15, 2025. Giri is a business leader with over 25 years of strategic and operating experience in pharmaceuticals, devices, diagnostics and healthcare services in leading Indian and multinational organisations across Asia, Africa, MENA & LATAM markets. He possesses rich experience in creating new ventures and improving existing businesses, developing leaders, identifying opportunities for value creation, and executing with discipline. His specialties include Business Development, Operations, Strategy, Product Marketing, startups, and turnarounds. Giri is currently the President (India Business & Emerging Markets) of Amneal Pharmaceuticals, responsible for the commercial expansion and growth in India and Rest of the World markets. Previously, Giri was associated with Rivaara Labs as the Chief Executive Officer. Earlier, Giri was associated in various roles with Abbott India, AbbVie (India Region) and Abbott Diagnostics for almost eighteen years (2002-2020).

SpeeDx appoints Jeremy Stackawitz as CEO to expand molecular diagnostics solutions

SpeeDx, a leading innovator in molecular diagnostic solutions based in Australia, has announced the appointment of Jeremy Stackawitz as Chief Executive Officer (CEO). With more than 25 years of leadership experience in the life sciences and diagnostics sectors, Stackawitz will focus on accelerating SpeeDx's commercialisation, partnering and regulatory activities across key markets, including the United States. His proven success in scaling businesses globally, along with his deep understanding of the diagnostics landscape, makes him the ideal leader to guide the company's next phase of growth. Stackawitz joins SpeeDx from Senzo, where he served as CEO, driving the financing, growth, and product expansion of the company.

LigaChem Biosciences names Dr Rodrigo Ruiz Soto as CMO

South Korea-based LigaChem Biosciences, Inc., a leader in the development of innovative antibody-drug conjugates (ADCs) for the treatment of cancer, has announced the appointment of Rodrigo Ruiz Soto, M.D., as Chief Medical Officer (CMO). Dr Ruiz Soto will play a pivotal role in driving the company's clinical strategy and advancing its robust pipeline of therapeutic candidates.

Dr Ruiz Soto brings to the table over 20 years of global experience in oncology clinical development, having held senior leadership positions at renowned biopharmaceutical companies. Most recently, he served as Senior Vice President of Clinical Development at Deciphera Pharmaceuticals, where he led the clinical development function and successfully advanced small molecules, including the global approval of Ripretinib. His expertise encompasses a wide range of oncology indications, including solid tumours and hematological malignancies. Prior to his role at Deciphera, Dr Ruiz Soto served as Senior Medical Director at ImmunoGen, Inc., where he was the medical lead for the Mirvetuximab Soravtansine programme, which was approved by the FDA in 2022. He also held key positions at Sanofi Oncology, where he oversaw the clinical development of several oncology clinical trials, including a pan-PI3K and mTOR inhibitor.

Virtus Fertility Centre Singapore expands medical team with addition of Dr Tan Heng Hao

Virtus Fertility Centre Singapore has announced that Dr Tan Heng Hao, a specialist in fertility care and obstetrics and gynaecology, will be on its medical panel effective November 1, 2024. Dr Tan Heng Hao is a consultant fertility specialist and obstetrician-gynaecologist (OBGYN) in Singapore. With extensive experience and qualifications, he specialises in advanced fertility treatments like IVF, surgical sperm retrieval, and laparoscopic tubal reversals. He also specialises in minimally invasive surgeries for endometriosis and other gynaecological conditions. Dr Tan held key positions at KK Women's and Children's Hospital (KKH), including Head of the Department of Reproductive Medicine, Senior Consultant in the Endometriosis Centre and Maternity Services, and Director of the IVF Centre and National Sperm Bank. He is also a clinical faculty member at several universities' OBGYN residency programmes.

I-Mab ropes in Dr Sean Fu as CEO

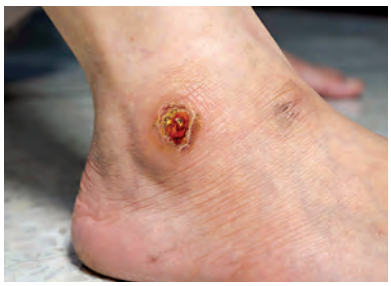
I-Mab, a US-based, global biotech company exclusively focused on the development of highly differentiated immunotherapies for the treatment of cancer, has announced that Sean (Xi-Yong) Fu, PhD, MBA has been appointed as the company's permanent Chief Executive Officer (CEO) effective November 1, 2024. Dr Fu has served as Interim CEO since July 15, 2024. He will continue to serve as a member of the Board of Directors of I-Mab. Dr Fu has over 20 years of industry experience in the life sciences industry, leading and developing clinical-stage assets. Most recently, Dr Fu served as the Operating Partner of ABio-X, an incubation platform for life sciences companies. Before joining ABio-X, he was co-founder and CEO of RVAC Medicines (RVAC), an mRNA platform company. Prior to founding RVAC, Dr Fu was Group VP and head of International R&D for Luye Pharma Group, overseeing organisations in Boston, Princeton, Germany, Switzerland, and Japan. He was also the CEO of GeneLeap, a Luye subsidiary company focused on DNA and RNA therapeutics. Previously, Dr Fu worked at Merck & Co. (Merck) for 15 years, with responsibilities covering R&D, business development, finance, and operational management.

Senhwa Biosciences brings Dr Yiu-Lian Fong on board as new Corporate Director

Taiwan's Senhwa Biosciences, Inc., a drug development company focusing on first-in-class therapeutics for oncology, rare diseases, and infectious diseases, has announced the appointment of Dr Yiu-Lian Fong to the board of directors for Ding Li Development. Dr Yiu-Lian Fong, a present member of the Bio Taiwan Committee (BTC) under the Executive Yuan since 2020, has served various organisations in Taiwan including the BTC, the Ministry of Science and Technology Council, and the Medical Device Innovation Center, NCKU as an expert consultant since 2017 to help drive the growth of Biotech industry. Dr Yiu-Lian Fong previously served as the Global Head, Diagnostic Innovation and R&D and Clinical Biomarker Strategy and Development at Janssen, Johnson & Johnson. Having nearly 30 years of successful R&D leadership experience for new drug discovery and development in the global pharmaceutical companies, she is dedicated to addressing unmet medical needs for major diseases such as cancer. Her versatile experiences will provide valuable insights into Senhwa's strategic approaches to developing new drugs, help accelerate development timelines, and position Senhwa for the global market.

India creates sprayable hydrogel for improving wound healing

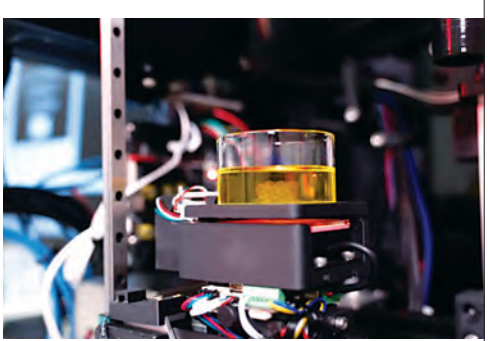
Researchers at the Indian Institute of Technology Delhi (IIT-D)'s Centre of Biomedical Engineering (CBME) have initiated a study to explore methods to improve wound healing by promoting the human body's natural healing process. The research has led to the creation of a new sprayable hydrogel system, which they tested in a rat model during the preclinical trials and got encouraging results. Like a human body that releases important metal ions namely calcium, copper, and zinc in



a certain order at injury sites, this engineered biocompatible sprayable hydrogel fills the wound and releases these multi-ions from medical grade Polylactic acid (PLA) based micro-carriers in sync with the body's natural process, effectively enhancing the healing process. These metal ions are the unsung heroes of the natural healing process, fighting infection, reducing inflammation, supporting cell migration, and stimulating new tissue growth. The preclinical trial results showed that the sprayable hydrogel, on which the IIT Delhi researchers are working, provided faster and more effective healing within 6 days in comparison to 12 days by similar products available in the market.

Australia designs high-speed 3D bioprinter as game changer for drug discovery

Biomedical engineers from the University of Melbourne, Australia have invented a 3D printing system, or bioprinter, capable of fabricating structures that closely mimic the diverse tissues in the human body, from soft brain tissue to harder materials like cartilage and bone. This cutting-edge technology offers cancer researchers an advanced tool for replicating specific organs and tissues, significantly improving the potential to predict and develop new pharmaceutical therapies. This would pave the way for more advanced and ethical drug discovery by reducing the need for animal testing. Most commercially available 3D bioprinters rely on a slow, layer-by-layer fabrication approach, which presents several challenges. This method can take hours to finish, jeopardising the viability of living cells during the printing process. Additionally, once printed, the cell structures must be carefully transferred into standard laboratory plates for analysis and imaging, a delicate step that risks compromising the integrity of these fragile structures.

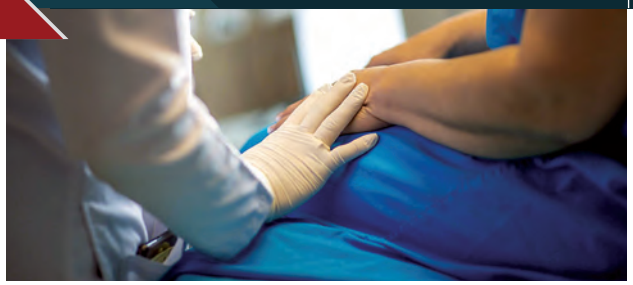


Singapore develops grain-sized soft robots for drug delivery

A team of scientists at Nanyang Technological University (NTU), Singapore has developed grain-sized soft robots that can be controlled using magnetic fields for targeted drug delivery, paving the way to possible improved therapies in future. The study is believed to be the first reported instance of miniature robots that can transport up to four different drugs and release them in reprogrammable orders and doses. Compared to earlier small-scale robots which can only carry up to three types of drugs and cannot be programmed for release in order, the newly developed miniature robots offer precision functions that have the potential to significantly improve therapeutic outcomes while minimising side effects, said the research team. The NTU team had previously developed magnetically controlled miniature robots capable of complex manoeuvres such as 'swimming' through tight spaces and gripping tiny objects.

Hong Kong develops soft microelectronics technologies enabling wearable AI for digital health

A research team at the Department of Electrical and Electronic Engineering at the University of Hong Kong (HKU) has introduced a groundbreaking wearable in-sensor computing platform. This platform is built on an emerging microelectronic device, an organic electrochemical transistor (OECT), invented explicitly for bioelectronics applications. The team established a standardised materials and fabrication protocol to endow OECTs with stretchability. Through those efforts, the built microelectronics platform integrates sensing, computing, and stretchability into one hardware entity, endowing it with an exclusive capability for wearable in-sensor computing applications. The research team further developed an accessible, multi-channel printing platform to ease the fabrication of the sensors at scale. Through integration with circuits, they demonstrated the platform's ability to measure human electrophysiological signals in real time. Results showed stable, low-power in-situ computing even during motion. The research team believes their work will push the boundaries of wearables and edge-AI for health.

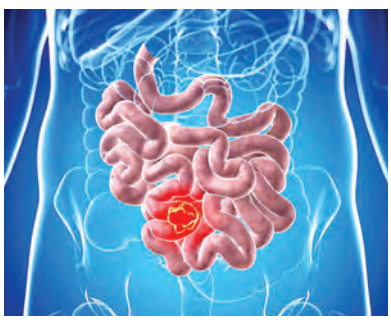


Thailand explores use of stool DNA as non-invasive alternative for colorectal cancer screening

A recent prospective cross-sectional study in Thailand demonstrates that multi-target stool DNA testing is highly sensitive and specific for detecting colorectal cancer (CRC) among Thai individuals. Researchers believe that this testing method could serve as a viable non-invasive alternative to colonoscopy, especially in settings where colonoscopy is less accessible or less accepted by patients. This study was conducted by BGI Genomics, in collaboration with Professor Varut Lohsiriwat's team from the Faculty of Medicine, Siriraj Hospital, Mahidol University, Thailand. Researchers focused on evaluating the diagnostic performance of the multi-target stool DNA testing for detecting CRC and advanced adenoma, using colonoscopy as the reference standard. The study included both asymptomatic and symptomatic patients who underwent stool DNA testing followed by colonoscopy. The multi-target stool DNA test targeted methylation statuses of SDC2, ADHFE1, and PPP2R5C genes. Sensitivity, specificity, and other diagnostic parameters were analysed. BGI Genomics' COLOTECT stool DNA testing kits were used for sample and raw data collection.

New Zealand lays focus on bowel cancer detection breakthrough

Researchers in New Zealand hope identification of new RNA molecules will help doctors predict if a patient's bowel cancer will return or not. The University of Otago-led study could enable health professionals to separate colorectal cancer patients, present at an early stage, into groups of who will and won't go on to develop metastasis and disease recurrence. According to the researchers, this would result



in better treatment outcomes as high-risk patients would receive additional chemotherapy, while those who are at low risk would avoid overtreatment. The researchers identified three long noncoding RNAs (lncRNAs) which were found only in the cancer cells and not in any healthy tissues of the body. High levels of these lncRNAs were associated with worse outcomes for patients, meaning they have the potential to be predictors of patient prognosis.

Waters unveils new software to deliver lab-centric business intelligence

Waters Corporation has announced the launch of waters_connect Data Intelligence software, a new cloud-based application that helps customers in regulated industries improve how they access, organise, analyse, and drive productivity from laboratory information. The software leverages data from Waters Empower Chromatography Data System (CDS) enabling laboratories to achieve confident audit-readiness, helping laboratory managers respond more quickly to audit inquiries with insights, and making informed decisions faster. Designed to work with Empower CDS, waters_connect Data Intelligence software generates in-depth, configurable dashboards that deliver advanced analytical insights on laboratory data such as aborted injections and sample sets to help reduce the risks associated with adverse findings in regulatory audits. Where users of Empower CDS can take, on average, two days to respond to an auditor's question, they can instead avoid costly manual data consolidation and interpretation that could lead to data analysis errors.

BioIVT and Krishgen BioSystems partner to enhance clinical research in South Asia

US-based BioIVT, a global research partner and biospecimen solutions provider for drug and diagnostic development, has announced an exclusive agreement with India headquartered Krishgen BioSystems, a leading provider of life science research tools and services for over two decades in India, Bangladesh and Nepal. Krishgen's long-standing experience and strong presence in the region, combined with BioIVT's industry-leading products, will create unparalleled opportunities for researchers to access high-quality, reliable solutions. Through this agreement, Krishgen BioSystems exclusively represents BioIVT's comprehensive portfolio of biofluids, tissues, cell products, media, and subcellular fractions/enzymes in India, Bangladesh and Nepal. This diverse range of biological materials is essential for research in areas such as drug discovery, development, toxicology and personalised medicine. The commercial relationship will not only provide faster lead times and competitive pricing but also ensure ongoing technical support and customer service, further enhancing the overall research experience.

Shimadzu releases CellTune software for supporting optimisation of cell culture conditions

Japan's Shimadzu Corporation has released CellTune software for supporting optimisation of cell culture conditions that uses artificial intelligence (AI) to assist with selecting optimal cell culture conditions. This product suggests optimal conditions, such as the optimal culture medium composition or culturing environment, based on data from culture supernatant analysed using a liquid chromatograph mass spectrometer (LC-MS) system and LC/MS/MS method package for cell culture profiling. Since February 2022, Shimadzu has been working with an AI startup Epistra Inc. (based in Minato-ku, Tokyo) to develop solutions for optimising culture conditions. That collaboration resulted in the development of CellTune, which includes a feature extraction module for identifying parameters that have a major influence on culturing results based on data from analysing 144 components in culture supernatant using a Shimadzu LC-MS system and an AI automatic optimisation module for suggesting optimal culture conditions.

Nikon inaugurates India's first experience centre for healthcare range

Nikon India, a 100 per cent subsidiary of Japan's Nikon Corporation, has inaugurated India's first experience centre dedicated exclusively to the healthcare product range at its headquarters in Gurugram, India. The Healthcare Business is one of the largest business segments of Nikon Corporation that owes the responsibility to lead a life science market through core optics and image analysis technologies. Nikon has been a significant player in the Indian market for over four decades, primarily through its imaging and precision technologies. With the launch of this healthcare experience centre, Nikon India aims to provide a hands-on experience to healthcare professionals, researchers, and academic institutions to explore and utilise its cutting-edge microscopy solutions. This experience centre will also focus on microscopy workshops and training for skill development of the latest microscopy technologies in this region. The healthcare product range showcased at the experience centre includes Nikon's flagship Confocal Microscope System AX R with NSPARC, renowned for offering the largest Field of View (25mm) on both inverted and upright microscope. Additionally, it also showcases prominent products like Digital Imaging Microscope ECLIPSE Ui and The Smart Imaging System ECLIPSE Ji.

Agilent releases next-gen HPLC systems with enhanced automation and sustainability capabilities

Agilent Technologies Inc. has announced the release of its next generation Agilent InfinityLab LC Series portfolio, which includes the 1290 Infinity III LC, 1260 Infinity III Prime LC, and 1260 Infinity III LC systems, all including the biocompatible versions. These are the first HPLC systems on the market to feature the new Agilent InfinityLab Assist Technology, offering enhanced, built-in system assistance capabilities. This technology allows labs to focus more on achieving results rather than on daily operation and maintenance tasks. With the introduction of these new LC systems, Agilent is revolutionising the LC user experience. These systems significantly enhance task automation, connectivity, predictive feedback, and error reduction. The innovative built-in sample tracking, utilising barcoding and camera technologies ensures the elimination of sample mix-ups, providing users with greater accuracy.

BD announces new robotics solution to automate, standardise single-cell research

US-based BD (Becton, Dickinson and Company) has announced the commercial launch of the first in a family of high-throughput, robotics-compatible reagent kits that will enable automation to ensure greater consistency and increased efficiency of large-scale, single-cell discovery studies. The automated solution from the BD and Hamilton collaboration standardises traditionally manual processes and speeds the generation of material for genetic sequencing. The solution includes the newly released BD OMICS-One XT WTA Assay and the Hamilton Microlab NGS STAR automated liquid handling platform. Because the NGS STAR is already installed in many laboratories and facilities worldwide, more researchers, processing samples across an array of genomics applications, can easily integrate the new automation-ready BD assay into existing workflows. The BD OMICS-One XT Library Preparation Reagent Kits and Hamilton Microlab NGS STAR automated liquid handling platform and applications are commercially available globally.

Trump Healthcare 2.0: it will be much more to Americans

With clear mandate given by the US citizens in the November 5 polls to Donald Trump, the President Elect, who in his poll campaign announced 20 promises that his Republican Party will accomplish quickly when it will win the White House elections, has started nominating the right people who will deliver what is promised to the American people under 2024 GOP Platform Make America Great Again popularly known as MAGA!

Trump has appointed Robert F Kennedy Jr as Secretary of the Department of Health and Human Services (HHS). The independent candidate for 2024 had questioned the origin of the COVID-19 virus and criticised mass immunisation campaigns. Most famously, he had drawn a correlation between children's immunisations and autism. Trump appointed Dr Mehmet Oz, a physician and television celebrity, to lead the Department of Health and Human Services' Centers for Medicare and Medicaid Services.

Trump picked former Florida Republican Congressman Dr Dave Weldon to serve as the Director for the Centers for Disease Control (CDC). While in Congress, Weldon introduced a bill that would give responsibility for the nation's vaccine safety to an independent agency within the Department of Health and Human Services, removing most vaccine safety research from CDC.

At the Food and Drug Administration, Trump appointed Dr Marty Makary as a commissioner. In addition to serving in senior positions at the World Health Organization (WHO) Patient Safety Program, Makary is currently the chief of Islet Transplant Surgery at Johns Hopkins. He has been a think tank Paragon Health Institute's public adviser, a member of the National Academy of Medicine, and a frequent expert guest on Fox News. Amidst a lot of geopolitical crises and healthcare issues, the world is keen to know how Trump will fulfil the promises he had made during the election rallies.

The Republican Party has made the following promises to the people of America in its poll agenda. The party noted that healthcare and prescription drug costs were out of control during Democratic regime under Biden's leadership. Republicans will increase Transparency, promote Choice and Competition, and expand access to new Affordable Healthcare and prescription drug options. It also noted that it will protect Medicare, and ensure Senior citizens receive the care they need without being burdened by excessive costs.

President Trump has made absolutely clear that he will not cut one penny from Medicare or Social Security. Republicans will support increased focus on Chronic Disease prevention and management, Long-Term Care, and Benefit flexibility. It will expand access to Primary Care and support Policies that help Seniors remain in their homes and maintain Financial Security.

President-elect Trump's second term marks a significant shift in the political landscape that could have considerable implications for the health industry, noted PwC in its report. The report added that Donald Trump will maintain his strong stance on deregulation and prioritise policies that address healthcare access and costs. Looking ahead, the Trump administration intends to uphold campaign promises for the health sector with four key themes: Promote access to healthcare via market competition and transparency, Enhance flexibility and choice in healthcare to states and individuals, Focus on deregulation by reversing or modifying Biden-era policies, Enhance national security with "America First" principles.

Paul Keckley in his The Keckley Report noted that Trump Healthcare 2.0 will bring heightened transparency to the health system and be premised on pillars that are popular with working class voters. It will not be a duplicate of Trump Healthcare 1.0; rather it will be much more to local Americans.

Being the WHO's second-largest Member State contributor, the USA has been a steadfast supporter of the Organisation's work to combat polio, HIV/AIDS, tuberculosis and malaria, while helping advance global health priorities such as primary care for mothers and children, food and drug safety, and global health security. With the change in guard at the helm and focus on 'America First' let's see what the new regime in the USA will offer to the world from 2025. BS

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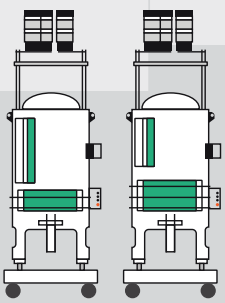
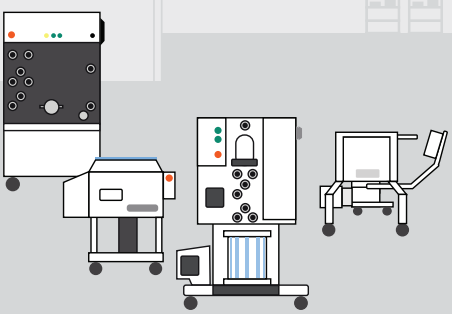
cytiva

Your helping hand in delivering advanced therapeutics

Plasmid manufacturing

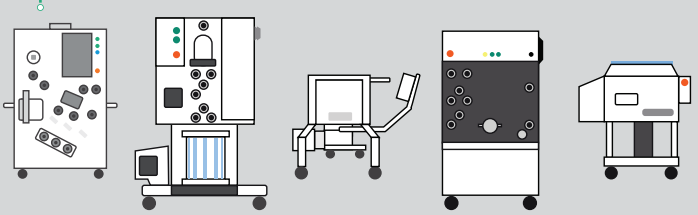


Conditioning, capture, and polishing



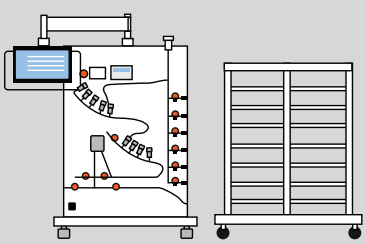
mRNA synthesis

LNP formulation

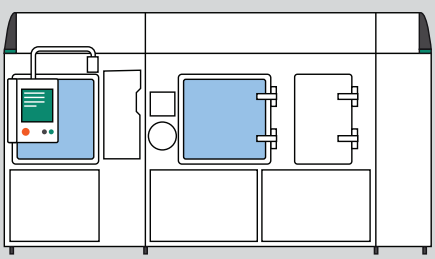


Drug discovery
Process development

Drug substance fill



Drug product fill



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