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TRANSFORMATIVE LIFE SCIENCES TRENDS FOR 2024

"Pharma companies in South Korea will need to invest in skill development"
- Journey Hong, General Manager, West Pharmaceutical Services, Inc., South Korea

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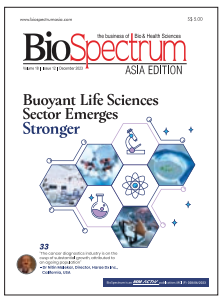

Acknowledgement/ Feedback

It is a beautifully put-together edition for December 2023, and motivating to end the year on a positive note. Thank you for the coverage on BC Platforms in the cover story.

- Daniel, UK

I cannot express my thanks enough for running the article by Baker McKenzie, within the cover story of BioSpectrum Asia's December edition.

- Jamie, Australia

We appreciate the representation of our company Bertis' content in the cover story and find the article to be greatly beneficial in reflecting on 2023! We are delighted to have participated in this feature.

- Yujin, Korea

Thank you BioSpectrum Asia. The article titled 'Focusing on Women's Cancers' looks great. We really appreciate you using Dr Heather White's article in your December 2023 edition.

- Taera Shapoorjee, India

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Letter from Publisher

Ravindra Boratkar
Publisher &
Managing Editor,
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Dear Readers,

Let me begin this letter by wishing you a very happy and prosperous 2024. Let us all wish that let there be many many more innovations in the digital health arena in the year to make human life healthier.

Digital health is the intersection of technology and healthcare. It has become a buzzword in healthcare sector as its emergence is making us see tremendous shift in the way the healthcare industry operates. In digital health, technology is used to improve the efficiency, effectiveness, and delivery of healthcare services. From mobile health apps to wearable devices, digital health has revolutionised the way we think about healthcare.

Still further, digital health holds immense potential for the life sciences industry in future. As we welcome 2024, our content team is set out to predict the tech trends that will shape the life sciences industry in the new year. Generative AI (GenAI) is set to hyper-personalise care services, as 49.6 per cent of the healthcare provider's plan to invest in GenAI use cases and this will further gain foothold in 2024. Another trend likely to gain momentum is the use of Augmented Reality (AR) and Virtual Reality (VR) applications to enhance medical training and surgeries.

There has been a flurry of activities in the personalised medicines space, with Australia unlocking the potential of personalised medicine through a $66 million investment in genomics research. BCC Research has forecasted that the Asia Pacific market for bioinformatics in genomics is expected to register a Compound Annual Growth Rate (CAGR) of 11 per cent from 2020 to 2025.

Our second important topic in this issue is cervical cancer which stands as the second most prevalent cancer. Projections indicate a rise in the annual incidence of new cases from 570,000 to 700,000 between 2018 and 2030, with corresponding deaths expected to increase from 311,000 to 400,000.

We also have a thought leadership piece that explores the connection between climate change and neglected tropical diseases.

Once again, a happy new year and happy reading!

Thanks & Regards,

Ravindra Boratkar
Publisher & Managing Editor

COVER 19

Transformative Life Sciences Trends for 2024

The intersection of tech and healthcare holds immense potential for the life sciences industry. From generative artificial intelligence (GenAI), augmented reality (AR), and virtual reality (VR) to decentralised clinical trials and 3D printing, we delve into the latest tech trends such Cellular Multi-Omics, Gene Editing CRISPR Technologies, Decentralised Clinical Trial (DCTs), digital health, digital twins, smart manufacturing, and wearables poised to lead the life sciences landscape in 2024.

Cervical Cancer

Bacteriophages

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Neglected Diseases

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INDIA'S CDMO ASCENSION

Dr Milind Kokje
Chief Editor
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We are ushering in 2024 with a good development for the Indian pharmaceutical sector. A news report states that drug makers are seeking to limit their reliance on Chinese contractors who produce drugs used in clinical trials and early-stage manufacturing. They are now shifting their focus from China to India, favouring Indian manufacturers over their Chinese counterparts.

This is a significantly positive move for Indian drugmakers since China has been the preferred destination for over two decades when it came to a range of pharmaceutical research and manufacturing services. Two main reasons that were in favour of China then were low cost and the rapid production capabilities of the Chinese contract drugmakers. However, this trade relationship started weakening with the US China trade conflict and subsequent disruptions in the trade since the pandemic. Finally, it appears to be culminating into the drugmakers shifting their focus from China to India.

This shift from China to India is particularly more important and significant at this juncture when the image of the Indian pharma sector is tarnished due to deaths of children abroad allegedly due to cough syrups produced by Indian pharma companies. Though only a few cough syrup making companies are to be blamed for these deaths, unfortunately the image of the entire sector gets impacted and people lose confidence in the sector. But foreign companies looking at India for contract production of clinical trials and early stage drugs amounts to reaffirming their confidence in the Indian companies and their products. Indian pharma needed that at this stage.

The Indian companies are gaining trust in one more way. Drugs for the clinical trial have to be the most perfect in every respect as they are in the trial and test stage. Indian companies are being chosen for such a sensitive job. As a result, Indian contract development and manufacturing organisations (CDMOs) have started receiving more requests for proposals from western pharma companies and multinationals.

This development is attributed to two reasons. The industry feels that China is a less attractive option now compared to India. Western industry has also been advised by their respective governments to de-risk their supply chain. The dependence on China is too much. As a result, pharma companies are enquiring with Indian CDMOs to produce active pharmaceutical ingredients (APIs) for clinical trials and other outsourced work.

On its part, Indian companies are progressing well in different areas including manufacturing of APIs. India was importing nearly 70 per cent APIs from China prior to COVID-19 as it was a cheaper option. But, as the supplies of APIs from China were affected due to the COVID-19-induced shutdowns, the government realised the danger of over dependence on China. It encouraged Indian companies to manufacture APIs domestically.

The government announced production linked incentives (PLI) schemes under which Rs 6,000 crore were earmarked for companies to start producing 53 APIs that are imported from China on large scale. Of them, 45 APIs have already being produced by Indian companies. These steps are expected to reduce India's dependence on China for APIs by 35 per cent in the next few years. Domestic manufacturing of APIs not only helped Indian pharma companies to source them locally, but also made the western and other companies abroad look at India as one more reliable source of APIs other than China. One recent news report says that India's bulk drug import from China has increased from 62 per cent to 75 per cent in the last nine years. However, experts feel that it will take some time to witness the change.

When the dependence on Indian CDMOs or API manufacturers is growing, the responsibility of these companies has also increased exponentially. Western pharma companies are expecting more steps from the CDMOs to ensure reputation on quality standards matching their own. This is particularly important when certain incidents affect the reputation of quality of medicines produced in India. The Indian companies will have to meet these expectations to sustain and even enhance the confidence that western companies are showing in Indian companies. BS

Korea, Japan and China pledge to cooperate closely on healthcare

Second Vice-Minister of Health and Welfare in South Korea, Park Minsoo attended the 16th Tripartite Health Ministers' Meeting, which was held recently in Beijing, China, to discuss ways of strengthening cooperation in healthcare, including joint responses to infectious diseases, under the theme of "Work together for a healthier and safer future". At the first face-to-face meeting in four years, the representatives of the three countries (South Korea, China and Japan) confirmed their commitment to strengthening bilateral and tripartite strategic cooperation in the area of healthcare, including health security for peace and security in the Asia-Pacific region. Specifically, the health ministers of the three countries endorsed a joint statement, the final outcome of the meeting, signed a Memorandum of Consideration (MoC), and agreed to expressly stipulate that the three countries shall work together to jointly respond to public health crisis including future pandemics at the next Trilateral Summit. Notably, Korea and China signed a revised Memorandum of Understanding (MoU) on bilateral healthcare cooperation, under which the two countries agreed to expand cooperation in new fields including digital health.

Taiwan partners with US to develop digital health ecosystem

The Healthcare Information and Management Systems Society, US and the National Health Insurance Administration (NHIA), an agency under the Ministry of Health and Welfare of Taiwan, have formed an agreement to drive digital transformation in population health, digital capacity building, cybersecurity resilience and workforce development. This collaboration will develop a digital health ecosystem through an evidence-driven approach that is based on HIMSS digital capacity and maturity frameworks. This provides a quantified understanding of the current state and priorities at the country, health system and provider levels and helps refine priorities maximising population health outcomes. This collaboration will also strengthen Taiwan's cybersecurity resilience, with the support of HIMSS subject matter experts, thought leadership and advice. Through curated courses, professional certifications and accredited continuing education from world-class healthcare professionals, HIMSS and the NHIA will collaborate to build digital health workforce capacity to support a digital health ecosystem.

Australia launches first National Health & Climate Strategy

The Australian government has launched Australia's first National Health and Climate Strategy that is aimed at ensuring the health system can meet the challenges of climate change. With more frequent and extreme climate events, climate change presents a serious health and wellbeing challenge to Australians. The World Health Organisation (WHO) has described climate change as the greatest threat to global health this century. Australia's first National Health and Climate Strategy sets out as an ambitious whole-of-government plan aimed at addressing the health and wellbeing impacts of climate change and outlining priorities for reducing greenhouse gas emissions from the health system. The National Strategy brings together actions from across the Australian Government and partners around the world to set out an ambitious vision for healthy, climate-resilient communities, and a sustainable, resilient, high-quality, net zero health system. It incorporates feedback provided from over 270 submissions made by stakeholders in the health and aged care sectors, First Nations organisations, civil society groups, academia, and industry, as well as consultation from workshops and roundtables attended by more than 300 stakeholders.

NZ to design cancer control programme

New Zealand's Ministry of Health's Polynesian Health Corridors (PHC) programme is working with partners to design a multi-year cancer control programme to improve cancer outcomes in Polynesia. PHC is working with Cancer Research Centre, the Centre for Pacific and Global Health, within the University of Auckland and six partner countries on the design of this programme. The cancer control programme will be designed in partnership with PHC's partner countries, the Cook

Islands, Niue, Tokelau, Samoa, Tonga, and Tuvalu. Cancer control has been identified by Polynesian health leaders as a priority, and a key focus area for the PHC programme. Following the design phase undertaken by the University of Auckland, PHC will support the six countries to implement planned activities. This will include connecting to the New Zealand Health System. The design phase is expected to be largely completed by the middle of next year, with next steps starting soon after. PHC is a New Zealand Ministry of Foreign Affairs and Trade (MFAT) funded programme set up in 2020 to strengthen links between New Zealand's health system and partner countries.

WHO & India ink Traditional and Complementary Medicine 'Project Collaboration Agreement'

The Ministry of Ayush, Government of India, and World Health Organization (WHO) have signed a Traditional and Complementary Medicine 'Project Collaboration Agreement' in Geneva. Indra Mani Pandey, Permanent Representative of India to the United Nations, on behalf of the Ministry of Ayush, and Dr Bruce Aylward, Assistant Director General, Universal Health Coverage and Life Course Division, on behalf of WHO, signed the agreement. The main objective of this agreement is to standardise Traditional and Complementary Medical Systems, integrate their quality and safety aspects into the National Health System, and disseminate them at the international level. Through this cooperation agreement, efforts will be made to connect Traditional and Complementary Medical Systems with the mainstream of the National Health System. To fulfil this objective, Traditional Medicine Global Strategy 2025-34 will be prepared by WHO with the support of the Ministry of Ayush.

Nepal partners with World Bank to strengthen healthcare system

The Nepal Quality Health Systems Programme has been jointly launched by the Additional Health Secretary of Nepal, Dr Tanka Barakoti and World Bank Practice Manager for the Health, Nutrition and Population Global Practice, Feng Zhao. The programme aims to improve the readiness of the health system for delivery of quality healthcare, enhance coverage of health insurance, and strengthen health emergency preparedness and response capacity at the provincial and local levels. The five-year programme is financed by a $100 million concessional loan from the International Development Association and a $3.84 million grant from the Health Emergency Preparedness and Response Trust Fund. It will be implemented by the Ministry of Health and Population with the coordination of the Health Insurance Board at the federal, provincial and local levels in Koshi & Gandaki provinces to help achieve the strategic objectives of Nepal's Health Sector Strategic Plan, 2023-2030. These include enhancing efficiency & responsiveness of Nepal's health system, promoting sustainable financing & social protection in health, & promoting equitable access to quality health services.

Lunit buys Volpara Health Technologies for $193M

South Korea-based startup Lunit, a leading provider of artificial intelligence (AI)-powered solutions for cancer diagnostics and therapeutics, has announced its proposal to acquire New Zealand (NZ)-based Volpara Health Technologies, a global leader in AI-enabled software for the early detection and prevention of cancer. The strategic move comes as a result of an exhaustive evaluation of potential avenues for growth and innovation by Lunit. Combining Volpara's established presence in the US with Lunit's complementing global footprint and AI expertise will create a compelling portfolio of advanced AI-enabled solutions for radiology and for other healthcare specialties. Lunit is set to acquire a total of 254 million shares, translating to a deal worth about AUD 292 million ($193 million). Subject to the successful completion of these steps, Lunit anticipates finalising the acquisition by the end of the second quarter of 2024.

ADB provides $650M to support upgrading Indonesia's healthcare facilities and labs

The Asian Development Bank (ADB) has approved a $650 million investment loan to Indonesia to upgrade and enhance primary healthcare facilities and public health laboratories nationwide to improve prevention, detection, and treatment of communicable diseases, non-communicable diseases, and other health conditions.

The Primary Healthcare and Public Health Laboratories Upgrading and Strengthening (PLUS) project directly supports two government projects under the Health System Transformation Agenda: the Strengthening of Primary Healthcare in Indonesia (SOPHI); and the Indonesia-Public Health Laboratory System Strengthening (InPULS). The PLUS project will equip more than 10,000 primary health care facilities and more than 500 public health laboratories nationwide to fully meet the minimum service standards stipulated by the government. The support will include equipment procurement, delivery, commissioning, user training, operations and maintenance services (O&M), and capacity development in O&M.

MTaI unveils India's historic $464M medtech FDI leap

India has witnessed a record-breaking surge of $464 million in foreign investments in medtech in the first 3 quarters, said the Medical Technology Association of India (MTaI), which represents leading research-based medical technology companies with a large footprint in manufacturing and training in India. The government's focus on increasing the ease of doing business in the country, the creation of a globally harmonised regulatory regime for the medical device sector, and initiatives like the National Medical Device Policy (NMDP) 2023 and Promotion of Research and Innovation in Pharma Medtech Sector (PRIP) scheme have been welcomed by the industry as reflected by the growing confidence of investors. Notably, this surge also indicates a shift in global dynamics, with Western nations, including Japan, increasingly favouring India as their preferred destination for friend-shoring activities. The medtech FDI inflow for the first quarter of this year (Jan-March 2023) was around $39 million which rose to $301 million in the second quarter (April-June 2023). For the third quarter (July- September 2023), the figures were $124 million with a cumulative total inflow of $464 million for the period of January-September 2023.

GHIT Fund injects $8.8M in new drug development projects for malaria

The Global Health Innovative Technology (GHIT) Fund, headquartered in Japan, has announced an investment of approximately 1.3 billion yen ($8.8 million) for the development of new drugs for malaria and Chagas disease. The GHIT Fund will invest approximately 500 million yen ($3.3 million) in a clinical phase III trial for a triple artemisinin combination drug against malaria, in partnership with a leading Japanese integrated trading and investment business conglomerate, Marubeni, a major Chinese pharmaceutical

and health care company, Fosun Pharma, a Thailand-based research collaboration of universities, Mahidol-Oxford Tropical Medicine Research Unit (MORU), and the product development partnership Medicines for Malaria Venture (MMV), which provides technical support and market access expertise. The GHIT Fund will also invest approximately 800 million yen ($5.4 million) in the anti-malarial drug project by Eisai Co., and the University of Kentucky to develop a radical cure for P. vivax malaria. In addition, the GHIT Fund will invest approximately 16 million yen ($0.1 million) in Nagasaki University and Drugs for Neglected Diseases initiative (DNDi) for a screening project against Chagas disease, which is one of the neglected tropical diseases.

Novartis invests $84.6M in new radiopharmaceutical production base in China

Swiss firm Novartis has announced that it will invest in setting up a new radiopharmaceutical production base in China to accelerate the introduction of innovative radioligand therapies into China and benefit domestic cancer patients with clinical needs. This production base will be located in the Nuclear Technology Application (Isotope) Industrial Park in Haiyan County, Zhejiang Province, and the total investment is expected to exceed RMB 600 million ($84.6 million). In March 2022, an innovative drug from Novartis' targeted radioligand therapy was approved by the US Food and Drug Administration (FDA) for the treatment of prostate-specific prostate cancer that has progressed through androgen receptor pathway inhibitors and taxane chemotherapy. In December 2022, this innovative drug was approved in the EU, but has not yet been approved in China.

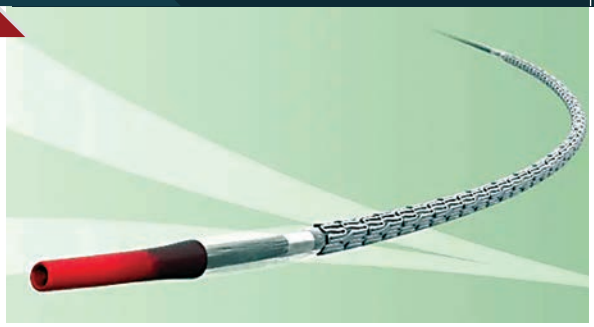
Fujifilm puts $200M into cell therapy development and manufacturing capabilities in US

Japan-headquartered Fujifilm Corporation has announced the investment of $200 million in two subsidiaries to significantly expand global cell therapy contract development and manufacturing (CDMO) capabilities. The investment will enable Fujifilm to support the expanding cell therapy market which is anticipated to grow by more than 30 per cent per year up from $3.3 billion in FY2022.

The $200 million investment in cell therapy manufacturing capabilities is earmarked for both the new headquarters of Fujifilm Cellular Dynamics, Inc., a leading global developer and manufacturer of human induced pluripotent stem cells (iPSC) and iPSC-derived cells, and the California site of Fujifilm Diosynth Biotechnologies, a world-leading CDMO in biologics and advanced therapies. This investment will strengthen Fujifilm's manufacturing capacity to support iPSC-derived cell therapies, as well as Cytoxic Tlymphocyte (CTL), Chimeric antigen receptor (CAR), T-cell receptor (TCR), Natural killer (NK) and tissue-derived therapies.

GC Genome partners with MP Group to commercialise genetic health services in Thailand

South Korea's GC Genome Corporation has entered into a collaboration and exclusive licence agreement with MP Group in Bangkok, Thailand, to commercialise 'Genome Health' for genetic health check-ups. Genome Health, a SNP genotyping service, utilising next-generation sequencing (NGS) to identify risk alleles associated with major cancer types and general diseases, has been developed by GC Genome. Under the terms of the agreement, GC Genome will grant MP Group an exclusive licence to commercialise Genome Health within the territory of Thailand. This collaboration includes the transfer of essential wet lab technology and know-how required to operate a genetic laboratory within Thailand by GC Genome. Once the technology is handed over, MP Group plans to launch the product under the name "genechecks" and initiate a marketing programme to promote it in Thailand. Along with this collaboration, GC Genome and MP Group have inked a Memorandum of Understanding (MoU) to further their partnership in expanding the range of products developed by GC Genome. This expansion includes technology transfer and encompasses areas such as Health Checkup, Pre & Neonatal Health, Precision Oncology, and Rare Diseases within the territory of Thailand.

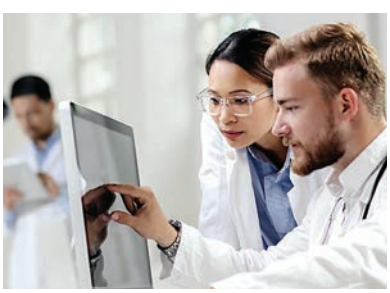


Japan's Terumo introduces drug-eluting stent for treatment of coronary artery disease in India

Terumo India, the Indian arm of Japan based Terumo Corporation, a global leader in medical technology, recently announced the launch of Ultimaster Nagomi, a Drug-Eluting Stent intended for use in the treatment of coronary artery disease. Cardiovascular disease is the cause of 25 per cent of all deaths in India with a prevalence of around 54.5 million in the country. Drug-Eluting Stents are specialised types of stents meant for use in the treatment of coronary artery disease. Investments are being made towards newer generation stents which can enhance the safety and effectiveness of coronary artery treatments. Ultimaster Nagomi, by Terumo India, is one such new generation Drug-Eluting Stent that can facilitate smooth navigation to complex arteries and adapt to any vessel size with ease. The optimal design of the Ultimaster Nagomi makes it suitable for any small or large sized coronary artery, enabling customised stent selection for a larger patient subset.

GC Biopharma establishes mRNA production facility in Korea

GC Biopharma, a South Korean biopharmaceutical company, has completed the construction of mRNA (messenger ribonucleic acid) production facility in its own vaccine production plant in Hwasun, Jeollanam-do, Korea, and will soon start the operation. The production facility is a GMP pilot plant that will support the company's strategy to internalise various mRNA-related technologies while continuously building up related capabilities. The new facility offers an "all-in-one" production capability



that accommodates all phases of mRNA production. It can, therefore, significantly reduce the contamination risk of transfer and allows prompt production response. In addition, the pilot plant has a single-use production facility that will reduce the cross-contamination risk and enable the production of multiple products at once. Based on the technologies and capabilities it would accumulate in the new mRNA production facility by testing the effectiveness and safety of various vaccines & treatment candidates, the company is planning to produce drugs for clinical trials in the GMP pilot plant with a roadmap to move on to commercialisation and further to contract manufacturing business.

German medtech firm BIOTRONIK opens new APAC hub in Singapore

BIOTRONIK has announced the opening of its new Asia Pacific Manufacturing and Research Hub. The 20,000 m² site will serve as the company's central hub in Asia Pacific (APAC), with hundreds of employees working in manufacturing, quality, research & development (R&D), and sales and marketing. BIOTRONIK, founded in Berlin, Germany, in 1963 is a pioneer in implantable pacemakers, defibrillators, and vascular intervention for 60 years. BIOTRONIK's presence in Singapore began in 2012, and in 2016, the company inaugurated its first manufacturing site, complementing its high-quality manufacturing sites in Germany, Switzerland and the United States. Now in 2023, the new facility has been designed with an emphasis on workspace agility for modern, optimised collaboration. The new site includes several spacious cleanrooms and laboratories developing and manufacturing state-of-the art Cardiac Rhythm Management (CRM) devices.

China's MGI Tech takes cutting-edge DNA, Cell and Spatial Omics capabilities to Australia

MGI Australia, a subsidiary of China headquartered MGI Tech Co., a global leader in life science technology, has announced a substantial expansion of its Brisbane Customer Experience Centre (CEC), now providing Australian and New Zealand researchers first access to MGI's cutting-edge DNA, Cell and Spatial Omics (DCS) capabilities.

The Customer Experience Centre established in 2021 was launched to provide users in Australia and New Zealand (ANZ) unique access to MGI's innovative technology portfolio, including the proprietary DNBSEQ platforms, laboratory automation systems, and bioinformatics appliances. After two years of continuous commitment to innovation, the CEC has undergone a significant expansion of capabilities to support research efforts in the region. It stands as the inaugural CEC with DCS lab products outside of MGI's home market in China.

Nipro partners with FPT Medicare to develop IoMT in Vietnam

Nipro, a multinational medical corporation from Japan, has recently partnered with Vietnam-based FPT Telecom's FPT Medicare on a strategic cooperation agreement to deliver digital medical devices with international standards and affordability. Through this collaboration, the two companies aim to provide esteemed global smart medical devices and services to the Vietnamese population. This initiative directly addresses the pressing demand for high-quality healthcare and helps alleviate the escalating financial burden associated with healthcare services. The Internet of Medical Things (IoMT), especially continuous bio-monitoring devices, are connected with health platforms to provide available personal health data and a comprehensive medical picture. FPT Medicare has obtained full authorisation for the distribution of the Nipro Premier, α Blood Glucose Monitoring System, for all pharmacies and medical device stores throughout Vietnam.

MedTech Innovator in partnership with APACMed announces winners of APAC Accelerator programme

US-based MedTech Innovator, the world's largest accelerator of medical technology companies, in partnership with Singapore-based Asia Pacific Medical Technology Association (APACMed), the first and only regional association to provide a unified voice for the medical technology industry, has announced that Medipixel is the winner of the 2023 Asia Pacific (APAC) Accelerator programme. Medipixel is a South Korea-based company that has developed MPXA, empowering physicians to better diagnose and treat cardiovascular disease, the leading cause of death in the world. The transformative healthtech AI company was awarded a prestigious $175,000 Grand Prize. The other finalists, Healium Medical (Israel), Module Innovations (India) and Vivo Surgical (Singapore) each received $10,000. Additionally, Neurowyzr was announced the winner of Enterprise Singapore's (EnterpriseSG) Startup SG award, comprising an SGD$ 30,000 grant prize and access to extensive resources and networks within Singapore's startup ecosystem.

DeepTek.ai makes US FDA cleared CADe Chest X-Ray AI solution commercially available

Indian startup DeepTek.ai, a leading provider of artificial intelligence (AI) solutions for medical imaging, has announced the commercial availability of Augmento X-Ray, a one of its kind CADe Chest X-Ray AI solution powered by US FDA Cleared CXR AI, at the world's largest radiology conference - Radiology Society of North America's (RSNA) 109th Annual Meeting. Augmento X-Ray is designed to significantly reduce radiologist workload and improve the quality of chest X-ray reporting. DeepTek's AI solutions have already made a significant impact in India and the Asia-Pacific region, transforming healthcare by increasing access to quality care at a lower cost. The company's products are deployed in over 500 hospitals and imaging centres, impacting the lives of over a million individuals every year. In Singapore, DeepTek's US FDA-approved platform, Augmento Enterprise, has been chosen as the national radiology AI platform, contributing to improved productivity and quality of care across public hospitals. DeepTek.ai has about 200 members and has partners like TATA Capital, NTT DATA Japan and Shimadzu Asia Pacific.

Singapore's Experimental Drug Development Centre inks new collaboration with Chinese startup XtalPi

XtalPi, an innovative technology company powered by artificial intelligence (AI) and robotics from China, has signed a Memorandum of Understanding (MoU) with the Experimental Drug Development Centre (EDDC), Singapore's national drug discovery and development platform hosted by A*STAR, for the expansion of their collaboration to encompass potential projects that will focus on the application of automated synthesis solutions and large language models in pharmaceutical research. Building upon an ongoing collaboration that was initiated in December 2022 to utilise AI and automation to develop targeted therapies for non-small cell lung cancer, the new collaboration aims to expedite the conversion of scientific discoveries into robust pipeline assets by advancing the domain of intelligent automated pharmaceutical research. Under the MoU, the two parties will explore collaborations in the fields of automated chemical compound synthesis and AI-driven drug discovery, including the application of XtalPi's robotics and AI-driven drug design capabilities in EDDC's R&D, such as automated library synthesis and other drug chemical synthesis services.

Fujitsu delivers advanced technology to Delight Health for treating delirium

Japan-based Fujitsu and Delight Health, a Bay Area startup, have announced that Fujitsu will licence its Topological Data Analysis (TDA) technology to Delight Health in exchange for an equity position in the company. This licence transfer will support Delight Health's plans to gain rapid US FDA approval by fiscal 2024 and bring to market an advanced delirium detection device to accurately predict the onset of the disorder and address the needs of patients suffering from this ailment. Fujitsu has developed TDA, an artificial intelligence (AI) technology that enables analysis of abnormalities and disturbances in complex, distorted and volatile time series data with broad applications in a range of industries including healthcare, manufacturing and infrastructure. From July 2018 to May 2021, Fujitsu researchers and Dr Shinozaki at Stanford University conducted joint research on the application of TDA to delirium detection using electroencephalogram (EEG) data. In July 2023, Dr Shinozaki co-founded Delight Health (DH) as a new company to commercialise this award-winning technology. Delirium is a serious disorder that impacts millions of people around the world.

Canadian startup Lydia AI expands reach in Korea

Lydia AI, a Canadian health artificial intelligence (AI) company, has announced its strategic collaborations with Hecto Data and Tobecon Inc., two prominent technology companies in South Korea. These partnerships aim to amplify the market potential of AI-enhanced solutions in the healthcare and insurance sectors. Hecto Data and Lydia AI have partnered to establish an intelligent data ecosystem, fostering innovative applications that promote the concept of "health is wealth." This innovative collaboration is currently being piloted by Metlife Korea inside their 360Health application. Simultaneously, Tobecon and Lydia AI have solidified their partnership to integrate AI capabilities into insurance software, elevating customer experiences through more intelligent and streamlined processes. A Memorandum of Understanding (MoU) signing ceremony to announce the partnerships was hosted by the Asia Pacific Foundation of Canada during their business mission to Seoul. The ceremony was witnessed by Tamara Mawhinney, the Ambassador of Canada to the Republic of Korea.

Takeda announces partnership with BIRAC to foster healthcare innovation in India

Japan-headquartered pharmaceutical firm Takeda has announced the signing of a three-year Memorandum of Understanding (MoU) with the Biotechnology Industry Research Assistance Council (BIRAC), a public sector enterprise set up by the Department of Biotechnology, Government of India. The partnership will allow Takeda to extend advisory and mentoring support to innovators and entrepreneurs while assisting them from ideation to market deployment of new-age healthcare solutions. The collaboration resonates with BIRAC's vision to stimulate, foster and enhance the strategic research and innovation capabilities of the Indian biotech industry for creation of affordable products addressing the needs of the largest section of society.

WHO calls on governments for urgent action to invest in Universal Health Coverage

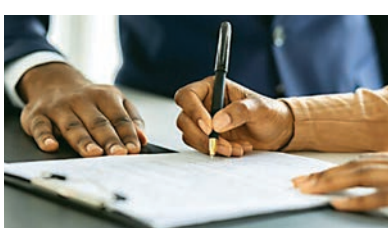
The World Health Organization (WHO) has published the 2023 global health expenditure report, which sheds new light on the evolution of global health spending at the height of the COVID-19 pandemic. The report reveals that in 2021, global spending on health reached a new high of $ 9.8 trillion or 10.3 per cent of global gross domestic product (GDP). Nevertheless, the distribution of spending remained grossly unequal. Public spending on health had increased across the world, except in low-income countries where government health spending decreased and external health aid played an essential supporting role. The 2023 global health expenditure report also draws on disaggregated spending data by health service providers from 50 countries. Spending at hospitals, ambulatory care providers and pharmacies accounted for most health spending across all income groups. The report calls for actions to improve data quality, data availability and timeliness. Key to this is the general institutionalisation of health accounts practices, in line with the global standard for the System of Health Accounts framework at the country level.

WHO's Science Council issues report on mRNA vaccine technology

Prompted by the life-saving impact of messenger ribonucleic acid (mRNA) vaccines during the COVID-19 pandemic, the World Health Organization's Science Council has released a report reviewing the potential benefits and limitations of mRNA vaccine technology. The report conveys the importance of research and development (R&D) efforts to COVID-19 mRNA vaccines and outlines challenges of inequitable access. The report recommends a framework to assess the value of mRNA technology in developing vaccines and therapeutics against other infectious diseases. A framework could also help establish the technology's potential role in addressing cancer and autoimmune diseases. To inform such a framework, the report maps out the clinical trial status of mRNA vaccines in the most advanced stages of development. The report also calls for further research to address the potential of this technology as well as its limitations.

France signs agreements to support WHO's work

Jérôme Bonnafont, Permanent Representative of France to the United Nations in Geneva, and Dr Tedros Adhanom Ghebreyesus, WHO Director-General, have signed several funding agreements totaling € 25.5 million to support critical health priorities. The agreements include € 4.5 million of funding for the CVCA of WHO; these are fully flexible funds which allow WHO to allocate resources to key priorities outlined in its General Programme of Work. An additional € 15 million will be used to deliver on specific key priorities, such as One Health, the advancement of universal health coverage, and primary health care, communicable and noncommunicable diseases, the medical countermeasure initiative, and the country readiness strengthening through WHO's office in Lyon. A large part of the contribution (€ 6 million) is aimed at covering the humanitarian response on several fronts: € 2 million will go towards enhancing mental health initiatives in Ukraine; € 0.35 million is to support the response to the cholera outbreak in Malawi; € 1 million will support WHO's humanitarian response in Gaza, with an additional € 2 million dedicated to strengthening the technical and human activities of the WHO Office in the occupied Palestinian territory.

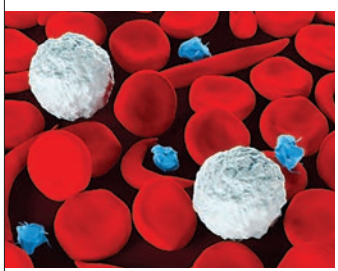


Testing to combat AMR in low-resource settings gets $10M boost from UK

FIND, a global health non-profit organisation based in Switzerland, has announced that a new $10 million grant agreement has been signed with the UK Department of Health and Social Care's Global AMR Innovation Fund (GAMRIF), extending GAMRIF's support to FIND for a period of 4 years. Antimicrobial resistance (AMR) is one of the top ten threats to global public health. The highest burden of AMR is in low- and middle-income countries (LMICs), and the growth of AMR is projected to result in a 25 per cent increase in healthcare costs in low-income countries by 2050, compared with a 6 per cent increase in high-income countries. The GAMRIF funding will be used in support of FIND's three-pronged strategy to prevent AMR emergence and halt its development. First, testing is essential to guide clinical decision-making. Second, there is a shortage of AMR-specific tools in LMIC hospitals, for conditions including hospital-acquired infections and bloodstream infections such as sepsis, with special attention needed for sepsis in newborns.

US FDA approves first gene therapies to treat patients with sickle cell disease

The US Food and Drug Administration (FDA) has approved two milestone treatments, Casgevy (Vertex Pharmaceuticals Inc.) and Lyfgenia (Bluebird Bio Inc.), representing the first cell-based gene therapies for the treatment of sickle cell disease (SCD) in patients 12 years and older. Additionally, one of these therapies, Casgevy, is the first FDA-approved treatment to utilise a type of novel genome editing technology, signalling an innovative advancement in the field of gene therapy. Casgevy, a cell-based gene therapy, is approved for the treatment of sickle cell disease in patients 12 years of age and older with recurrent vaso-occlusive crises. Casgevy is the first FDA-approved therapy utilising CRISPR/Cas9, a type of genome editing technology. Patients' hematopoietic (blood) stem cells are modified by genome editing using CRISPR/Cas9 technology. On the other hand, Lyfgenia is a cell-based gene therapy.



CEPI and PATH strengthen partnership to accelerate development of vaccines

Norway-based Coalition for Epidemic Preparedness Innovations (CEPI) and US-based nonprofit global health organisation PATH have announced a renewed collaboration to accelerate the rapid development of vaccines against emerging infectious diseases, and in support of CEPI's 100 Days Mission, a goal to reduce the time taken to develop safe and effective vaccines against pathogens with epidemic or pandemic potential to 100 days. Under the terms of the CEPI-PATH Implementing Partnership Agreement, PATH will help CEPI continue to enhance its capacities for project design and management, implementation, coordination and operational oversight. In doing so, PATH will also work with CEPI partners to provide such services that enable the rapid development of vaccines against pathogens with epidemic or pandemic potential, from proof of concept through to licensure. PATH will work across multiple CEPI-funded projects, including providing strategic, technical and scientific support for the clinical and manufacturing development process of vaccines, boosting innovative technology development, and facilitating capacity-strengthening initiatives that enhance local resources to help establish or improve research preparedness and emergency evidence generation for future outbreaks.

Transformative Life Sciences Trends for 2024

The intersection of tech and healthcare holds immense potential for the life sciences industry. From generative artificial intelligence (GenAI), augmented reality (AR), and virtual reality (VR) to decentralised clinical trials and 3D printing, we delve into the latest tech trends such Cellular Multi-Omics, Gene Editing CRISPR Technologies, Decentralised Clinical Trial (DCTs), digital health, digital twins, smart manufacturing, and wearables poised to lead the life sciences landscape in 2024.

As we enter 2024, we predict the technology trends that will influence the life sciences industry in the upcoming year. The evolution of GenAI is poised to revolutionise healthcare, with 49.6 per cent of healthcare providers planning to invest in GenAI use cases, as per a recent IDC report. Augmented Reality (AR) and Virtual Reality (VR) applications are gaining traction for enhancing medical training and surgeries. Trends such as 3D printing, Cellular Multi-Omics, Gene Editing CRISPR Technologies, Decentralised Clinical Trial (DCTs), digital health, digital twins, smart manufacturing, and wearables are expected to redefine the landscape in the new year. Let's delve into these trends in detail.

Gene Editing CRISPR Technologies propel cell and gene therapies

On December 8, 2023, the US FDA (United States Food and Drug Administration) approved the first-ever CRISPR-based treatment, CASGEVY, for sickle cell disease by Vertex and CRISPR Therapeutics. This marks a pivotal moment in gene editing, offering hope for genetic disorders and fueling the CRISPR therapeutics sector, one of pharma's buzziest areas.

"In the dynamic realm of gene editing and CRISPR technologies, the pace of advancement is nothing short of remarkable. Developers in the cell and gene therapy arena are fervently working to create improved therapies characterised by greater efficacy, improved safety profiles, and streamlined manufacturing processes. At the heart of this pursuit lie innovations in payload and delivery mechanisms. Within the gene editing landscape, developers are narrowing in on novel nucleases with specificity to, and optimal activity, at the targeted site. This endeavour seeks to navigate regions that may elude the original Cas9 nuclease. Simultaneously, developers are honing deaminases with high editing efficiency, coupled with a meticulous avoidance of bystander or off-target editing. The quest for precision extends to the realm of guide RNA design algorithms, ensuring the accurate navigation of nucleases to their intended target sites," said ***Michelle Fraser, Head of Cell & Gene Therapy, Revvity, USA.*** Revvity is a science-based solutions company that leverages innovation across life sciences and diagnostics to help improve lives.

In Asia, Korean firms like ToolGen and GenKOre are utilising CRISPR for gene-editing therapies. ToolGen focuses on wet macular degeneration and Charcot-Marie-Tooth (CMT) disease, while GenKOre is developing treatments for muscular, brain, and eye disorders. In January 2023, GenKOre partnered with a US-based pharma company for the development of in vivo gene editing therapies.

"Anticipating the trajectory in 2024, the horizon is set for substantial strides in gene modulation technologies. Expect to see a surge in the adoption of more intricate gene editing approaches, signalling a year marked by significant advancements in the refinement and application of these transformative technologies," said Michelle.

Cellular Multi-Omics advances shaping life sciences and diagnostics

The coming year promises to be a transformative one for the life sciences, with cellular multi-omics taking a leading role in helping to advance our understanding of cellular composition and function, and potentially revolutionising clinical diagnostics.

"In the rapidly evolving field of cellular multi omics, we can anticipate significant breakthroughs that will shape the future of life sciences. Cellular profiling assays are transitioning from traditional reliance on a limited set of markers within a singular molecular class to newer high-plex, high-cell number multi-omics assays. These assays target a combination of RNA, proteins, DNA, and various other marker types, and they are deepening our understanding of cellular composition and function. We can expect this very active applications development area to deliver significant advances in assays including expanded marker numbers and diversity; increased numbers of cell interrogation; streamlined workflows; enhanced resolution in spatial analysis; and reductions in the cost per cell or marker analysed. These improvements will make multi-omics technologies more accessible and drive their adoption. Additionally, AI/ML-driven informatics will simplify the interpretation of complex multi-omic datasets, making it easier to extract meaningful insights from vast amounts of data. While researchers in the highly competitive life sciences arena are rapidly making progress, we can also expect to see CROs and life science tool providers working diligently to standardise specific assays. This standardisation is a crucial step toward incorporating these technologies into clinical trials and eventually deploying multi-omic signature-based and companion diagnostics," said ***Dr Craig Monell, Senior Vice President, Business Operations, BioLegend,*** part of Revvity. BioLegend is a global developer and manufacturer of antibodies and reagents used in biomedical research.

3D printing will surge

In life sciences, 3D printing, once associated with organs, is now gaining momentum in printing drugs. As the pharmaceutical industry shifts to personalised models, 3D-printed drugs have the potential to revolutionise production.

"Biopharma and biotech companies in 2024 should keep an eye on the 3D printing of pharmaceuticals since the technology is at an emerging stage as the next high-potential segment of the pharmaceutical industry. This innovative technology enables complex drug delivery and

programmed drug release that is impossible using conventional technologies. These digital and diverse solutions to drug delivery challenges are accelerating the development of new drug molecules and extending the life cycle of branded products," said ***Dr Senping Cheng, founder and CEO of Triastek, China.*** Triastek is a global leader in 3D printing pharmaceuticals, pioneering the next generation of digital pharmaceutical processes.

Echoing the similar views, ***Alexander Ruckdaeschel, Chief Strategy Officer of Laxxon Medical, USA,*** said, "In the pharma industry, key players are eager to discover new, sustainable approaches to smarter medicine that can keep up with the demands of customers, providers and patients while also earning their loyalty. Noteworthy technologies will not only enhance treatment effectiveness and improve patient adherence but also streamline manufacturing processes and unlock disruptive commercial opportunities. Smart drug delivery systems with tailored pharmacokinetics, multi-drug tablets, optimised release profiles and anti-counterfeit primary labelling are just the beginning of what is already underway for companies like ours." Laxxon Medical is pioneering a novel additive manufacturing technology platform, SPID-Technology.

The APAC region is witnessing a surge in 3D printing innovations. Singapore General Hospital partnered with Nanyang Technological University for a Joint R&D Lab, aiming to deliver personalised medical solutions through additive manufacturing. Korea followed suit as Ulsan National Institute of Science and Technology collaborated with Pusan National University Yangsan Hospital to advance 3D printing for medical devices. Australia contributes to the frontier with a team from the University of Sydney and Children's Medical Research Institute (CMRI) utilising 3D photolithographic printing to replicate organ architecture for tissue creation. In the pharmaceutical sector, China-based Triastek and Eli Lilly explore 3D printing for oral drug delivery.

Digital demands shaping biopharma manufacturing

As pharma shifts from generic drugs to personalised medicines, it has become apparent that conventional systems need more capabilities to keep up with complex manufacturing processes. An increasing number of companies, including major biopharma firms, and contract development and manufacturing organisations (CDMOs), are digitising their processes. Sanofi inaugurated its first digitally enabled continuous manufacturing facility back in 2019. By June 2023, the company declared a comprehensive commitment to AI and data science across all operations. In manufacturing and supply, Sanofi is digitising quality assessment, transitioning from paper to electronic batch records, and harnessing digital capabilities for enhanced asset utilisation and increased productivity under manufacturing 4.0. With an in-house AI-enabled yield optimisation solution, Sanofi achieves consistently higher yields, optimising raw material use and supporting environmental goals.

After the successful completion of a proof-of-concept project with Siemens and Atos that focused on the production of particles of a vaccine adjuvant, GSK has gradually begun implementing digital twins into its development activities. Pfizer has also been utilising digital twins in its manufacturing process.

The University of Melbourne launched the ARC Digital Bioprocess Development Hub, an $18 million, five-year research programme funded with $5 million from the Australian Research Council (ARC). This initiative aims to enhance the Australian pharmaceutical sector's global competitiveness by integrating digitisation and AI into pharmaceutical manufacturing. The hub, led by an interdisciplinary team, focuses on developing advanced manufacturing processes that leverage big data for industry-wide adoption.

2024 will see increased adoption of industry 4.0 capabilities in the biomanufacturing process.

Pharma's digital health ambitions will solidify

Big pharma and digital health, once on opposite ends of the spectrum, are now coming together. The pharmaceutical industry increasingly relies on digital solutions to make further inroads into healthcare delivery, with broad-spectrum implications. Pharmaceutical giants have forged partnerships with digital health players; for example, South Korea-based startup Kakao Healthcare signed a business agreement with Denmark-headquartered Novo Nordisk Pharmaceuticals, a leading global diabetes treatment company, to provide smart healthcare services for chronic diseases. Japanese digital health firm Ubie also inked multiple partnerships with prominent pharmaceutical giants. In April 2023, Ubie partnered with Takeda to address Hereditary Angioedema (HAE), and in March 2023, Ubie collaborated with Pfizer to facilitate over 17,000 provider visits for OAB (overactive bladder) patients

Tech Trends for 2024

- GenAI
- AR/VR
- Wearables
- 3D Printing
- Multi-omics Diagnostics
- Gene editing
- Smart Manufacturing
- Genomics
- Pharma's digital health ambition
- Decentralised clinical trials

in Japan through integrated digital health solutions.

Some companies have launched separate entities for their digital health businesses. In May 2023, Bayer launched a business unit focused on developing new precision health products. In November 2023, AstraZeneca launched Evinova, poised to become a leading provider of digital health solutions catering to the needs of healthcare professionals, regulators, and patients.

In September 2023, leaders from Gilead, Merck, Novartis, Bayer, and Sanofi united to launch the Digital Pharma Circle (DPC). The Digital Pharma Circle brings together decision-makers within the digital health sector of the pharmaceutical industry, fostering meaningful discussions to drive the advancement of digital technology within the industry. DPC aims to drive practical implementation, ensuring members possess the expertise to catalyse transformative changes in the industry.

In 2024, anticipate a surge in collaborations, with pharmaceutical giants solidifying their digital health ambitions.

Decentralised clinical trial (DCTs) will reach new peak

Regulatory bodies are actively supporting DCTs. In May 2023, the USFDA issued draft guidance to facilitate their implementation, emphasising elements such as local laboratory tests and telemedicine-driven clinical follow-ups.

China, recognising the value of DCTs, issued guidelines in July 2023 supporting their implementation through telemedicine. Beijing encourages local pharmaceutical players to initiate DCT pilot projects, potentially paving the way for broader APAC interest in 2024, particularly in cost-constrained environments.

Another development in cross-border DCTs involves a Memorandum of Cooperation between Thailand's Department of Medical Services and Japan's National Cancer Center. This marks the first time patients from Thailand can participate online in a Japanese DCT, enabled by the granting of temporary medical licence in Thailand. This initiative promotes international collaboration, facilitating convenient patient participation and early enrollment.

GenAI takes centre stage

GenAI took the world by storm last year, and this is expected to catalyse progress in 2024. The healthcare industry also tested the waters with this latest tech, with almost all companies announcing projects with the potential to revolutionise the field.

Last year witnessed various initiatives and investments in the Asia-Pacific region. Singapore's Integrated Health Information Systems (IHiS) has formalised collaboration with Microsoft through a Memorandum of Understanding (MOU), marking a significant leap in generative AI and cloud innovation. This partnership introduces secure GPT for Healthcare Professionals, powered by Azure OpenAI Service, empowering healthcare workers with insights and task automation for heightened efficiency. In Japan, a cutting-edge generative AI tool has been introduced to aid doctors in summarising extensive patient interviews. Ubie's new GenAI feature achieves a remarkable 90 per cent user satisfaction rate, effortlessly condensing patient findings and streamlining medical record documentation. Australia reinforces its commitment to addressing health and medical challenges through strategic investments in GenAI.

The tech is expected to make greater strides in 2024. According to Deloitte, over 90 per cent of biopharma and medtech leaders foresee the impact of generative AI. Sixty-six per cent of life sciences companies are experimenting with generative AI, focusing on automating functions, transforming supply chains, and enhancing compliance. While 25 per cent of biopharma has established governance for generative AI, 50 per cent aim to do so within a year. For medtech, 20 per cent have governance in place, with 57 per cent expecting it by 2024. About 70 per cent of biopharma prioritises using generative AI for research, while half of medtech companies prioritise it. Some executives (25 per cent medtech, 18 per cent biopharma) await more evidence before investing in generative AI. In Medtech Digital Innovation, over 80 per cent allocate their largest digital investments to AI.

Wearables wave to continue

Weatbales- once seen as trendy accessories have now become an important healthcare device. GlobalData's IoT Thematic Research indicates a pivotal role for wearables in healthcare, driven by ageing populations, the rise of remote patient care etc.

Several APAC firms secured regulatory clearance

for their wearable devices. Indian Startoon obtained a US FDA clearance for its wearable recovery tracking device. Singapore approved Aevice Health's wearable stethoscope for respiratory monitoring, and Respiree, another Singaporean startup, received US FDA 510(k) clearance for its respiration monitor.

Researchers and companies are actively developing new, small, and sophisticated wearable devices. South Korea-based Sky Labs, known for its ring-type BP monitor, secured $15 million in Series C funding. Researchers at Monash University also developed a new ultra-thin skin patch with nanotechnology capable of monitoring 11 human health signals.

In an article in the British Journal of Sports Medicine, scientists emphasise the urgent need for improved integration of wearables in clinical trials and cohort studies. They propose regulators approve specific devices as add-ons to standard care, advocating for increased collaboration between industry and academia to unlock wearables' full potential in chronic disease diagnosis, prevention, and treatment.

AR/VR will soar to new heights

AR and VR in healthcare are revolutionising patient care, medical training, and treatment methodologies. With advancements in software and hardware, these technologies promise improved diagnostics, patient engagement, and overall healthcare outcomes. In 2024, it will become even more integrated into medical practices.

The most obvious and widespread application of VR has been in the space of medical education. Medical institutes and hospitals have been incorporating this technology in education. Thailand-based Mahidol University adopted virtual reality for medical education. While Hong Kong pioneered nursing education with first-of-its-kind VR learning. Japan-based startup Jolly Good in collaboration with Brigham and Women's Hospital, a hospital affiliated with Harvard University, developed emergency careVR content. Jolly is also developing a virtual reality-based cognitive behavioural therapy (CBT) programme for the spatial computer Apple Vision Pro.

The technology is also enhancing remote care and diagnosis. Australian researchers have developed smart glasses to improve diagnosis and treatment of foot wounds. Enosis Therapeutics, an Australian medical technology and research company, is exploring the integration of VR into existing psychedelic protocols. Singapore-based Mediwave unveiled the world's first mixed reality and AI-powered connected ambulance, with successful

launches already implemented in Malaysia and Sri Lanka.

"In 2024, biopharma and biotech companies should pay close attention to non-traditional, industry-disrupting technologies and clever business models which catalyse innovation, minimise cost and time, and integrate digital tools amidst the rapid growth of virtual health and artificial intelligence," said Alexander.

Genomics growth

In recent years, the fields of genomics and healthcare have experienced significant growth, with experts predicting a continued upward trajectory. Genomics is the backbone of personalised medicines. More than two decades after the completion of the first Human Genome Project, numerous countries are engaged in initiatives to collect and sequence health data. These efforts aim to enhance healthcare delivery for both large patient populations & personalised care.

The Asia-Pacific region has seen notable initiatives and investments. Australia introduced a genomic profiling initiative, bringing hope to 23,000 cancer patients. In Singapore, Agilent Technologies signed an agreement with the National Cancer Centre to accelerate translational cancer research on the genomic landscape of prevalent Asian cancers. Additionally, LifeStrands Genomics and Ambry Genetics are poised to offer laboratory testing for clinical implementation pilots in Phase II of Singapore's National Precision Medicine Programme. Indonesia has also taken substantial strides in developing its genomics ecosystem.

The life sciences industry is experiencing a digital revolution, with technology permeating almost all aspects of drug development and healthcare. In 2024, we expect further advancements and continued integration of technology to enhance clinical development, manufacturing & healthcare delivery. BS

Ayesha Siddiqui

Digitalisation Pharma Tech Trends to look for in 2024

« **Kai Vogt,**
Senior Vice President
Corporate Development,
Legal & Compliance,
IT, Vetter

As companies look ahead to 2024 trends, those that are well prepared for the future will not ignore technology and digitalisation trends, but rather find new and valuable ways to leverage them.

Year after year, trends in life sciences evolve to meet the industry's ever-changing needs. This includes growing demands of customer and patient expectations, aligning with the heightened capabilities of contract development and manufacturing organisations (CDMO), as well as remaining in front of the regulatory requirements for drug products with highly sensitive substances. When it comes to technology and digitalization trends, the landscape changes even faster.

In fact, the World Economic Forum states that 87 per cent of companies believe digitisation will disrupt their industry, but only half feel prepared for it. Life sciences, including pharma and biotech as well as their partners are not immune to this drastic transformation. As companies look ahead to 2024 trends, those that are well prepared for the future will not ignore technological developments, but rather find new and valuable ways to leverage them.

Driving Transformation

CDMOs, which manufacture sensitive drug products, develop digitisation strategies to carry through the current transformation and to prevent the use of outdated processes which could harm the quality of drug products. Technologies like virtual reality (VR), and autonomous, collaborative robots are sample tools driving this transformation. While the implementation of these technologies forecast a much more consistent manufacturing process which can bring drug products from start to finish more quickly and effectively than in the past, it also brings targeted and traceable improvements which only strengthen over time.

Making room for robots as teammates, not competitors

Robots are already heavily relied upon in the pharmaceutical working environment and this trend is only growing. The global market for cleanroom robots is estimated to grow from $6.4 billion in 2022 to $25.6 billion in 2030, according to a Research & Markets report. This signifies a major investment in robots for cleanroom tasks throughout the next decade. In 2024, expect the continued use of collaborative, two-arm robots which work alongside human counterparts. Robots, like YuMi receive training from an employee and then carry out the learned steps independently, opening availability for the employee to work on less-routine projects. The result is the utilisation of digitisation to reduce workload, improve the individual working atmosphere, and expand potential outputs.

Cleanroom technology sees continued advancement

State-of-the-art cleanrooms leverage both isolators and restricted access barrier systems (RABS) to meet increasingly strict regulatory requirements. Isolators are widely utilised but have limitations due to an ongoing need for decontamination. Additionally, RABS are a valuable tool to increase efficiency, variability, and speed of set-up. The combination of both technologies, which Vetter refers to as Vetter Cleanroom Technology (V-CRT), uses the advantages of both RABS and isolators to streamline the entire pharmaceutical manufacturing process with all potential pitfalls taken into account.

The future of life sciences will continue to transform to meet growing demands and leverage new technologies. CDMOs which change-proof their processes now and incorporate new technologies quickly will be better prepared to adapt to the future of the industry. BS

Tech Trends for Life Sciences to Watch in 2024

Trends to watch in the life sciences industry are ones that support personalised, preventative healthcare, including high quality collection of samples, and the trends in data analysis resulting from the sensitive measurements of thousands of molecules by LC-MS/MS.

« **Dr Andrew Gooley,** Chief Scientific Officer, Trajan Scientific and Medical, Australia

There are three key areas changing the face of life sciences globally – precision medicine, artificial intelligence (AI) and digital health.

What all three have in common is their dependency on the **collection of large data** sets, which we believe will inevitably drive the first trend we are looking out for in 2024: biotech companies improving the quality and efficiency of their data collection. Initiatives on our watch list include JoinUs and SHARE which are focused on more efficient approaches to clinical trial enrolment where the objective is to obtain the patients' consent for their health records to be added to a database from which researchers can find potential participants.

A second trend particularly close to Trajan, is the **decentralisation of healthcare** through the adoption of microsampling technologies. The primary objective of microsampling is to make home blood collection accurate, safe, and efficient, bringing health monitoring out of the hospital or GP and to a place of convenience for the patient. Many new collection devices on the market overcome the limitations of dried blood spots which were prone to volumetric errors. Coupled with advanced analytical techniques such as high-performance liquid chromatography tandem mass spectrometry (LC-MS/MS), hundreds to thousands of analytes can be extracted and analysed from blood microsamples with great specificity, leading to substantial progress in precision medicine research projects.

Precision medicine is our third trend to watch as we increasingly see the amalgamation of different "omics" data sets from genomics, proteomics, lipidomics and metabolomics to personalise treatment plans for individuals. In combination with AI and machine learning in data analysis, large data sets can be analysed measuring hundreds to thousands of different biomarkers to identify patterns and provide valuable insights into disease risk such as cardiovascular disease and cancer. We are also watching the emerging trend of monitoring the concentration of environmental pollutants such as the per- and polyfluoroalkyl substances (PFAS) in blood microsamples, again using "state-of-the-art" LC-MS/MS. The persistence of PFAS in the environment and known adverse effects on human health remains a serious concern beyond 2024 globally.

Finally, while the **adoption of wearables and digital health** is not a new trend, how we align the various health and wellness applications to complement precision medicine is certainly on our watch list. Smartwatches are increasingly sophisticated, collecting aspects of an individual's health including fitness, nutrition, and real-time heart data. Clinical trials are now asking the participant for consent to access their wearable data to overcome one of the major drawbacks in trials which are dependent on subjective participant entries.

In summary, trends to watch are ones that support personalised, preventative healthcare, including high quality collection of samples, and the trends in data analysis resulting from the sensitive measurements of thousands of molecules by LC-MS/MS. These systems have the capacity to generate enormous amounts of personalised data, and coupled with advances in AI and machine learning, could identify disease risk long before traditional healthcare needs to intervene. BS

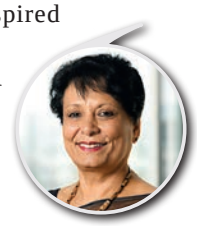
Targeted Battle Against HPV

Since the launch of the global strategy against cervical cancer in 2020, the World Health Organization (WHO) has accelerated the initiative by virtue of commitments and strategies offered by governments and organisations worldwide. Australia is on track to become one of the first nations to achieve this, and countries like Bangladesh and Indonesia have introduced HPV vaccines. Let's examine Asia's efforts in eliminating cervical cancer and whether the continent is on track to meet WHO's targets by 2030.

Cervical cancer is the second most prevalent cancer affecting women globally. Projections indicate a rise in the annual incidence of new cases from 570,000 to 700,000 between 2018 and 2030, with corresponding deaths expected to increase from 311,000 to 400,000. The majority of these fatalities are concentrated in low-and lower-middle-income countries (LMICs), highlighting the challenge posed by insufficient access to cervical cancer prevention, screening, and treatment.

To urgently address the disparity, the WHO launched the global strategy in 2020 to eliminate cervical cancer. Targets for 2030 include 90 per cent HPV (human papillomavirus) vaccination for girls by the age of 15, 70 per cent high-performance screening for women at 35 and 45, and treating 90 per cent of pre-cancer and invasive cases. Meeting these 90–70–90 targets is essential for each country to eliminate cervical cancer globally by the next century.

"The WHO's call to eliminate cervical cancer from 2018 was bolstered by the 2020 Global Strategy to eliminate cervical cancer, which included targets for prevention, screening, and treatment by 2030. This initiative inspired attention for what is currently a lagging effort around the world," said ***Anuradha Gupta, President, Global Immunisation at Sabin Vaccine Institute, USA.*** Sabin is dedicated to making vaccines more accessible, enabling innovation and expanding immunisation across the globe.



Various countries have announced action plans in response to WHO's call to eliminate cervical cancer. Let's examine the initiatives in detail.

APAC initiatives

There has been significant progress in terms of immunisation, screenings, and raising awareness. Countries in the Asia Pacific region have launched specific cervical cancer programmes or bolstered existing ones in terms of infrastructure and outreach efforts.

Leading among them is Australia which is set to be among the first countries in the world to eliminate cervical cancer, which the country anticipates to achieve in the next 10 years. In November 2023, Australia announced investments totaling $48.2 million over four years in the National Strategy, with an aim of eradicating cervical cancer by 2035. The strategy involves extending HPV vaccination to boys, setting a 70 per cent screening target for 25- to 74-year-olds every five years, and allocating $8.3 million for innovative screening models in priority populations. Initiatives, such as self-collected Cervical Screening Tests, address barriers for underrepresented groups. Additionally, the Australian Government committed $12.5 million to the Indo-Pacific Elimination Partnership for Cervical Cancer (EPICC).

Indonesia has also taken various initiatives recently. In November 2023, the country declared a commitment to achieve the WHO's 90-70-90 targets for cervical cancer elimination through its National Cervical Cancer Elimination Plan (2023-2030). In September 2023, Indonesia's Ministry of Health and the Sabin Vaccine Institute entered into a three-year agreement to collaborate on cervical cancer prevention and elimination strategy.

In October 2023, Bangladesh rolled out a nationwide HPV vaccination campaign. The campaign will be rolled out across the country in three phases. Upon the completion of all three phases, the HPV vaccine will be integrated into the routine immunisation programme for girls. India has initiated HPV vaccination targeting cervical cancer in the northeastern state of Sikkim, with plans to expand the programme to other states.

Malaysia has been proactive in eliminating cervical cancer, evident through its national HPV immunisation programme. Since its inception in 2010, the programme has consistently achieved

an impressive 80-95 per cent coverage among adolescent girls. In response to WHO's goals, Malaysia has rolled out the 'Action Plan Towards the Elimination of Cervical Cancer in Malaysia 2021-2030.' This initiative outlines objectives for increasing HPV vaccination, intensifying cervical screening, and improving precancer and cancer treatment.

Malaysia has achieved high coverage of HPV vaccination, but screening rates remain low. The ROSE (removing obstacles to cervical screening) Programme, integrating self-sampling, HPV testing, and e-health technology, has been a revolutionary solution. The ROSE Foundation celebrated a significant milestone in November 2023, having successfully screened over 25,000 women and ensured 90 per cent of women with abnormal tests receive proper follow-up.

Singapore launched the Temasek Foundation Human Papillomavirus (HPV) Immunisation Programme, in partnership with the Singapore Cancer Society (SCS) in 2022. This new programme will be helmed and implemented by SCS and seeks to cover the out-of-pocket costs for each HPV vaccine dose for women from low-income backgrounds, enhancing accessibility and promoting higher vaccine uptake. Singapore also provides subsidised cervical cancer screening at Community Health Assist Scheme (CHAS) since 2017.

In 2009, China launched a cervical and breast cancer screening programme for rural women, which later became a National Basic Public Health Service Project in 2019. Aligned with the Healthy China Action Plan (2019–2030) and responding to the WHO's 2020 Global Strategy, China aims to achieve the 90-70-90 goal by 2030. The China Women's Development Guidelines (2021–2030) and the 'Accelerate the Elimination of Cervical Cancer (2023–2030)' issued in January 2023 further emphasise awareness, free HPV vaccination, innovative screening technologies, and comprehensive control capacity to accelerate cervical cancer elimination in the country.

Concept to Action

Although efforts have been made to reduce the incidence of the disease, the progress is somewhat insufficient.

According to a Lancet study, global completion of the full HPV vaccination course for adolescent girls dropped from 14 per cent in 2019 to 12 per cent in 2021. In Asia, first-dose HPV vaccination coverage is as low as 6 per cent in the Western Pacific Region and 3 per cent in the South East Asia Region. About half of ANCCA (Asian National Cancer Centers Alliance) member countries (Bangladesh, Bhutan, Brunei, China, India, Indonesia, Japan, Laos, Malaysia, Mongolia, Singapore, South Korea, Thailand and Vietnam) include HPV vaccination in their national or school health programs. While nearly 76 per cent of ANCCA member countries have a national cervical cancer screening programme, only 24 per cent achieve over 50 per cent screening coverage among women aged 30 to 49 in the previous 5 years, including Bhutan, Japan, South Korea, Singapore, and Thailand.

According to a Lancet study, global completion of the full HPV vaccination course for adolescent girls dropped from 14 per cent in 2019 to 12 per cent in 2021. In Asia, first-dose HPV vaccination coverage is as low as 6 per cent in the Western Pacific Region and 3 per cent in the South East Asia Region. About half of ANCCA (Asian National Cancer Centers Alliance) member countries include HPV vaccination in their national or school health programmes.

"To turn this initiative into action, organisations like those in the Global HPV Consortium are coming together to build momentum, amplify and share messaging and develop sustainable cervical cancer elimination efforts for individual countries," said Anuradha. Sabin is the Secretariat for the Global

Latest Developments

- In December 2023, New Australian research shows WHO screening guidelines could reduce cervical cancer death rates by more than 63 per cent
- In October 2023, Korean startup Noul entered cancer diagnostic business with launch of cervical cell analysis product
- In September 2023, Korea developed novel DNA biosensor for early diagnosis of cervical cancer
- In September 2023, China approved Gloria Biosciences' drug for cervical cancer treatment
- In September 2023, Global HPV Consortium launched in Kuala Lumpur to end cervical cancer
- In August 2023, BD (Becton, Dickinson, and Company) hosts symposium on awareness building around cervical cancer screening at Nepal
- In January 2023, Korea gave fast track approval to Genexine's promising DNA vaccine for advanced cervical cancer

HPV Consortium.

In June 2023, Crowell & Moring International partnered with Roche, TogetHER for Health, CAPED, and Jhpiego to form the Asia-Pacific Women's Cancer Coalition, addressing rising breast and cervical cancer cases. The coalition focuses on strategic partnerships, innovative technologies, and advocacy to reduce incidence and mortality. In September 2023, the Global HPV Consortium was launched in Kuala Lumpur, led by the Sabin Vaccine Institute. This worldwide collaboration aims to accelerate HPV prevention and eliminate cervical cancer. It involves public and private stakeholders, including vaccination, cancer control, and reproductive health organisations.

Project Teal, a joint initiative by the University of Hong Kong, Roche Diagnostics, Karen Leung Foundation, Christian Action, and the Family Planning Association of Hong Kong, incorporates self-sampling for cervical cancer screening. In phase 3, nearly 600 participants were enrolled, achieving a 65 per cent return rate. The project offers free screening tests for eligible women and explores the potential of home-based self-sampling as a research project.

Cervical cancer is treatable, and we possess the tools to eliminate it. The primary obstacles lie in ensuring access for those in need.

"Cervical cancer is a leading cause of death in women in many countries. While Pap testing was developed last century and has been an important screening tool, many countries have not had the capacity to implement it," said ***Professor Karen Canfell, Director of the Daffodil Centre*** (a joint venture between Cancer Council New South Wales and the University of Sydney in Australia).

New research, led by the Daffodil Centre and published in the journal Nature Medicine, shows cervical cancer death rates in low-to-middle-income countries could be reduced by more than 63 per cent through implementation of WHO guidelines.

"Insufficient health system capacity represents a massive barrier to achieving global scale-up goals for many health areas, including elimination of HPV/cervical cancer. I am encouraged by new cervical cancer prevention strategies that both reduce burdens on system capacity and provide for a more patient-centric approach. The two most notable examples are the move toward single-dose HPV vaccination schedules, now officially endorsed by WHO/SAGE, and the still-untapped potential to expand access to diagnostics which utilise self-sampling – both of which simplify service delivery and provide an opportunity to increase coverage for vaccination and screening among underserved women and girls globally," said ***Dr Heather White, Executive Director, TogetHER for Health, USA.***

TogetHER is a global partnership ensuring the elimination of cervical cancer through advocacy, partnership, and knowledge-sharing, enabling equitable access to effective prevention and care.

Professor Canfell, says the disease could be eliminated through a three-pillar approach combining vaccination, screening and referral to treatment.

Asian countries have intensified their efforts in combating cervical cancer, yet there is still considerable work to be done to eradicate the disease completely. Early screening and immunisations continue to be the most effective tools in putting an end to the scourge. It is imperative to address access gaps, ensuring that treatments and prevention techniques reach all individuals. BS

Ayesha Siddiqui

Combating AMR with Bacteriophages

India is among the countries with a high burden of antibiotic-resistant infections. However, in recent years, the discovery of bacteriophages, simply referred to as phages, and phage-based therapy as an alternative to antibiotics, is witnessing rapid developments. BioSpectrum brings out an in-depth report on how bacteriophages are turning out to be one of the best choices to combat antimicrobial resistance (AMR), its advantages over antibiotics, and how Indian researchers and entrepreneurs are striving to make phage therapy a clinically-validated option to combat AMR. But are the regulations in favour?

It is known that India faces a significant challenge when it comes to antibiotic resistance and the menace of superbugs (largely owing to overuse and misuse of antimicrobials). Reports say that the economic impact of superbugs is significant in our country. Even in the United States, treating antibiotic-resistant infections costs an estimated $2.2 billion in extra healthcare expenses each year. These costs include longer hospital stays, additional testing, and more expensive medications.

The World Health Organisation (WHO) warns that as these superbugs become more prevalent, our arsenal of effective antibiotics will become less potent. This makes routine medical procedures such as surgeries, chemotherapy, and organ transplants riskier due to the increased likelihood of infection. This validates the immediate requirement as an alternative to antimicrobials and researchers trust their bet on bacteriophages as that alternative.

According to ***Rachna Dave, Founder & CEO of MicroGO,*** AMR is indeed a far more significant and pressing issue than it might initially appear, primarily due to underreporting. She says, “Estimates indicate that the toll of AMR could result in more than 10 million deaths by 2023. This looming crisis is exacerbated by the extremely limited availability of new antibiotics in the market, making it an incredibly challenging problem to address. In this dire context, bacteriophages are emerging as one of the most promising solutions to combat AMR infections. With the scarcity of effective antibiotics, bacteriophages offer a viable alternative. In India, there have been approximately 200 patients successfully treated with phage therapy, boasting an impressive success rate exceeding 80 per cent. This number is steadily increasing as more clinicians and infection prevention specialists embrace this innovative technology.”

India – The land of abundant bacteriophages

Phages are natural predators of bacteria. They can infect and kill specific bacterial strains, making them valuable tools for controlling bacterial populations, especially harmful pathogens. Phages are known for being highly specific in their host range. Each phage typically infects only one or a few closely related bacterial species, which means they do not harm beneficial bacteria in the body. This specificity is advantageous for targeted bacterial treatment and avoiding disruption to the common microbiota of the host organism.

Sharing more facts on bacteriophages, ***Dr Satheesh K, Senior Research Scientist, India Diabetes Research Foundation & Dr A Ramachandran’s Diabetes Hospitals***, says, “Bacteriophages or phages thrive in environments like rivers and sewage-contaminated waters. These microscopic predators have a unique potential to latch onto particular bacterial species, inject their genetic

material, and hijack the bacterial machinery to copy themselves, and in the long run causing the bacterial cellular to burst, and launch new phage particles. In essence, they are natural bacterial killers."

India is home to an abundant variety of phages. Researchers of the ICAR-Central Inland Fisheries Research Institute, West Bengal, have detailed in a research paper that Bacteriophages are abundantly present in the river Ganga.

Atif Khan, Scientist, Water and Steam Chemistry Division, Biofouling and Biofilm Processes Section, Bhabha Atomic Research Centre, Kalpakkam, says, "India is considered to be the richest source of bacteriophages compared to any other country. If you like to talk about the competitive advantage, the opportunity lies in the phages of the bacterial host that rarely cause any diseases (Staphylococcus simulans). In case of multidrug resistant S. simulans infection, most of the labs and their surrounding environment may not have phages for this host. India could be a country where the phages can be found in a system like local sewage."

Presently, more than 20 to 30 research facilities across the country are dedicated to isolating and characterising bacteriophages, with a specific focus on combating pathogens prioritised by the Indian Council of Medical Research (ICMR).

Phage Banks and Phage Engineering

In India, where antibiotic-resistant bacterial infections are a significant public health concern and where biodiversity is high, the establishment of phage banks can be particularly important. These banks can contribute to the development of phage-based therapies, facilitate research into new phages, and aid in the control of bacterial infections in various settings, including healthcare, agriculture, and environmental management.

Furthermore, they can play a crucial role in advancing the understanding of phage biology and their interactions with bacteria in India's unique ecological and clinical contexts.

According to ***Dr Hiren Joshi, Scientific Officer, Bhabha Atomic Reserach Centre, Kalpakkam,*** "It is imperative to leverage this rich resource to

"I anticipate substantial global growth in phage therapy"

« **Pranav Johri,** Founder, Vitalis Phage Therapy and a Fellow of the Society of Bacteriophage Research and Therapy

Johri is a pioneer in establishing a company based on phage therapy. In a brief discussion, Johri reveals what led him to founding Vitalis Phage Therapy and his outlook to the future of bacteriophage therapy in India. ***Edited Excerpts:***

What made you venture and create a company based on phage therapy?

My personal experience with phage therapy, which proved to be a successful treatment for my multi-drug resistant infection in 2016, inspired me to establish Vitalis Phage Therapy, India's foremost phage therapy initiative. In 2016, I was diagnosed with chronic bacterial prostatitis, caused by a multidrug resistant polymicrobial infection. After months of extensive research, I embarked on a journey to the renowned 100-year-old Eliava Institute of Bacteriophages, Microbiology, and Virology to undergo phage treatment for my condition. The successful outcome of phage therapy in treating my multi-drug resistant infections fuelled my commitment to raise awareness of and provide access to phage therapy in India, ultimately resulting in me establishing Vitalis Phage Therapy. Thereafter, Vitalis inked partnerships with the Eliava Institute and the Eliava Phage Therapy

Centre to develop the necessary infrastructure for phage therapy in India.

What market opportunity do you envisage for phage therapeutics in the years to come?

The issue of antibiotic resistance is escalating worldwide. Forecasts predict increased fatalities due to antibiotic-resistant infections by 2050. The extensive and inappropriate use of antibiotics during the COVID-19 pandemic further amplified this trend. I am of the opinion that phage therapy represents one of the most promising approaches to combatting multidrug-resistant infections, thereby lessening the severity and fatality rates associated with such infections. Looking ahead, I anticipate substantial global growth in phage therapy. This growth will be propelled by increased phage research at academic institutions, the establishment of phage therapy units in hospitals, and the widespread adoption of phage therapy in cases where patients suffer from drug-resistant infections.

How do you think India has to progress in making phage therapy as the most suitable way of tackling AMR?

While India is the land where phages were first discovered over a century ago, our healthcare systems are still far away from adopting phage therapy as an efficient way to tackle AMR. Currently, phage therapy is only available as compassionate treatment for patients whose infections have become multidrug resistant.

To reach a situation where phage therapy is readily available and can be deployed by doctors across the country, from big cities to small towns, the following steps need to be enforced:

Awareness - Large scale awareness campaigns are needed to educate the healthcare sector of the mechanism and utility of phages in cases of antibiotic resistant infections.

Development of Phage Banks - Phage research and development needs to be accelerated so that as awareness increases, ready-to-use phage banks are made available at the same time for patients for whom antibiotic use is no longer an option.

Clinical Trials - These are needed to study the clinical application of phages so that they can be regulated for use beyond compassionate treatment. BS

establish comprehensive phage libraries and cocktails. These collections can prove highly effective against a broad spectrum of bacterial infections. By tapping into the wealth of bacteriophages in India's diverse microbial ecosystems, we can potentially develop innovative solutions for combating infectious diseases and antimicrobial resistance on a global scale. This approach holds great promise for the future of healthcare and pathogen control."

Dr Ranga Reddy Burri, President, Infection Control Academy of India opines, "Phages hold significant promise in addressing AMR due to their specificity, adaptability, and potential for personalised treatment. While there are success stories in India like AIIMS-ICMR PhageBank, ongoing research, international academia, industry collaborations, regulatory support, and clinical validation are crucial for realising their full potential as alternatives or complements to traditional antibiotics.

Talking about the bacteriophage market Dr Burri says "The current market size of bacteriophage-based products and therapies in India is insignificant at the moment. Even globally the estimated size is less than $50 million. The rising threat of AMR and awareness about the benefits of phage therapy is expected to propel market growth. The use in agriculture, veterinary and consumption as phage probiotics will be major growth drivers. Aristogene, Gangagen, Sciinv Biosciences, Vital Therapeutics, Proteon Pharma are visible players in this market."

Sharing her thoughts on the market growth Rachna Dave, says "The growth is further substantiated by recent developments, such as the establishment of a new production facility in Nasik by Proteom Biotech, a Polish company. Additionally, several other companies are currently in the process of setting up pilot-scale plants for bacteriophage production, underscoring the increasing interest and investment in this promising field."

Adding her thoughts, ***Dr Ellie Jameson, Researcher, Bangor University School of Natural Sciences, UK*** says, "The next developments that will be expanded in India and across the globe are well stocked and characterised phage banks combined with a Good Manufacturing Practice

(GMP) facility for phage production. These central repositories will hold thousands of characterised, sequenced phages to ensure that they do not contain any harmful elements, but that phages can be quickly accessed to treat 100s of different bacteria, as needed. There is a strong call to ensure that phages are manufactured to GMP standard so that phage therapy can be controlled as a drug for widespread use."

She further says "To step up phage therapy I foresee that a GMP facility for phage production will need to be established in India to keep cost manageable and enable production to meet demand. This will ensure each batch is identical and that endotoxin levels are negligible to prevent adverse effects. With these in place I believe that due to the positive stories of phage therapy it will continue to grow and work with our antibiotics to help more and more patients."

Scope to expand from diagnostics to therapeutics

Phage engineering isn't always restrained to improving the phages themselves; it additionally opens doorways to growing novel phage-based equipment for various applications. For instance, researchers at the Indian Institute of Science in Bengaluru have validated the capacity of engineered phages within combat in opposition to mycobacteria—the causative dealers of tuberculosis and leprosy. By modifying the tail fibre proteins of a mycobacteriophage, they were able to apprehend distinctive receptors on the floor of mycobacteria. These engineered phages successfully lysed various lines of Mycobacterium tuberculosis and Mycobacterium leprae in both laboratory settings and in vivo.

Regulatory hurdles and market boundaries

India, though, has developed a National Action Plan on Antimicrobial Resistance (NAP-AMR) to address the growing threat of antibiotic resistance, plans that include strategies for promoting responsible antibiotic use, improving surveillance, and enhancing infection prevention and control need to be hastened along with making phage therapy a viable option.

Also, Dr Burri says that regulatory authorities classify bacteriophages as biological substances and currently, there is no established framework that explicitly defines the role of bacteriophages in the context of medicinal products for human use in India and globally. Very few countries have clear regulatory pathways.

One such example is Georgia, where bacteriophages have been seamlessly integrated into the healthcare system as a standard medical practice, and a range of phage preparations are available over-the-counter, along with a more extensive selection of products supplied directly to medical practitioners. The US FDA also approved several phage treatments, which are employed in the food industry, largely in the dairy and meat industry, to combat bacterial growth. To fuel rapid progress towards phage therapeutics, as a sustainable antibiotic alternative, regulatory processes must be refined and should be pragmatic to reach a tipping point sooner.

We cannot deny that India has made progress in adopting phage therapy, but to make it a more mainstream solution to combat AMR, concerted efforts in research, regulation, education, and infrastructure development are crucial. Collaboration between all the stakeholders and a dedicated approach from both government and private sectors will be essential. The funding into this sector is mostly from grants, philanthropy, altruistic researchers, and good Samaritans only.

There is a need to promote this therapy in the country. "The level of public awareness and acceptance of bacteriophages as an alternative to antibiotics in India is abysmal," says Dr Burri and adds that compared to more established treatments like antibiotics. Even among healthcare professionals, the awareness is low, which is a significant deterrent to mainstreaming this alternative. Organisations like Society for Bacteriophage Research and Therapy, Infection Control Academy of India and others are working towards awareness and providing a platform for researchers, clinicians, and other stakeholders to collaborate.

Traditional life science and biotech companies have no participation in research or investments in this segment as the perceived demand is low and the risk of return is high. Maybe, providing incentives and financial support, including grants, tax incentives, or other financial benefits, to encourage investment for budding companies could be a possible way to lure them into phage therapy development.

Hence, in conclusion, it can be said that India has to step-up and establish clear regulatory pathways for phage therapy, ensuring safety, efficacy, and quality standards. The country needs specific guidelines and protocols for the approval and use of phage therapy. It is also important for the government to facilitate collaborations between pharmaceutical companies, research institutions, and government bodies to foster the development and distribution of phage therapeutics. BS

Anusha Ashwin

"The Open Innovation Program has become a trend in the molecular diagnostics industry"

Established in 2000, South Korea based Seegene Inc is a leader in molecular diagnostics and achieved remarkable financial success with over $1 billion in revenue and 65 per cent gross margins. With a mission for a disease-free world and proactive pandemic prevention, Seegene seamlessly integrates high multiplex diagnostic assays with automated testing systems. In an interaction with BioSpectrum, Dr Seong-Youl Kim, Seegene's Senior Vice President, shares insights on the company, the molecular diagnostics landscape, challenges and opportunities etc. ***Edited excerpts:***

« **Dr Seong-Youl Kim,** Senior Vice President, Seegene, South Korea

Molecular diagnostics (MDx) is a powerful tool in healthcare. Could you explain why it's considered the most effective method for accurately diagnosing ailments and the importance of early diagnosis?

With its high accuracy, sensitivity, and rapid testing capabilities, MDx enables early detection and thus leads to appropriate treatment. Particularly, among MDx technologies, Polymerase Chain Reaction (PCR) is a powerful tool for detecting minuscule amounts of biological material in a sample. This allows the early detection of pathogens in asymptomatic patients, COVID-19 being one of many examples. Early diagnosis can also reshape how we deal with diseases. For example, if we can detect cancer at very early stages, far before symptoms start to show, treatments can make a real difference.

Seegene, a leading South Korean company providing a total solution for PCR molecular diagnostics, has pursued to further refine this technology. Unlike conventional technologies that can detect a few pathogens at a time, our syndromic quantitative PCR (qPCR) reagents are highly multiplexed which can detect up to 15 multiple pathogens in a single tube using Seegene's proprietary technologies. For example, our Human papillomavirus (HPV) products can test for 14 high-risk HPV types and also provide quantitative information of types in a single tube. We have four key technologies such as DPO, TOCE, MuDT and 3Ct.

Seegene is known for its industry-leading intellectual property (IP) in molecular diagnostics reagent assays. What sets your technologies apart, and how are you leveraging them to expand your product portfolio and market coverage?

Seegene has been building a comprehensive patent portfolio covering all aspects of multiplex PCR testing including oligo chemistry technologies, reagent development solution, testing instruments, as well as manufacturing system. We have all key proprietary technologies required for development of multiplex PCR reagents. We developed the DPO primer technology for multiple gene amplification in 2006, the TOCE technology for multi-target detection in 2012, and the MuDT technology for quantitative analysis of multiplexed real-time PCR results in 2014. In 2022, all these technologies were integrated into 3Ct (cycle threshold) technology that can simultaneously detect up to 15 targets with quantitative information based on Ct values in a single channel without compromising sensitivity and specificity simultaneously. This achievement marked a new era of 'real' syndromic PCR-based molecular diagnostics. Going forward, under the Open Innovation Program and OneSystem business, we plan to develop a vast array of new products based on these technologies with our partners.

Seegene has achieved remarkable financial success with over $1 billion in revenue and 65 per cent gross margins. What factors have contributed to this success, and what role does international expansion play in your revenue generation?

We responded promptly to the initial reports of the virus and made diagnostic kits available before COVID-19 was declared as a pandemic by the World Health Organization (WHO). It took just two weeks for us to develop the diagnostic kit. Performance evaluation and regulatory approval by the Korean government were obtained the following week. Our COVID-19 assays were designed to detect multiple target genes of SARS-COV-2 virus using our innovative technologies. Excellent performances of these assays were validated in several international studies and publications. As a result, 350 million tests were delivered worldwide during the pandemic. Our global network comprising nearly a hundred of distributors contributed strongly to our $1 billion annual revenue generation during the COVID-19 pandemic.

Seegene's world-leading technologies and dedicated presence in global markets are some of the key factors that led to our financial success. We have eight subsidiaries in Europe, North America, South America and the Middle East and North Africa. Although we had been exporting our products for much longer, our first subsidiary in Italy was established in 2012. Other subsidiaries were established subsequently and built from the ground up. Our drive for product innovation and long-term dedication to Europe and other export regions resulted in Europe having the largest contribution to our overall sales (55 per cent in first half of 2023). Other large regions included Asia (24 per cent) and North America (8 per cent). All in all, exports accounted for 87 per cent of our first half of 2023 revenue.

What are some of the key challenges and opportunities that Seegene anticipates as it continues to work towards its mission of making a meaningful difference in the world through molecular diagnostics?

Over the past 20 years, Seegene has been building itself with an end goal in mind: creating a society where everyone in the world is able to live a happy and healthy life, free from all diseases. This vision can only be realised by channelling the collective wisdom and capabilities of scientists, experts, and companies toward this single goal. As we've experienced from the global COVID-19 pandemic, it is crucial to develop diagnostic products for all diseases in every field. Nevertheless, due to hurdles in menu, regulation, manufacture and distribution, it is difficult for a single company to develop ten new products per year. To overcome such challenges, Seegene is introducing a global OneSystem business for global democratisation of PCR in all fields. We believe that companies and scientists worldwide participating in our Seegene OneSystem business can develop hundreds or even thousands of diagnostic products annually. Seegene OneSystem business is a new business strategy where representative companies from each country develop qPCR products localised to its need through Seegene's standardised technology. Under this plan, we will establish new companies in over 100 countries with leading companies in each country to develop diagnostic products.

Seegene started its One System business by signing strategic partnerships with top tier MDx companies in Spain and Israel. As part of Seegene OneSystem business, the company recently launched the 'Open Innovation Program powered by Seegene' in partnership with Springer Nature. The programme enables scientists and experts worldwide to develop syndromic qPCR assays across all fields.

What are the current trends and emerging technologies in the molecular diagnostics industry that are driving innovation and improving diagnostic accuracy?

The Open Innovation Program has become a trend in the MDx industry. Yet, Seegene's approach stands apart from its competitors. As Open Innovation in general allows companies to cooperate with external professionals and organisations, we stay ahead of the curve with our Seegene Digitalized Development System (SGDDS), which provides support for researchers to easily develop syndromic PCR products, even to those with limited development experience. It consists of two key systems: SG in-sillico that automates oligo (primer and probe) design, and SG IDEA that automates the entire experimental and documentation process. With our automated systems, a wide array of participants can easily contribute to our open innovation ecosystem which eventually will lead to a world free from all diseases. BS

Ayesha Siddiqui

"We are looking at NIPT, cancer screening tests, and infectious disease surveillance as growth areas"

BGI Genomics, a pioneering institution that has embarked on a remarkable journey from its involvement in the Human Genome Project to establishing itself as a global frontrunner in the field of precision medicine. Headquartered in Shenzhen, China, it is the one of leading integrated solutions providers of precision medicine, with services covering more than 100 countries and regions, involving more than 2,300 medical institutions. In this an email interview with Jeremy Cao, General Manager of BGI Genomics and BGI Group Southeast Asia, delves into the organisation's transformative trajectory and its substantial contributions to the world of genomics. ***Edited excerpts:***

« **Jeremy Cao,** General Manager of BGI Genomics and BGI Group Southeast Asia

BGI Genomics has a strong foundation in supporting the Human Genome Project. How has the organisation evolved over the years in terms of its research focus and contributions to the field of genomics?

BGI Group, our parent company, was founded in 1999 to participate in the Human Genome Project, often referred to as one of the three major scientific endeavours of the 20th century, alongside the Manhattan Project and the Apollo Moon Landing Program. As the sole developing country participating in this project, China took on 1 per cent of the task, completing the sequencing of 30 million base pairs on Chromosome 3.

BGI Genomics has evolved into a leading integrated solutions provider of precision medicine. We are committed to enabling and accelerating scientific innovation, strengthening the prevention and control of genetic diseases, and making meaningful contributions to developing precision medicine and diagnoses.

We have contributed to the development of genomics, in particular cancer research. As of November 2022, BGI Genomics has published over 440 SCI (Science Citation Index) papers in cancer research, with a cumulative impact factor of over 4,000 points. Several BGI Genomics papers have been published in Nature Medicine, Cell, Nature, Science, Cell Research, Nature Genetics and other top scientific journals.

Papers published on cancer research with cumulative impact factor

RESEARCH TYPE	NUMBER OF SCI ARTICLES	CUMULATIVE IMPACT FACTORS
Lung Cancer	54	432.271
Bowel Cancer	47	358.515
Breast Cancer	46	279.531
Liver Cancer	46	498.157
Esophageal Cancer	27	291.486
Stomach Cancer	23	274.858
Cervical Cancer	18	175.967
Bladder Cancer	12	178.952
Other Cancer Types	37	364.419
Technological Innovation	123	1581.012

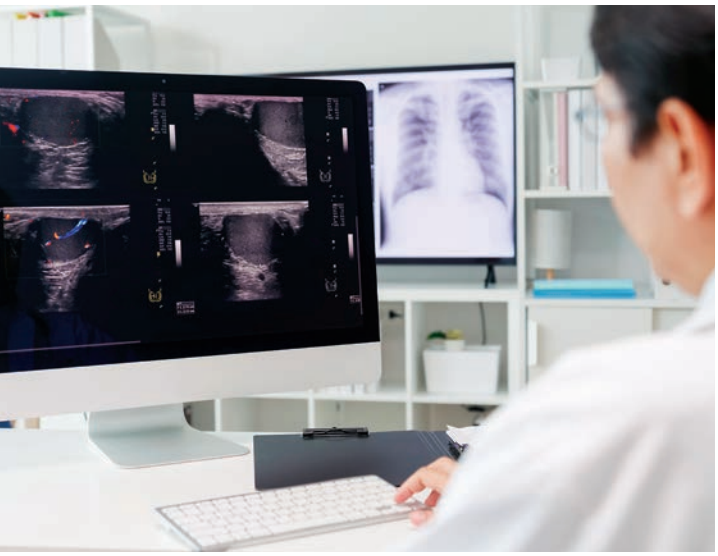
As of November 2022

Could you highlight some of BGI Genomics' notable contributions to the field of genomics?

Relying on cutting-edge sequencing and bioinformatics technology, we provide our customers with expert and affordable clinical molecular diagnostic solutions and massive parallel sequencing (MPS) research services. Our services cover over 100 countries and regions, involving more than 2,300 medical institutions.

In Southeast Asia, BGI Genomics has a diverse portfolio of projects. This includes but is not limited to collaborations such as the thalassemia "Screening, diagnosis, treatment" closed-loop programme in Thailand and Indonesia, colorectal cancer screening programme in Thailand, rare cancer research at the National Cancer Centre Singapore, and cervical cancer screening cooperation with Brunei's Ministry of Health.

One noteworthy project is Thailand's thalassemia



"Screening, diagnosis, treatment" closed-loop programme. Thalassemia is an inherited blood disorder caused by insufficient or nonfunctional haemoglobin that affects over 345 million people worldwide. This initiative involves cooperation with the Eastern Economic Corridor (EEC) Office and the Thai Ministry of Health in conducting clinical trials for thalassemia gene therapy. Mahidol University's Siriraj Medical School, Chulalongkorn University's Medical School, and the Thai Clinical Research Center are project partners collaborating with BGI Genomics to facilitate thalassemia gene screening and treatment, ensuring the smooth initiation and execution of clinical trial projects.

As part of the EEC's efforts to establish a commercial clinical thalassemia gene therapy centre, EEC provides the facility while jointly constructing specialised hospitals and offering legal and policy support. In addition to this, BGI Genomics is collaborating to introduce cell storage facilities, leveraging the "cell + gene" platform's advantages.

What challenges and opportunities does the genomics and proteomics industry face in terms of regulatory and ethical considerations, data privacy, and public perception?

Firstly, we must stay true to our mission of 'Omics for all' to make genomics technology more accessible, available, and affordable to enhance health outcomes for all. In line with our guiding principles, we place a lot of emphasis on regulatory and ethical considerations as well as data privacy. We follow the applicable regulations across the countries and regions of our operations. Regarding data management, we follow industry best practices such as purpose limitation, data minimisation, storage limitation, and confidentiality.

Research must pass our Institute of Review Board of Bioethics and Biosafety (BGI-IRB) review and follow the corresponding international regulations such as the WHO Review of the Work Guidelines for Ethical Committees for the Evaluation of Biomedical Research and the Council for International Organizations of Medical Sciences (CIOMS) International Code of Ethics for Human Health-Related Research.

Looking ahead, what are the future plans and goals for BGI Genomics in terms of advancing genomics research and expanding its services globally?

We are committed to the continued development of precision medicine and diagnoses to enhance health outcomes worldwide. Within Southeast Asia, we are looking at three key growth areas: non-invasive prenatal tests (NIPT), cancer screening tests, and infectious disease surveillance.

Take DNA-based NIPT, for example; our NIFTY test offers screening for some of the most common trisomies present at birth, including trisomy 21 (Down Syndrome), trisomy 18 (Edwards Syndrome), and trisomy 13 (Patau Syndrome). Yet, based on my observations, take-up across Southeast Asia is relatively low at less than 10 per cent. Given NIPT involves a simple blood test that can be done in the first trimester of pregnancy, there is more room for further adoption.

There were over 1.9 million new cases of colorectal cancer in 2020, making it the third most common cancer worldwide. Colorectal cancer (CRC) is often diagnosed at a late stage due to the lack of symptoms – which is why it's often referred to as a 'silent killer.' When CRC is detected at an early stage, the 5-year relative survival rate is about 90 per cent. But only about 4 out of 10 CRC cases are found at this early stage. Our COLOTECT screening test is non-invasive and has 88 per cent CRC sensitivity, and for early detection, its sensitivity for advanced adenoma is 46 per cent, which is superior to conventional faecal tests.

Infectious disease surveillance is also crucial in the post-COVID-19 new normal. Our PMSeq solution leverages high-throughput sequencing, microbial-specific database comparison, and intelligent algorithm analysis to identify complicated and critical-to-detect infections. This also promotes insights into antimicrobial resistance and susceptibility (AMR) and contributes to solving problems such as tuberculosis drug resistance. BS

Ayesha Siddiqui

"Pharma companies in South Korea will need to invest in skill development"

South Korea is an attractive destination for biologics contract manufacturing owing to its strategic location in the Asia Pacific region. Additionally, there is active support and encouragement from the government, making South Korea a global giant in the advanced manufacturing sector. Among many players, US headquartered West Pharmaceutical Services, Inc. is leveraging this opportunity. As local pharmaceutical companies expand their capacity and enhance their capabilities in contract manufacturing, research, and development in biologics, West sees significant potential in the South Korean market. In conversation with BioSpectrum Asia, Journey Hong, General Manager, South Korea, West Pharmaceutical Services, Inc. reveals the growth plans of the company within the Korean market. ***Edited excerpts-***

« **Journey Hong,** General Manager, South Korea, West Pharmaceutical Services, Inc.

How is the contract manufacturing/ development sector evolving in Korea? How is West leveraging opportunities in this space?

In line with our customer-focused and market-led approach, a key priority for us is to continue building trust with our South Korean customers by consistently delivering high-quality products and solutions and leveraging our strong scientific and technical expertise. This is where West excels, and we believe it is how we can help our customers succeed to better serve the end patients in Korea and across the world.

Another focus is to assist South Korean pharmaceutical companies in gaining a better understanding of the role that containment solutions play in ensuring the successful launch of a biologic drug. Discussions concerning packaging decisions should be initiated as early as possible within the drug development process between stakeholders. By doing so, the unique needs of a biologic drug and regulatory requirements can be adequately addressed upon the drug's impending launch.

Simultaneously, we are also focused on growing and developing our local team in South Korea to provide better and more tailored services to all our customers.

What are the key plans for the Korean market in FY 24-25? Are you planning new investments, partnerships in the country?

Currently, our team is operating out of a multi-functional space that combines our commercial staff with our warehouse to serve our customers in South Korea. To further boost our operations and support growth while still serving our customers optimally, an expansion of both team size and warehouse capability is one of our key considerations.

More importantly, it is our hope to cultivate stronger relations with our customers via physical interactions and training sessions. We believe this will be particularly informative for our customers, as more players enter the biologics and biomanufacturing sector within South Korea, they may require more support in understanding the local regulatory guidelines for containment services.

Lastly, we are always actively looking into further developing our people's capabilities and operations through new trainings and use of the latest technological systems.

These areas are our key objectives in the coming year, and we look forward to working closer with our local pool of customers and regional stakeholders.

How much revenue is generated from the Korean market for the West? How much growth is expected this fiscal?

West has been serving the South Korean market since the 1980s and we have seen strong growth during the past years, leading South Korea to become one of West's strongest markets within APAC. Especially as the market focuses on high quality biologics, we see an excellent fit for our high-value products. We believe we are well positioned to support our customers in South Korea, and in turn further strengthen our local presence.

Korea's pharma industry is set to receive an extra boost from increased government spending. How do you foresee the growth of the pharma industry in Korea?

In South Korea, the pharmaceutical market is mainly driven by the biologics sector, while generic therapies and medicines comprising the remaining market share. As South Korea fields more support to foster the growth of the industry, aiming to reach a production capacity of 100 trillion won and double export values by 2030, significant opportunities will emerge for Korean pharmaceutical companies.

These opportunities may attract new players to the South Korean market, while existing pharmaceutical companies also have the potential to flourish. But as the market grows, so does the demand from consumers and customers. To tap into these opportunities, the pharmaceutical industry must prioritise quality. Consistent research and development will be needed, and companies must be ready to upgrade their production pipelines to meet evolving expectations and customer requirements. This encompasses not only the development of new medicines but also innovation in drug delivery systems, platform technologies, medical devices, among others.

Despite the potential for growth, South Korean pharmaceutical companies may continue to face supply chain disruptions as a challenge. Hence, it is likely that businesses will invest more time in understanding delivery lead times, aligning containment solutions with certain types of drugs, and navigating the regulatory complexities that impact order fulfilment.

Lastly, the industry will require a skilled and capable workforce to sustain and support its growth. Companies will need to invest in skill development and enhance the capacity and capabilities of their workforce. These efforts collectively contribute to a positive outlook for the pharmaceutical industry in Korea, ultimately benefitting patients in the long run.

What are some of the other current challenges facing the pharma industry in Korea and how is West addressing those?

Globally, the rapidly changing landscape and increasing regulatory focus on product quality coupled with accelerated timelines to bring the product to market are challenges that the pharmaceutical industry faces overall.

Especially in South Korea, the pharma companies do not just serve the home market, in fact most of them have their businesses expanded across Asia. This is why cross-border regulations are perhaps one of the main challenges for the local sector. Organisations looking to expand manufacturing processes outside Korea will have to deepen their understanding of other markets, in various aspects such as customer requirements and fulfilment processes, as well as market regulations.

To stand out, drug developers now must ensure speed of bringing their products to the market with minimised risk, through cutting-edge solutions. The West team in South Korea is making consistent efforts on this front, as an example we offer the innovative West Ready Pack containment solution with Corning Valor RTU Vials to provide drug developers with a complete vial containment solution from development through to commercialisation, streamlining the time taken to launch in market.

Any major expectations from the Korean government to enhance the growth of the pharma industry?

Within the global market, South Korea is gradually cementing a flagship status for companies that are in the field of biologics. Favourable government and business conducive environments that support tax concessions, cash grant, site location support etc. have paved the growth trajectory for the South Korean pharma and biosimilars market.

Given the country's unrelenting focus on high quality biologics as well as the government's push in the overall healthcare sector, we are expecting the momentum to continue and receive consistent support – across investments, policy, regulatory, research & development, and logistics etc.

It would be interesting to see stakeholders in the private and public sector collaborate and identify opportunities for growth that can help establish South Korea as a pharmaceutical powerhouse. BS

Dr Manbeena Chawla
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Biomedical Innovation the Answer for Climate-sensitive Diseases

The world is finally paying attention to the impact of climate change on neglected diseases. What we need now is medical innovation.

Dr Kavita Singh,
Director,
Drugs for Neglected Diseases initiative,
South Asia

There is consensus among scientists that climate change is having a disastrous impact on health, particularly on the incidence of infectious diseases – that health, in short, is the human face of climate change.

That global leaders are listening was demonstrated during the recent COP28, where a dedicated Health Day was held for the first time. During this Health Day, partners and governments pledged $777 million to address neglected tropical diseases (NTDs), which the World Health Organization (WHO) described as 'particularly [climate]-sensitive'.

This is encouraging, but there needs to be more focus on medical innovation.

The geographical spread of neglected diseases, including dengue and leishmaniasis, is worsened by climate change as vectors, such as mosquitoes and sandflies, thrive due to warmer temperatures, increased rainfall, and flooding.

And yet, these diseases receive little attention in conventional medical research. Diagnostics, treatments, and vaccines are too often not good enough, unsuitable, inaccessible, or unaffordable – sometimes they don't exist at all.

For example, there is no treatment for dengue, a disease spreading rapidly because of climate change. Half of the world's population is at risk: last year, many countries experienced their worst dengue outbreaks ever. In Bangladesh, 1,500 people died – 160 of them children. We urgently need treatment solutions to prevent progression to severe dengue and stop hospitals from being overwhelmed.

To respond to these threats to human health, we need effective medical innovations as intervention tools i.e. diagnostics, treatments and vaccines. Biomedical innovation must therefore be at the core of climate adaptation strategies.

And it is also crucial that the fruits of this medical innovation will be accessible to everyone, regardless of their income or where they live. COVID taught us no one is safe until everyone is safe. We need to make sure the biomedical innovation to tackle climate-sensitive diseases is supported by an enabling environment that allows for equitable access.

Access is particularly important because the most vulnerable communities will bear the brunt of the climate crisis. A recent WHO systematic review highlighted that NTDs 'are prevalent amongst vulnerable populations in countries expected to experience the greatest environmental change in the coming decade.'

COVID also taught us that innovation should happen close to patients and tap into existing expertise. That is why, to identify and develop an accessible treatment for dengue, we co-created a dengue alliance with research institutes from India, Thailand, Malaysia, and Brazil. We see a role for industry partners, researchers, and governments of the Global South to take the lead in driving the response.

It can be done. My own medical research organisation has delivered 13 new, safe, effective, and accessible treatments for six diseases since its creation 20 years ago – using an alternative not-for-profit model that brings together the best of public and private sectors, including from endemic countries.

For dengue for example, we started a promising partnership with Benevolent AI, a drug discovery biotech company, to use artificial intelligence to identify a potential repurposed treatment.

Biomedical companies have therefore a central role to play to prepare for the impending climate crisis. And to support those efforts, governments and development partners must urgently invest in research for new health tools for climate-sensitive diseases. We cannot afford to wait. BS

What's Propelling mRNA Therapies Today?

« **Ruplekha Choudhurie,** Team Lead/Senior Industry Analyst, TechVision Practice, Frost & Sullivan

Over the next three to five years, it is anticipated that the portfolio of mRNA treatments and vaccines will grow significantly due to the potential that mRNA has across indications. Asian biotech businesses have also stepped up and are aggressively pursuing in-house R&D and working with companies to enrich their mRNA pipelines. However, the US and Europe will continue to be the centres of mRNA R&D and product development. Let's explore the mRNA therapeutics world.

The commercialisation of the first mRNA vaccine for COVID-19 in 2021 was a turning point in the journey of this four decade long researched area. The success of mRNA vaccines has bolstered a wave of innovations and accelerated pipelines around this platform technology. In the last two years, mRNA therapy developers have received tremendous attention from the research community, federal funding agencies, VC firms and biopharma companies, which invested heavily in this segment. Many pharma companies realigned their portfolios to prioritise mRNA R&D.

mRNA is a versatile platform and its obvious advantages include flexibility, safety, rapid design and manufacture, and modularity when compared to other modalities, such as DNA, cell-based vaccines, viral vector vaccines and recombinantly expressed proteins.

The industry waging forward to develop solutions that could enable widespread adoption across multiple indications, and along with key global mRNA companies such as Moderna, CureVac and BioNTech, Asian counterparts Gennova, Abogen Biosciences, Stemirna Therapeutics, mCureX are also pursuing to develop a mRNA vaccine and therapeutic portfolio.

Tremendous Potential

Being a broadly applicable platform, mRNA is a promising therapeutic strategy, and has a much broader potential beyond just being used as a prophylactic vaccination strategy for infectious diseases. The other key applications of IVT mRNA are personalised cancer vaccines, engineered cellular immunotherapies (CAR-T), protein replacement, and expression of gene editing tools in rare diseases, cardiovascular disease, cancer, autoimmune disease among others. mRNA-based therapy is also garnering traction due to its potential advantages over traditional biologics and gene therapy. They can mitigate the challenges with recombinantly expressed proteins therapeutics and can also be used to encode multiple proteins for immunogens consisting multiple subunits simultaneously. Production and manufacture of mRNA is rapid, flexible, convenient, simple, and less expensive than recombinantly expressed proteins and viral vectors.

Since mRNA does not enter the nucleus and its expression is transient, there is no risk of long-term exposure to antigen or mutagenesis as there is with gene therapy. mRNA by nature is immunogenic, giving rise to both innate and humoral immunity making it an ideal choice for vaccines. However, for successful translation in other therapeutic indications mRNA needs to be modified to reduce the reactogenicity.

Companies such as Moderna, CureVac, Translate Bio (acquired by Sanofi), Ethris GmbH had been investing in mRNA cancer vaccines, infectious disease vaccines and mRNA-based protein replacement therapies for multiple therapeutic indications for several years now. The mRNA COVID-19 vaccine approval only rekindled R&D activity and faith to pursue this platform, and several late-stage candidates are now progressing rapidly.

Even within infectious diseases, mRNA vaccine developers had a diverse pipeline of candidates for other diseases including RSV, Influenza, Zika, HSV, HIV, Nipah, MPV and other viruses before the development of the vaccine against the SARS-

Co-V2 and other variants. Since it is a plug and play technology, it is very amenable to modifications, and designing a new mRNA vaccine for emerging variants/mutants is quicker compared to cell-based vaccine or viral vectored vaccines. This makes it an ideal choice for developing universal flu vaccines and multivalent mRNA to tackle emerging variants of COVID-19, and other infectious diseases.

Next generation RNA vaccines using newer forms of RNA such as saRNA (self-amplifying RNA), trans amplifying RNA, and circular RNA, can be potentially safer, stable and require lower dosing than conventional mRNA. Additionally, shelf stable mRNA vaccines, and alternate delivery routes such as inhalable formulations, oral delivery and needle free patches will fuel adoption and subsequent market growth.

Bottlenecks

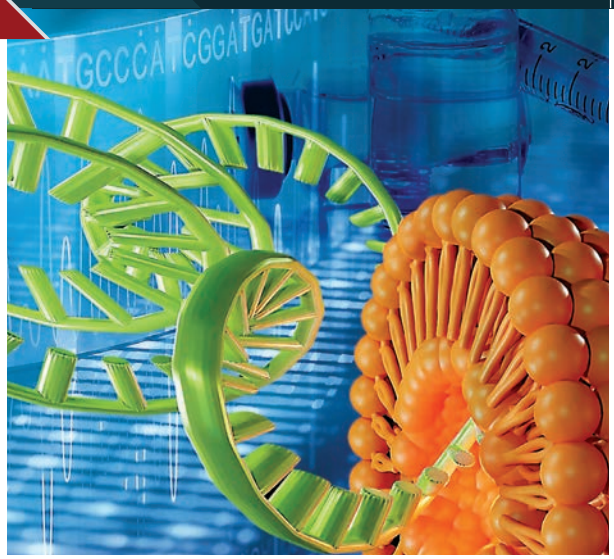
While there are certain roadblocks around delivery, stability, and immunogenicity/reactogenicity, recent developments focused on novel delivery technologies, sequence design, AI and advanced forms of mRNA are enabling development of next generation mRNA therapeutics and vaccines. Using saRNA and circRNA could mitigate the stability and sustained expression challenges.

Along with the stability challenges of mRNA, high reactogenicity of synthetic mRNA might lead to undesirable inflammatory reactions, resulting in adverse side effects. Traditional LNPs that are used to deliver mRNA cargo could result in inflammatory responses, and alternatives such as polymeric nanoparticles and exosomes are being explored to deliver mRNA for cellular immunity mediated cancer immunotherapy.

Targeting mRNA to tumours and organs beyond the liver remains challenging and can lead to adverse effects and systemic toxicity. Ethris and Translate Bio focus on inhalable mRNA therapeutics for pulmonary diseases has garnered much traction in recent years. In December 2022, Indian pharma company Cipla entered into a strategic collaboration with Ethris GmbH and invested 15 million Euros to expand Ethris' portfolio and make those mRNA therapies accessible to developing nations.

A Potential Immunotherapy Strategy

Immuno-oncology remains a complex and much researched area, and a "significant" impact of mRNA is expected to be realised in the field of cancer immunotherapy. mRNA-based cancer vaccines can have both prophylactic and therapeutic effects, and several vaccines are in clinical development for solid tumours. Recently, Moderna entered a partnership with Merck to advance phase 3 trials for Moderna's mRNA cancer vaccine mRNA-4157 for melanoma.



Circular RNA (circRNA) is a rapidly growing area of research within RNA therapeutics and vaccines space and has shown promise with better stability and protein expression that its linear mRNA counterpart. circRNA focused companies secured large VC funding in the last two years, with several company launches and collaborations. Circularisation of RNA can induce stable protein expression for long durations and players such as oRNA Therapeutics(US), Laronde(US), Circio, Norway, Circular Genomics, US and Therorna, China are exploring this type of RNA for cancer vaccines and other therapeutic applications.

At present, there are several mRNA vaccines in clinical trials using multiple tumour specific antigens (TSAs), tumour associated antigens (TAAs) and cytokines as immunologic stimulants. Compared with TAAs, TSAs (especially neoantigens) are more specific and enable better targeting to tumour cells. Personalised cancer vaccines targeting multiple tumour neoantigens are being developed. BioNTech and Moderna's personalised mRNA vaccines have shown promising anti-tumour effects in clinical trials, while CureVac recently began dosing in its Phase 1 trials for mRNA cancer vaccine for glioblastoma. China's Stemirna is also developing mRNA-based personalised cancer vaccines, along with its pipeline of infectious disease prophylactic vaccines. mRNA

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For mRNA to be successful as targeted and safer therapies, companies such as Strand Bio and Kernal Therapeutics are leveraging synthetic gene circuits to develop logic gated mRNA immunotherapy that can be spatio-temporally controlled and expressed only in the tumour.

In Situ Production of CAR-T Cells, Gene Editing and Protein Replacement Therapy

While CAR-T therapy has emerged as a promising option for several types of cancer, it usually requires ex vivo engineering of T cells using viral vectors, which induces persistent expression of CARs and is associated with serious side effects. mRNA mediated CAR-T engineering is being developed (oRNA Therapeutics) to overcome these challenges. Since they can engineer the T cells in situ, without the need to remove them from the body, it would be safer, but also simpler and cheaper as CAR-T manufacturing is complex and expensive. China/US dual headquartered Simnova partnered with oRNA Therapeutics in January 2023 to leverage its in situ CAR (is CAR) and lead clinical development and commercialisation across all oncology indications in Greater China.

mRNA also finds tremendous application in protein replacement therapy which conventionally uses exogenously expressed proteins or gene therapy, to replace or correct the faulty protein. While the primary focus of such therapies would be towards monogenic diseases, other conditions such as cardiovascular diseases and neurological diseases could also benefit from mRNA-based protein replacement.

mRNA therapeutics to express growth factors (VEGF-A) is being developed by Moderna as a regenerative therapy for cardiovascular indications, while many candidates are in pipeline for production of therapeutic proteins for monogenic diseases. Phase ½ trial of Moderna's mRNA-3927 for propionic acidemia (PA) is the first clinical trial of an mRNA therapeutic for intracellular protein replacement for this rare genetic disease. mRNA is being investigated to code enzymes such as nucleases, CRISPR, TALENs and others for gene editing applications. A recent example is South Korean mRNA company mCureX Therapeutics (subsidiary of OliX Pharmaceuticals) partnership with the gene editing expert Toolgen in June 2022 to develop gene edited therapies for rare inherited ocular diseases. India based Aarna Therapeutics has also forayed into the mRNA therapeutics space, and the company is developing mRNA expressing CRISPR-Cas to develop antiviral therapeutics and vaccines.

Considering the promise that mRNA holds across indications, the portfolio of mRNA therapeutics and vaccines is expected to expand rapidly over the next 3-5 years. While the US and Europe will remain the hubs of mRNA R&D and product development, Asian biotech companies have also geared up and are actively pursuing in-house R&D and collaborating with companies to enrich their mRNA pipelines. BS

Bharat Biotech joins hands with University of Sydney to advance academic research

India-based Bharat Biotech International and the University of Sydney Infectious Diseases Institute (Sydney ID), Australia have announced a Memorandum of Understanding (MoU) to advance vaccine research initiatives, strengthen academic-industry partnerships and augment global efforts to combat infectious diseases. The international agreement aims to build strong sectoral and cross-organisational

collaborations to design novel methodologies to tackle future epidemics and infectious diseases. Furthermore, leverage academia-industry strengths for advancing the science of vaccines and biotherapeutics. Both organisations intend to explore new opportunities to strengthen their shared vision, leverage the prowess of education, research capabilities to help build a healthier universe and improve people's lives by developing safer vaccine platforms. Most importantly, to build the talent of young scientists with a passion to innovate.

India's Dr. Bhatia Medical Coaching Institute partners with Japanese firm, M3

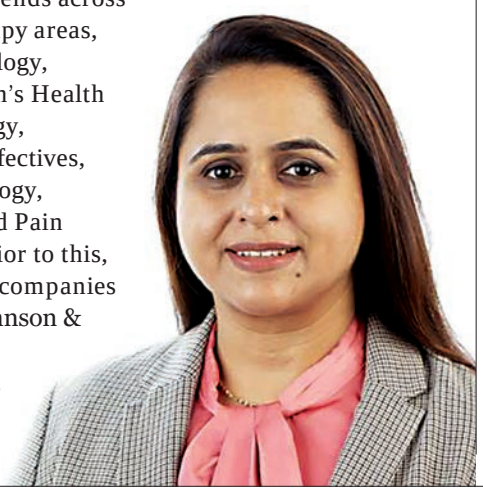
Dr. Bhatia Medical Coaching Institute (DBMCI) has announced a ground breaking joint venture with M3, Inc., a prominent Japanese entity. The collaboration aims to reinforce both offline and online preparatory services for medical students across India. Under this joint venture, DBMCI will strengthen its offline business operations, with a focus on in-person classes and live video-based coaching for national medical entrance examinations. By leveraging the expertise and technology of M3 Group, DBMCI seeks to enhance the digital learning experience for its students. This partnership marks M3's entry into the offline preparatory school business for doctors and medical students in India, complementing its existing online learning platform. The collaboration is expected to broaden the spectrum of learning opportunities and improve the quality of learning services, thereby contributing significantly to the advancement of medical care in India.

University of Melbourne signs research partnership with MoECRT, Indonesia

The University of Melbourne, Australia and Indonesia's Ministry of Education, Culture, Research and Technology (MoECRT) have announced the latest addition to PRIME – a bilateral research partnership that will focus on addressing global challenges through engineering. PRIME (Partnership in Research Indonesia and Melbourne) Engineering will commence in 2024 and bring together the University's Faculty of Engineering and Information Technology with leading Indonesian institutions, including the University of Indonesia, Gadjah Mada University, and the Institute of Technology Sepuluh Nopember (ITS). PRIME Engineering will focus on technology implementation in Indonesia's planned new capital city, Nusantara, contributing to the realisation of the Indonesian National Research Priorities (PRN) for 2020-2024. This will include bioengineering and biomaterials, water resources, cleaner energy, and sustainable, smart, resilient and liveable cities. Over four years, PRIME Engineering will foster joint publication writing, research product development, scientific events, and the development of post-doctoral and PhD student fellowships and programmes.

Shweta Rai to take over as MD of Bayer Zydus Pharma

German firm Bayer has announced that Shweta Rai will take over as Managing Director (MD) of Bayer Zydus Pharma and Country Division Head (CDH) for Bayer's Pharmaceuticals Business in South Asia effective January 1, 2024. Manoj Saxena will move out of his present role to take on the role of CDH for Bayer's Pharmaceuticals Division and Senior Bayer Representative, Bayer Group for the Australia & New Zealand (ANZ) cluster, with effect from the same date. Shweta joined Bayer in 2019 and her last assignment was as Business Unit Head. With a distinguished career spanning over 22 years, Shweta has a strong track record of leading high performance diverse teams across strategic business positions in the pharmaceuticals and medical device sectors. Her expertise extends across a myriad of therapy areas, including Cardiology, Diabetes, Women's Health Care, Immunology, Virology, Anti-infectives, Vaccines, Neurology, Orthopaedics and Pain Management. Prior to this, she worked with companies of repute like Johnson & Johnson, MSD Pharmaceuticals, IQVIA and Pfizer.



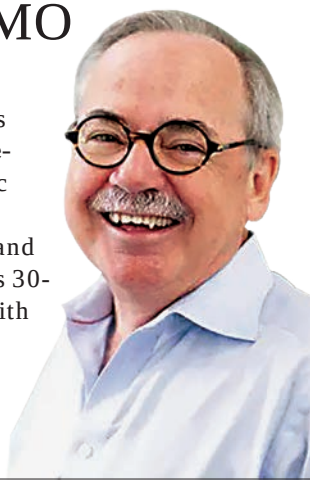
China's InnoCare Pharma appoints Xin Fu as CFO

InnoCare Pharma, with branches in Beijing, Nanjing, Shanghai, Guangzhou, Hong Kong, and the United States, has appointed Xin Fu, who has extensive finance-related experience, as the Chief Financial Officer (CFO). He reports to the Co-founder, Chairwoman and CEO of InnoCare Pharma, Dr Jasmine Cui. Fu is responsible for the company's growth strategy, financial management, investment and financing activities as well as investor relations management, aiming to contribute to the company's globalisation and operational efficiency to achieve the company's 2.0 objectives. Fu has over 20 years of financial management experience, including 15 years in the healthcare industry. Before joining InnoCare, he served as the CFO at JW Therapeutics, where he played a critical role in the completion of the IPO in the Hong Kong Stock Exchange, company strategy planning, investment and financing activities, etc. Prior to JW Therapeutics, Fu held multiple leadership positions at Pfizer China, including CFO and Chief Compliance Officer.

Hummingbird Bioscience names Dr Angèle Maki as CBO

Hummingbird Bioscience, a Singapore-based data-driven precision biotherapeutics company discovering and developing transformative biologic medicines for hard-to-treat diseases, announced the appointment of Dr Angèle Maki, as Chief Business Officer (CBO). Dr Angèle has two decades of experience in the biotech and pharma industry, with a track record of successful deals and partnerships across multiple therapeutic areas and modalities including significant numbers in antibody therapeutics. Most recently, she served as Senior Vice President and Head of Business Development at ReCode Therapeutics, where she led business development, corporate development, investor and public relations. At ReCode Therapeutics, she was part of the team that raised a $120 million series B extension. Prior to ReCode, Dr Angèle held business development roles with increasing responsibility starting at Medarex followed by BMS (which acquired Medarex), Genentech, Merck & Co, and Eli Lilly.

Sirnaomics promotes Dr Francois Lebel to CMO



Sirnaomics, a US and China-based biopharmaceutical company engaging in discovery and development of advanced RNAi therapeutics, has announced the promotion of Dr Francois Lebel to Chief Medical Officer (CMO. Dr Lebel enters this new role after serving as Senior Vice President for preclinical and clinical development since July 2023. As part of Dr Lebel's new leadership role, he will oversee the clinical development of Sirnaomics' lead therapeutic candidate, STP705, for the treatment of Squamous Cell Carcinoma in situ, a form of non-melanoma skin cancer. STP705 is currently in a Phase II clinical trial that is moving into a confirmatory study for late-stage development. Dr Lebel is a strategic leader with broad drug development experience including immuno-oncology and nucleic acid therapeutics. Throughout his 30-year strong biopharma industry career with Baxter, Medimmune, Chiron and others, Dr Lebel has designed and managed international research programmes and development organisations.

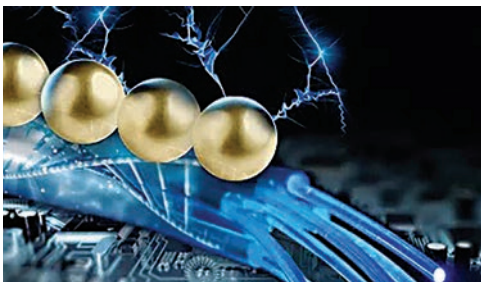
Sherene Azli takes charge of Chief Marketing Officer's role at KPJ Healthcare in Malaysia

KPJ Healthcare Berhad has announced the appointment of Sherene Azli as its new Chief Marketing Officer (CMO). A celebrated leader in her field, Sherene's professional journey is marked by significant roles in the telecommunications industry and government agencies. Notably, her tenure as CEO of the Malaysia Healthcare Travel Council (MHTC) was a period of remarkable transformation, where she led Malaysia to its recognition as the global number 1 Healthcare Destination by Volume in 2019 and earned the prestigious International Medical Travel Journal (IMTJ) Destination of the Year award multiple times. Sherene brings proven leadership skills and strategic insights, uniquely equipping her to tackle the complex challenges and opportunities in the healthcare industry. Her wealth of experience is expected to play a pivotal role in steering KPJ Healthcare's business growth.

Andrea Kelly steps in as Interim First Nations Aged Care Commissioner in Australia

First Nations leader Andrea Kelly has been appointed as the Interim First Nations Aged Care Commissioner, commencing in January 2024. Andrea's appointment is a first step in addressing Recommendation 49 of the Royal Commission into Aged Care Quality and Safety, which recommended a statutory First Nations Aged Care Commissioner to ensure culturally safe, tailored and flexible aged care services for First Nations people. As interim First Nations Aged Care Commissioner, she will undertake a range of key functions, expected to include a mandate to lead extensive public consultations with First Nations stakeholders and communities about the design and functions of the permanent Commissioner contributing to the changes necessary to bring improvements for First Nations people across all tiers of the aged care system in Australia. Andrea has 32 years of experience engaging with First Nations communities and developing public policy for First Nations populations. The First Nations Aged Care Commissioner is expected to be appointed in 2025.

Korea highlights golden future of wearable devices in healthcare



A research team from the Department of Materials Science and Engineering at Pohang University of Science and Technology (POSTECH), South Korea has developed an integrated wearable sensor device, using various shapes of gold nanowires, that effectively measures and processes two bio-signals simultaneously. While silver (Ag) nanowires, known for their extreme thinness, lightness, and conductivity, are commonly used in wearable devices, the team fused them with gold. Initially, they developed bulk gold nanowires by coating the exterior of the silver nanowires, suppressing the galvanic phenomenon. Subsequently, they created hollow gold nanowires by selectively etching the silver from the gold-coated nanowires. The bulk gold nanowires responded sensitively to temperature variations, whereas the hollow gold nanowires showed high sensitivity to minute changes in strain. The team's sensors exhibited remarkable performance in detecting subtle muscle tremors, identifying heartbeat patterns, recognising speech through vocal cord tremors, and monitoring changes in body temperature. Notably, these sensors maintained high stability without causing damage to the material interfaces.

Singapore takes step forward in diagnosing severe cases of dengue

Scientists and clinicians at Nanyang Technological University, Singapore (NTU Singapore) and the National Centre for Infectious Diseases (NCID) have identified two compounds, sST2 and suPAR, in the blood of dengue patients that could determine if a patient is at risk of severe dengue in the early phases of the disease. As lateral flow test kits for sST2 and suPAR are already commercially available and are used to test for heart failure, the researchers are working on validating and adapting these tests into a kit that could test for severe dengue. The researchers estimate that this new method of monitoring the levels of the two compounds would bring a higher accuracy, 55 to 60 per cent, of predicting severe dengue than the traditional assessment approaches. The researchers said the test kits would greatly aid clinicians in distinguishing between non-life-threatening cases of dengue fever and severe dengue, which requires hospitalisation. The scientists and clinicians discovered the importance of sST2 and suPAR in determining dengue severity during a study conducted between 2016 and 2019 involving 129 dengue patients treated in Tan Tock Seng Hospital, Singapore.

India set to boost immunotherapy in non-responsive cancer cells

In a new study, researchers at the Indian Institute of Science (IISc), Bengaluru tried to understand how different types of cancer cells respond to IFN-γ activation. They found that only some types of cancer cells respond well to IFN-γ activation, while others don't. They also suggest some approaches that can be used to make these non-responsive cancer cells better respond to immunotherapy. The production and functioning of a cytokine (a small signalling protein) known as Interferon-gamma (IFN-γ) is essential for the immune system to eliminate tumours effectively. The team found that cancer cell lines derived from the liver and the kidney showed increased production of nitric oxide (NO) and lactic acid upon IFN-γ activation. This, in turn, increased the production of toxic reactive oxygen species (ROS) leading to oxidative damage, which eventually kills the cancer cells. The team also observed that lactic acid plays an important role in the cancer cells' response to immunotherapy.

Australia announces world-first trial with slow-release of ketamine drug to treat depression

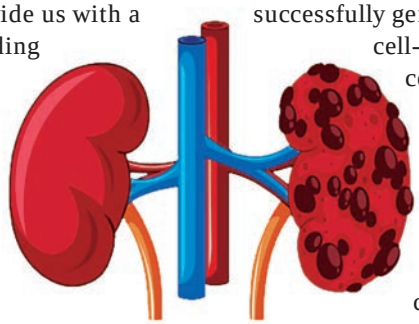
In a world-first, researchers at the Royal Adelaide Hospital (RAH) and the University of Adelaide in Australia are seeking participants to trial a new product that uses the drug ketamine as an alternative option to treat depression. The Central Adelaide Local Health Network (CALHN) and University of Adelaide-led study will see researchers test a new product, which, in a tablet form, releases the drug gradually into the body to treat depression that has not responded to other forms of treatment. Generally, there are more treatments available for depression compared to previous years, however up to 55 per cent of people can experience treatment-resistant depression where they do not respond well to the type of medications that are currently available on the market. Ketamine is commonly used in medicine for purposes such as pain relief and anaesthesia. It is a dissociative drug, meaning it acts on brain chemicals, and can change the way the brain interprets messages in what we see, hear, and feel.

Hong Kong develops novel drug delivery system for Alzheimer's disease treatment

A research team led by Hong Kong Baptist University (HKBU) has developed a novel drug delivery system for Alzheimer's disease (AD). The researchers have engineered exosomes, extracellular vesicles released by cells, to effectively carry the bioactive compound Corynoxine-B extracted from the Chinese herbal medicine Gouteng to the brain of mice with AD. As Corynoxine-B can induce autophagy, a process that maintains the health of cells, this new drug delivery system using exosomes can improve cognitive function and movement while reducing the symptoms of AD. The study suggests that exosomes could be a promising new way to deliver drugs to the brain and treat AD. Although more research is needed, this study provides hope that a cure for AD may be possible in the future. The scientists are hopeful that this research project will ultimately be beneficial to the elderly, individuals at high risk of neurodegeneration and neurodegenerative disease patients.

Japan designs advanced renal organoids to model polycystic kidney disease

A team of researchers at the Center for iPS Cell Research and Application, Kyoto University in Japan, building upon their previous work on differentiating Induced pluripotent stem cells (iPSCs) into kidney organoids, have made significant improvements to build a better model of kidney development and diseases and for use as a robust platform for drug discovery. Kidney organoids generated from human induced pluripotent stem cells (hiPSCs) represent a powerful biological tool that can provide us with a better understanding of the disease mechanism and a means to model diseases for drug discovery and testing purposes. However, organoids often remain in a developmental stage and do not accurately model disease conditions in adults. In this new study, researchers have successfully generated cortical cell-containing collecting duct organoids by establishing a method for long-term expansion culture of ureteric bud tip cells (UBTC) to reach the maturity required to model autosomal dominant polycystic kidney disease (ADPKD) accurately.



Cytiva transforms protein purification with new affinity technology

US-headquartered Cytiva, a global leader in life sciences, has introduced the innovative Cytiva Protein Select technology, designed to streamline and accelerate recombinant protein purification. The self-cleaving traceless tag and complementary affinity chromatography resin standardises purification for any protein, rendering it unnecessary to use specific affinity binding partners for each protein. Protein purification is integral to basic research, drug discovery, process development, and bioprocessing. However, the diverse family of recombinant proteins - of which there are 1800 in the global pipeline this year alone - often lacks affinity binding partners to facilitate purification. A common strategy to facilitate the purification has been to add a tag to the protein; however, it cannot be removed cleanly for biotherapeutic applications. Owing to Cytiva Protein Select technology, scientists can purify proteins using a simple protocol and receive highly pure, native proteins free of tag amino acids.

Agilent enhances BioTek Cytation C10 Confocal Imaging Reader with innovative water immersion technology

US-based Agilent Technologies Inc. has announced the addition of water immersion and new confocal spinning disk technology to the BioTek Cytation C10 confocal imaging reader. These features improve image quality and results by reducing deleterious effects on live-cell samples and enhancing clarity for thicker samples such as tissues and 3-D spheroids. In light microscopy, water immersion technology automatically and consistently places a layer of water between the objective lens and the sample. The higher refractive index of water, as compared to air, effectively increases the numerical aperture of the objective lens; this reduces z-axis distortion, resulting in higher image quality and a more true-to-life representation of thick and three-dimensional cell models. Water immersion also benefits researchers who are increasingly turning to physiologically relevant live-cell (as opposed to fixed-cell) applications by reducing exposure times, thus lowering the phototoxic effects traditionally associated with these experiments.

Waters Corp invests $16M in new state-of-the-art Global Capability Center in India

American firm Waters Corporation has inaugurated its new Global Capability Center (GCC) in Bengaluru, India, a strategic investment to accelerate technology adoption, innovation, digital transformation, and business efficiencies through a concentrated hub of talent that will operate across the Waters global enterprise. Waters India GCC will employ 300+ for roles in software engineering, technology & product development, data analytics and IT. The Waters India GCC is in a newly built facility in Bengaluru's RMZ Ecoworld technology park, a WELL and LEED Platinum-certified campus that exemplifies a commitment to a healthy and eco-conscious workspace. The new $16 million (Rs 1.3 billion) workspace will employ 300+ for roles that were formerly outsourced to various outside service providers and will transform into an India-based global hub designed to in-source talent, accelerate technology adoption, and drive technological innovation.

Revvity launches easy-to-use molecular diagnostics workflow for newborn screening

US-based Revvity, Inc. has announced the launch of its EONIS Q system, a CE-IVD declared platform enabling laboratories in countries that accept the CE marking to adopt molecular testing for spinal muscular atrophy (SMA) and severe combined immunodeficiency (SCID) in newborns. For both inherited conditions, immediate detection is critical to advancing a positive outcome. For SMA, disease modifying therapies exist to stop progression of disease, and for SCID, immunoglobulin treatments combined with stem cell therapies can potentially cure a child, if intervention comes in time. However, to date, molecular testing for these and other congenital disorders is relatively low, due in part to cost restrictions and the technical expertise required to perform and interpret these tests. The EONIS Q system simplifies and streamlines molecular testing for SMA and SCID with an innovative workflow, inclusive of the EONIS Q96 instrument, the EONIS SCID-SMA kit and dedicated EONIS EASI software.

Thermo Fisher simplifies respiratory diagnostic testing with new solutions

Thermo Fisher Scientific Inc. has announced the launch of the Thermo Scientific KingFisher Apex Dx, an automated nucleic acid purification instrument, & Applied Biosystems MagMAX Dx Viral/Pathogen NA Isolation Kit for the isolation & purification of viral & bacterial pathogens from respiratory biological specimens. Together these products provide laboratories with an in vitro diagnostic (IVD) & in vitro diagnostic regulation (IVD-R) approved automated sample preparation solutions for increased confidence in downstream results. KingFisher Apex Dx system enables scientists' labs to recover quality nucleic acids for sensitive downstream applications with maximum consistency, reproducibility, & reliability. The system is designed to be a part of a modular sample preparation to real-time PCR analysis workflow providing precise results, accurate data management, & robust security features that meet cybersecurity & diagnostic regulatory standards. Additionally, the MagMAX Dx Viral/Pathogen NA Isolation kit offers advanced formulation to ensure reproducible results & is automation compatible with the KingFisher Apex Dx.

Shimadzu releases new gas chromatograph mass spectrometer

Japan-based Shimadzu Corporation is releasing the GCMS-QP2050 quadrupole gas chromatograph mass spectrometer. The internal structure has been improved in comparison to previous models, so this product is more durable, and provides stable, highly reliable measurement data. Time required for maintenance of the component (ion source) that ionises complicated samples has been reduced up to 95 per cent in comparison to the conventional models. The efficiency of user operations has been increased by including a variety of functions, such as compatibility with optionally available automatic data analysis via artificial intelligence (AI) algorithm, time management that can assess the operating status of the instrument, and remote control of the instruments. This product combines the industry's smallest equipment size with high robustness due to the newly designed quadrupole rods. With simple component configuration, the maintenance burden on users has been eased by simplifying troublesome and difficult tasks.

UHC while Out-of-pocket Spending Soars

On December 12, observed as Universal Health Coverage (UHC) Day, the World Health Organization (WHO) released a report saying that while access to essential health services like antenatal care and management of infectious diseases has increased over the past two decades, it has come at a high cost to families in the Western Pacific Region, including Australia, China, Japan, Malaysia, New Zealand, Philippines, Singapore, South Korea, Taiwan, Vietnam and many more.

It noted that the percentage of people in the Western Pacific who suffered catastrophic health expenses – defined as out-of-pocket spending (OoPS) on health that exceeds 10 per cent of the household budget – doubled between 2000 and 2017. In 2000, one in 10 people in the region incurred catastrophic health spending. By 2017, this proportion had increased to one in five – totalling some 385 million people in the Western Pacific facing catastrophic spending on health care.

The report also finds that catastrophic health spending is mostly affecting people living in Asian countries and areas in the region. It further found that financial hardship from health spending is highest among those who live in poorer households, have older members or are in rural areas. Left unchecked, this situation can exacerbate health and socioeconomic inequalities in the region. For households in the region, medicines are the biggest drivers of out-of-pocket spending on health, followed by outpatient care. Other recent studies, too, have found that medicines account for a higher share of out-of-pocket expenses for poorer households compared to those that are better off.

On the contrary, the situation is not the same in the South-East Asia Region (SEAR). This is because the SEAR has maintained UHC as a Flagship Priority in the region since 2014. Over the last decade, very significant UHC-related reforms have and are currently in the process of implementation across the region. Between 2015 and 2021, the region increased its UHC service coverage index from 54 to 62. Between 2014 and 2020, alongside an increase in the share of public investment, out-of-pocket health spending as a share of current health spending decreased from 42.8 per cent to 37.9 per cent. Moreover, while catastrophic health spending remains a key concern, the population impoverished and further impoverished due to out-of-pocket health spending declined from 30.5 per cent in 2005 to 6.6 per cent in 2019.

A day before UHC day, the WHO launched a new Global Health Expenditure Report that revealed that in 2021 global spending on health reached a new high of $9.8 trillion or 10.3 per cent of global gross domestic product (GDP). Nevertheless, the distribution of spending remained grossly unequal. Public spending on health had increased across the world, except in low-income countries where government health spending decreased and external health aid played an essential supporting role.

The record spending on health in 2021 demonstrated how countries prioritised public health during the pandemic even as economies and societies reeled from the massive disruptions it caused. However, the report also highlights that the scale of growth in public spending on health observed during this period is unlikely to be sustained, as countries shift focus to handle other economic priorities such as slowing growth, high inflation rates and increased debt servicing obligations associated with rising indebtedness.

In 2021, about 11 per cent of the world's population lived in countries that spent less than $50 per person per year, while the average per capita spending on health was around $4000 in high-income countries. Low-income countries accounted for only 0.24 per cent of the global health expenditure, despite having an 8 per cent share of the world's population.

With rapidly ageing populations and increasing rates of noncommunicable diseases like heart disease, diabetes and cancer, the burden of paying for medicines is expected to rise in the years to come if bold actions are not taken to address the existing policy gaps.

While countries are implementing policies aimed at reducing financial hardship on the path towards UHC, faster progress is needed in areas such as increasing public funding for health, implementing strategies to allocate resources efficiently, prioritising the poorest and most vulnerable groups, and reducing out-of-pocket expenses on medicines. BS

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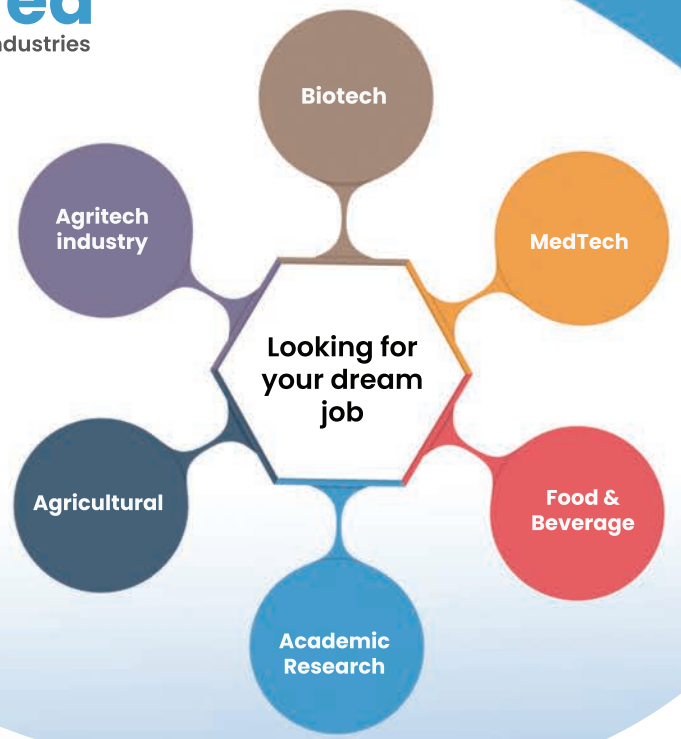

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