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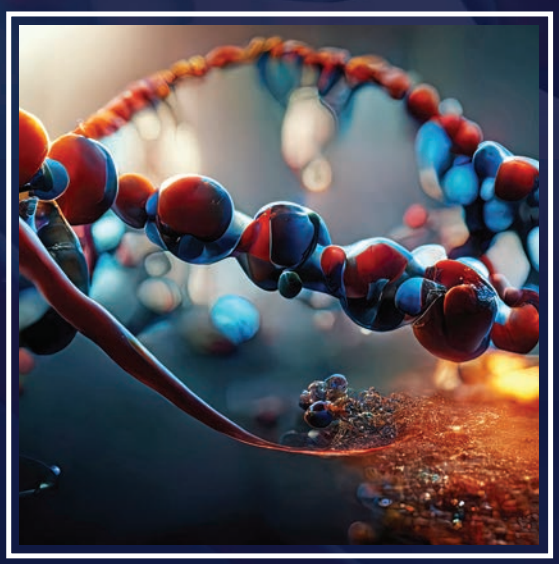
How GENOMICS can REVOLUTIONISE HEALTHCARE



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Acknowledgements/ Feedback

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- Shradha Jani, Mumbai

Thank you for featuring Repligen in the story- 'The Appeal of Single-use Tech'.

- Kanika Khetarpal, Bengaluru

The Indian medical devices industry has the potential to reach $50 billion by 2030. The Exports Promotion Council for Medical Devices is a big boost to the Indian medical devices industry.

- Rajiv Nath, New Delhi

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Letter from Publisher

Ravindra Boratkar
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MD, MM Activ Sci-Tech
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Dear Readers,

I wish all our readers and advertisers A Very Happy and Prosperous New Year.

For the Indian pharma sector, the transition from 2022 to 2023 was on a very positive note. This year, the Indian pharma industry looks to move from volume to value leadership. Rating agencies have forecast 6 to 8 per cent growth in revenue this year and the next year also.

The previous year, however, concluded on an issue of some concern. In all, 16 Indian pharma companies received flak from drug authorities of Nepal for not complying with manufacturing standards set by the World Health Organisation (WHO). This is the second incident in just six months. The first being one from Gambia in Africa. Our editorial analyses its impact on the sector.

However, the Indian government and the drug authorities must dig deep to find out the truth. In the case of Gambia, the authorities examined the samples of the cough syrups, while the government took a firm stand, supporting the company when the samples were, indeed, in compliance with required specifications and not contaminated with ethylene glycol and diethylene glycol. Maybe the authorities will have to do the same in this incident as well and stand by them, if they are victims of a larger smear campaign.

One positive development in India is the growing awareness about genomics. India is on the cusp of the genomic revolution as the people understand the value of genomic testing that helps provide more information on different diseases like diabetes, cancer etc. This further helps in identifying accurate prevention solutions as well as to chart out treatment options.

Genomics and genome sequencing assumes a lot of importance in disease management that includes prevention, diagnostics and cure. It is also playing an important role in drug development and is expected to transform the drug scenario in coming years. To highlight the importance of genomics, we have taken it as a subject for cover package. Our editorial team has put in its efforts to provide you with a good insight into the subject.

COVID vaccine is another important topic that has been highlighted in this issue. The vaccines developed in India had to be disposed off as there were few takers. We have experts commenting on why the two main COVID vaccine makers in India had to stop producing the vaccines.

With just a month left for the Union Budget 2023-24 to be presented in the Lok Sabha, pre-budget expectations of the industry assume a lot of importance. Various industry associations and organisations submit their suggestions on, and expectations from the Budget, to the government. A review of that is covered in this edition, to understand industry expectations.

With a toast to your good health, I wish you happy reading.

Thanks & regards,

Ravindra Boratkar

Publisher & Managing Editor

COVER STORY 20

How genomics Can REVOLUTIONISE HEALTHCARE

A genomic revolution is taking place in India, where the value of genomic tests is being recognised in the prevention and diagnosis of diabetes, cardiovascular, cancer, carrier status, among others. Having the power to identify accurate preventive solutions to chart out treatment options for patients, predictive genomic testing is seen as the next major weapon in the arsenal of cutting-edge healthcare tech that can improve patient outcomes without relying on a curative approach. Let's learn more from industry leaders and experts in the field of leveraging genomics.

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"The penetration of genetic testing still remains abysmally low in a country like India"

Dr Samir Vyas,
Country General Manager,
Agilent Technologies

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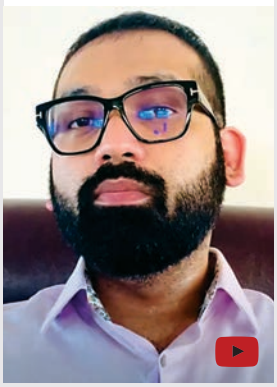

Nikkhil K Masurkar, Chief Executive Officer, Entod Pharmaceuticals shares his perspective on how the pharma sector can improve the rising cases of myopia in children.

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Vishal Gondal, Founder and Chief Executive Officer, GOQii talks about the challenges associated with health metaverse.

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Sajeev Nair, Founder & Chairman, Vieroots Wellness Solutions elaborates upon geno-metabolic analysis powered by artificial intelligence for personalised healthcare.

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Fooled Me Twice?

In yet another blow to the Indian pharma sector, Nepal has black listed 16 Indian pharma companies, including the one that produces yoga guru Baba Ramdev's Patanjali brand products. The drug regulatory authority of the neighbouring country has also asked the local distributors of those companies to recall the medicines supplied by their companies. This comes after the much publicised spurious medicine notification by the World Health Organisation (WHO) in Gambia, Africa which was resolved in favour of the Indian company.

Nepal's action has come in the wake of a WHO warning. The drug authority of Nepal inspected, between April and July, the production facilities of the Indian companies supplying drugs to them.

The regulators found, during inspection, that the companies were not complying with the production standards set by the WHO, exact details of which are not forthcoming. In some cases, even the products of some companies did not comply with regulatory requirements. As a result, the notices were issued and the import from these companies was stopped. Nonetheless, there's a possibility that such moves could end up tarnishing the image of Indian pharma prowess in the eyes of other nations, a larger impact to our economy.

Some of the companies that are blacklisted include Radiant Parenterals Ltd, Mercury Laboratories Ltd, Alliance Biotech, Captab Biotec, Aglowmed Ltd, Zee Laboratories, Daffodils Pharmaceuticals, GLS Pharma, Unijules Life Science, Concept Pharmaceuticals, Shree Anand Life Sciences, IPCA Laboratories, Cadila Healthcare Ltd, Dial Pharmaceuticals and Mackur Laboratories, among others. Divya Pharma is another company which produces Baba Ramdev's Patanjali products.

Black listing of 16 Indian pharma companies is another dent into the $42 billion pharma sector's reputation as a supplier of quality medicines in just three months. When the Indian pharma sector is earning a good name as the world's pharmacy, maintaining standards in such a situation is utmost important. But that seems to be not happening in the case of some companies.

Complying to manufacturing standards set by WHO and quality production are particularly important now as some other countries are trying to capture conventional generics. Just recently, Pharmexcil has warned that China, Vietnam, Indonesia and Bangladesh are competing with India to capture the market and their costing also matches India. Of them, Pharmexcil feels that Indonesia and Vietnam are likely to emerge as strong competitors.

Another challenge for Indian pharma is the low growth of the generic market. From 2016 to 2020 the global generic market grew only at CAGR 2 per cent. By some estimate in 2021 there was no growth at all. Though that did not affect India's performance as its generic export grew at 9 per cent in the last five years. But it is important to note here that India's pharma exports mainly depend on the growth of the global generic market. Pharmexcil has suggested that Indian pharma companies must develop high-technology and scientific products and capture the market of complex generics and biosimilar products.

This is a very crucial time for Indian companies to ensure quality. Though it is true that a large number of companies generally comply with norms, a few which do not endanger the reputation of the entire sector. In Nepal itself, as the drug regulator published a list of 16 companies for non-compliance to manufacturing norms, it has also published a list of 46 companies that do comply with the standards.

It is important that the practices of 46 companies are emulated by others. Some of the associations of pharma companies are making efforts in guiding the members about implementing standard production practices. But the number of pharma units are large and several of them are in the small and medium sector, also making it difficult to keep track of their production practices. They suddenly get exposed in situations like this. But there needs to be a strong internal mechanism to ensure quality and avoid such incidents that tarnish India's image in the global sphere. BS

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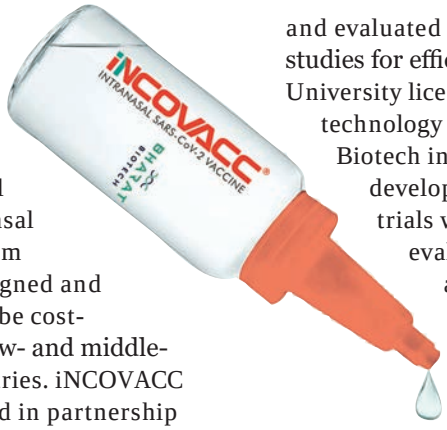
Bharat Biotech's intranasal vaccine iNCOVACC receives heterologous booster approval

Hyderabad-based Bharat Biotech has announced that iNCOVACC (BBV154), has received approval from the Central Drugs Standard Control Organisation (CDSCO) under Restricted Use in Emergency Situation for ages 18 and above, in India, for heterologous booster doses. iNCOVACC is a recombinant replication deficient adenovirus vectored vaccine with a pre-fusion stabilized SARS-CoV-2 spike protein. This vaccine candidate was evaluated in Phases I, II and III clinical trials with successful results. The vaccine has been specifically formulated to allow intranasal delivery through nasal drops. The nasal delivery system has been designed and developed to be cost-effective in low- and middle-income countries. iNCOVACC was developed in partnership with Washington University, St. Louis, which had designed and developed the recombinant adenoviral vectored construct and evaluated in preclinical studies for efficacy. Washington University licensed the vaccine technology to Bharat Biotech in 2020 for further development. Clinical trials were conducted to evaluate iNCOVACC as a primary dose schedule, and as heterologous booster dose for subjects who have previously received two doses of the two commonly administered COVID-19 vaccines in India.



CDSCO approves AstraZeneca's Dapagliflozin with additional indications

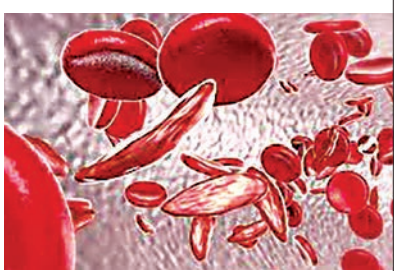
AstraZeneca India has received the Central Drugs Standard Control Organisation's (CDSCO) approval for their anti-diabetic drug Dapagliflozin in the treatment of adults with chronic kidney disease (CKD). Dapagliflozin is the first and only anti-diabetic drug approved to significantly reduce the risk of sustained eGFR (estimated Glomerular Filtration Rate), cardiovascular deaths and hospitalisations due to heart failure in adults with progressive CKD. This approval is applicable for both diabetic and non-diabetic CKD patients. The approval is based on the consistent results from the DAPA-CKD study, where the indication has now been recommended in adults with CKD, up to an eGFR greater than or equal to 25 ml per min per 1.73 m2. AstraZeneca's Dapagliflozin is an oral anti-diabetes drug which has shown increasing benefits in not only preventing heart failure but also in managing CKD and heart failure with reduced ejection fraction irrespective of diabetes status.

Ministry of Ayush inks MoU with DST to explore cooperation in the Ayush sector

A Memorandum of Understanding (MoU) has been signed between the Ministry of Ayush, Government of India and Department of Science and Technology (DST), Ministry of Science and Technology & Earth Sciences. The MoU will identify the potential areas of research to explore cooperation, convergence, and synergy for evidence-based scientific intervention in the Ayush sector and further application of these into the public healthcare system. The MoU was signed by Vaidya Rajesh Kotecha, Secretary, Ministry of Ayush and Dr Srivari Chandrasekhar, Secretary, DST in presence of senior officials from Ministry of Ayush and scientists of DST. Through the MoU, the Ministry of Ayush and DST have agreed to jointly undertake R&D activities on scientific validation of Ayush concepts, procedures and products, create a platform for the exchange of information and bring about the application of modern science toward understanding the Ayush-related basic concepts and principles.

Govt strengthens research on haemoglobinopathies and similar diseases

Prime Minister Narendra Modi inaugurated the Centre for Research, Management and Control of Haemoglobinopathies, in Nagpur. The prevalence of Sickle Cell disease in the Vidarbha region of Central India, especially in tribal population, is high, with expected carrier frequency as high as 35 per cent in certain tribal groups. Realising this issue and the spread of similar diseases in the country, ICMR - Centre for Research, Management & Control of Haemoglobinopathies has been set up that will play a leading role in research on haemoglobinopathies and similar diseases in the country. The centre is equipped with state-of-the-art diagnostic and research facilities including bio-banking and proteomics facilities, which will enable India to conduct pathbreaking research on the disease. This centre of medical excellence is dedicated to haemoglobinopathies, which are inherited disorders of haemoglobin and include β-thalassemia syndromes and sickle cell disease, amongst others. The centre will undertake interventions through community control programmes and translational research that will benefit the patients in the underserved region of Chandrapur and adjoining areas.



PM lays foundation stone for the National Institute for One Health in Nagpur

Prime Minister Narendra Modi recently laid the foundation stone for the National Institute for One Health in Nagpur. This new institute of medical excellence will further expedite the country's efforts in enhancing health research to serve the vulnerable populations. With increased interaction between humans and animals – domestic and wild, and influenced by climate change, human health can no longer be seen in isolation. More than half of all infections that people get, can be spread by animals. In this context, National Institute for One Health in Nagpur is an important infrastructural milestone for India. The institute will focus on increasing preparedness and laboratory capabilities for identification of novel and unknown zoonotic agents. This dedicated institute will be equipped with the Bio Safety Level (BSL-IV) laboratory. It will help in investigation of outbreaks of emerging zoonotic agents concerned with public health and developing better control strategies.

National Animal Resource Facility for Biomedical Research opens at Genome Valley

The Union Health Minister, Dr Mansukh Mandaviya recently inaugurated Indian Council of Medical Research- National Animal Resource Facility for Biomedical Research (ICMR-NARFBR) at Genome Valley, Hyderabad in presence of C Malla Reddy, Minister of Labour and Employment, Government of Telangana. The significance of NARFBR can be adjudged from the fact that study of animals in biomedical research becomes crucial in discovering causes, diagnosis and treatment of zoonotic agents and diseases. NARFBR is an apex facility which will provide ethical care and use and welfare of laboratory animals during research. The newly built centre will work as the state-of-the-art facility for not just ethical animal studies but spans from basic, applied to regulatory animal research. It will help in capacity building of new researchers and will create processes for pre-clinical testing of new drugs, vaccines and diagnostics within the country along with quality assurance checks. From availability of various animals for ethical research to strengthening various processes under one umbrella, NARFBR would be an asset for the country to deal with zoonotic diseases.

Gland Pharma buys Cenexi Group for €120 M

Hyderabad-based Gland Pharma, through its wholly owned subsidiary Gland Pharma International, Singapore has entered into a Put Option Agreement to acquire 100 per cent of Cenexi Group for an Equity Value not exceeding Euro 120 million. Founded in 2004, Cenexi, along with its subsidiaries, is engaged primarily in the business of Contract Development & Manufacturing Organisation (CDMO) of pharmaceutical products with expertise in sterile liquid and lyophilised fill-finished drugs, including capabilities on oncology and complex products. It has presence across four manufacturing sites in Europe which include three sites in France and one site in Belgium. It has experience in processing specific substances like hormones, suspensions and controlled substances. Gland Pharma has a strategic focus on expanding its CDMO offerings in the European market and building a manufacturing presence in the market. The acquisition provides Gland Pharma access to leading know-how and development capabilities in sterile forms including for ophthalmic gel, needleless injectors and hormones.

Mankind Pharma acquires majority stake in Upakarma Ayurveda

Mankind Pharma has announced that one of its subsidiaries has acquired a majority stake in New Delhi-based startup Upakarma Ayurveda, a brand that is engaged in developing, manufacturing and selling ayurvedic and herbal products. Upakarma Ayurveda offers products ranging from improving health and wellness to boosting immunity. It is driven by the vision to achieve the overall well-being of the human body with a focus on body, mind, and lifestyle. The company has repositioned Shilajit as a health and wellness product and sought to reimagine the stereotypical way Shilajit was perceived in the market as an aphrodisiac (sexual wellness product) for men. Mankind Pharma's decision to invest in Upakarma Ayurveda will empower the latter to strive to develop a wider range of products and offerings and penetrate the market leveraging the strong distribution network of Mankind Pharma.

JB Pharma buys Rosuvastatin franchise for Rs 314 Cr

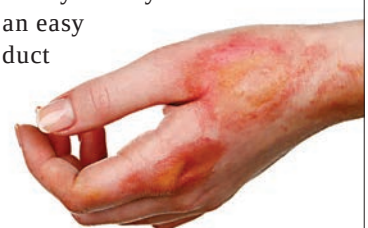
Mumbai-based JB Pharma has entered into an agreement with Glenmark Pharmaceuticals to acquire the entire Razel (Rosuvastatin) franchise for the India and Nepal region for Rs 314 crore. With this acquisition, JB Pharma will complete its cardiac portfolio making it a leader in this segment, as Razel ranks among the top 10 brands in the Rosuvastatin molecule category in the country. These brands are focused on the cardiac segment in India and Nepal with a total covered market size of Rs 2,444 crore as per IQVIA MAT Oct '22 numbers. With this addition, the company has established a strong position in statins besides being among the leaders in hypertension and heart failure – all the fastest growing therapeutic indications in cardiology. The company sees a good growth potential from the acquired brands and will help to leverage the existing Go-To-Market model focussed for the segment and further strengthen the chronic portfolio.

Indian Immunologicals first to venture into fish vaccines

Hyderabad-based vaccine manufacturer Indian Immunologicals Limited (IIL) has announced a partnership with Central Institute of Fisheries Education (CIFE), Mumbai, an Indian Council of Agricultural Research (ICAR) institute for the commercial development of vaccine against common bacterial diseases in freshwater fishes. IIL has forayed into Aqua business in October 2022 by launching products for aquaculture health market dealing with pond management and fish or shrimp gut management. CIFE will provide technology for two inactivated bacterial vaccines, one for Columnaris Disease, a serious condition affecting numerous freshwater fish species, and other for Edwardsiellosis that cause high degree of mortality, leading to severe economic losses. Both the diseases are extremely common in freshwater fishes and is generally considered to be ubiquitous. IIL is planning to introduce vaccines and immunostimulants with tech transfer from various fisheries institutes under ICAR. Several fish vaccine candidates are currently being evaluated by IIL for commercialisation.

Bharat Serums to market NexoBrid for treatment of severe burns in India

Mumbai-based biopharmaceutical company Bharat Serums and Vaccines (BSV) has entered into an exclusive distribution agreement with MediWound, a fully integrated biopharmaceutical company in Israel focused on next-generation biotherapeutic solutions for tissue repair and regeneration, for exclusive marketing and distribution of NexoBrid in India. NexoBrid, a new paradigm in treatment of severe burns, is a concentrate of proteolytic enzymes enriched in bromelain, and an easy to use, topically applied product that removes eschar in four hours without harming the surrounding healthy tissues. According to Vishwanath Swarup, COO-Domestic Operations, BSV, burn treatment and management continues to remain a public health challenge in India. As a leading player in the women's health segment, NexoBrid in India will improve the lives of several women in the country. NexoBrid is now approved and sold in 42 countries worldwide. Approval in India represents a significant opportunity for us. With a high incidence of burns in India, NexoBrid can offer a safer treatment towards burn management.



Torrent Pharma, Boehringer Ingelheim to co-market diabetes drug in India

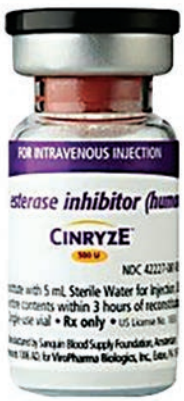
Ahmedabad-based Torrent Pharmaceuticals has entered into a strategic alliance with the Indian arm of Germany-headquartered Boehringer Ingelheim to co-market its anti-diabetic drug and its fixed dose combinations in India. The company will co-market Cospiaq (Empagliflozin), Cospiaq Met (Empagliflozin+ Metformin) and Xilingio (Empagliflozin+ Linagliptin) in India. Empagliflozin, a sodium glucose co-transporter-2 (SGLT-2) inhibitor, is a class of prescription medicines that are FDA-approved for use with diet and exercise to lower blood sugar in adults with type 2 diabetes. Empagliflozin is also used to reduce the risk of cardiovascular death, in adults with type 2 diabetes mellitus and established cardiovascular disease. Further, empagliflozin is indicated to reduce the risk of cardiovascular death and hospitalisation for adults who have greater chances of heart failure. As per International Diabetes Federation, India has the second largest diabetes patient base in the world with an estimated 74.2 million adults (20-79 years age group) as of 2021. This is expected to increase to almost 125 million patients by 2045.

Akums Drugs inks partnership for bringing first-of-its-kind therapeutics to India

To leverage the research expertise and combined manufacturing capacities for introducing first-of-its-kind products in India, New Delhi-based contract development and manufacturing organisation (CDMO), Akums Drugs & Pharmaceuticals has partnered with Leiutis Pharmaceuticals and Biophore India Pharmaceuticals (both based in Hyderabad) for research and development of a range of products for multiple therapies. This association is set to bring succour in therapy areas of central nervous system (CNS) disorders, pain management, and hormonal disorders, where there is a gap in meeting the needs of patients in an effective, safe, and convenient manner. This partnership leverages the strengths of each of the companies resulting in an innovation strategy creating a unique value proposition to doctors and patients in India. The focus of the companies in this partnership is to synergise capabilities, leverage research and bring innovative products in specific therapeutic areas, within the next five years, both in India and other global markets and with the first few products expected to be commercialised in the next two years.

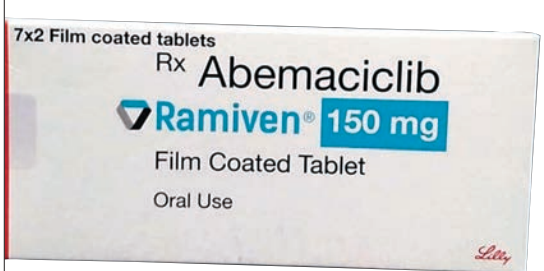
Takeda launches CINRYZE for treatment of hereditary angioedema patients

Takeda Biopharmaceuticals India, has launched CINRYZE, an innovative injectable prescription medicine for the treatment of hereditary angioedema (HAE) patients. With eight years of global clinical experience proving efficacy and safety, CINRYZE has the potential to mark a breakthrough in the episodic treatment, short and long-term prophylaxis for HAE. Moreover, CINRYZE is the pioneer C1 esterase inhibitor (C1-I NH) approved by the FDA & EMA for the symptomatic management of HAE and for preventing future angioedema attacks. CINRYZE is indicated in India for routine prevention (prophylaxis) of angioedema attacks in adults, adolescents and children six years of age and above with HAE; and treatment of angioedema attacks and pre-procedure prevention of angioedema attacks in adults, adolescents and children 2 years of age and above with HAE. Hereditary Angioedema (HAE) is a rare genetic condition that causes swelling in different parts of the body like limbs, face, abdomen, and larynx.



Eli Lilly introduces Ramiven for certain high-risk early breast cancer patients

Eli Lilly and Company (India) has announced the launch of the additional indication for Ramiven (abemaciclib), following approval from the Drug Controller General of India (DCGI) in combination with endocrine therapy for adjuvant treatment in adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative, node-positive early breast cancer (EBC) at high risk of recurrence. CDK 4/6 inhibitors are a class of medicines used to treat certain types of metastatic breast cancers. In India, over 50,000 patients are diagnosed with HR+/HER2- EBC every year. Close to 30 per cent of EBC patients with high-risk clinical or pathological features experience recurrence or metastasis despite receiving standard therapy. According to Vineet Gupta, Managing Director, Eli Lilly and Company - India & India Subcontinent the approval of Ramiven for treatment of EBC brings more optimism by providing a new treatment option to the healthcare professionals for their patients.

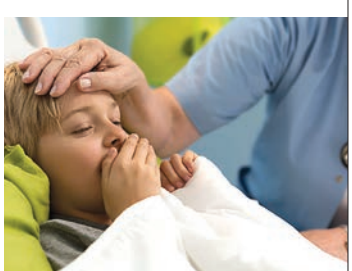


In-Med Prognostics raises $2.13M to expand AI-based image processing for healthcare

In-Med Prognostics, an artificial intelligence (AI) startup with expertise in multi-modal data and image processing, has raised $2.13 million led by Exxora with participation from prominent angels. The funds will be used to stabilise and expand the product portfolio and tap global markets. In-Med Prognostics leverages deep learning algorithms and machine learning to provide time saving accurate neuro analysis which aids in assessment and early detection of neurological disorders such as Dementia, Alzheimer's and Parkinson's at affordable prices. Their 'Neuroshield' solution provides a self-explanatory volumetric report within an analysis time of 20 minutes. The startup offers AI powered image processing proprietary software for neurologist decision support and radiologist workflow enhancement. The company is the first in the world to provide ethnicity specific neuro assessment reports and multi-modal data processing capability to develop integrated digital biomarkers. In India, In-Med Prognostics is already working with Aarthi Scans, Scansworld, Gujarat Scans, Nanavati, Cauvery hospitals.

India Health Fund backs development of novel collection device for testing TB in children

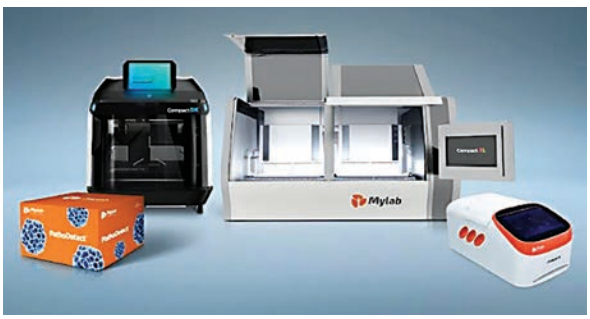
India Health Fund (IHF), a Tata Trusts initiative, has announced its funding and support for a first-of-its-kind lollipop- and chewing gum-inspired sputum collection device for testing tuberculosis (TB) among children. Being developed by Coimbatore-based startup 221B Biomedical, and christened 'Blow-Pop', it will help address lakhs of under-, mis- and delayed diagnosed cases of TB among children. The unique child-friendly sample collection device is expected to be ready for roll-out over the next two years. India Health Fund's latest grant to 221B Biomedical will pave the way for development and clinical validation of 221B Biomedical's simulated method. The innovation is a low-cost device that will improve the safety, efficacy, and ease of sputum collection for TB in children. Inspired from a lollipop, and chewing gum user experience, the conch-shaped device needs children to simply chew and blow or cough for easy sample collection of oral fluids. Moreover, owing to its simplicity, the tool will be ideal for low-resource settings, including primary healthcare setups.



MOBIS partners with NeoMotion to fund development of rehabilitative device

Global auto components major MOBIS has partnered with NeoMotion, a startup incubated at the Indian Institute of Technology, Madras (IIT-M) that works on developing indigenous rehabilitative devices, to provide personalised motorised wheelchairs for 500 people with disabilities. MOBIS has taken up this project under its CSR Initiative of 'Accessibility and Freedom.' More beneficiaries would be identified in other parts of the country. The wheelchairs were handed over to the first set of 50 beneficiaries at MOBIS plant in Sriperumbudur, Chennai. The wheelchairs, called 'NeoFly,' are custom-made after a clinical assessment of the beneficiary to provide the proper fitting and the correct posture. Further, a scooter clip-on device, called 'NeoBolt,' allows wheelchairs to be driven on the roads. This empowers them to complete their education, pursue employment opportunities and become empowered. Under this project, 500 beneficiaries will be assessed and their NeoFly and NeoBolt will be handed over. Till now, more than 300 have been assessed in Chennai, Hyderabad and Delhi.

Mylab unveils indigenous TB and multi-drug resistance detection kit



Pune-based startup Mylab has received Central Drugs Standard Control Organisation (CDSCO), TB Expert Committee and Indian Council of Medical Research (ICMR) approval for the first Made in India tuberculosis (TB) detection kit which simultaneously detects multiple drug resistance (MDR) to Rifampicin (RIF) and Isoniazid (INH) in a single test. The kit named PathoDetect MTB RIF and INH drug resistance kit is a RT-PCR based kit for accurate detection and will be used with Mylab Compact device systems, which will allow completely automated testing of multiple samples within two hours. Multicentre evaluation study and field feasibility testing studies were carried out for the PathoDetect MTB RIF and INH drug resistance kits & Compact device systems. The centres of trials included the most reputed TB research centres of India. The test kits have been designed to work in ambient temperatures compared to existing PCR options which need 2-8 degree cold storage. Mylab Compact device systems do not require special infrastructure for operations and feasibility studies done on mobile vans in rural areas indicate them to be very robust.

TrueMedix launches national reference laboratory in Bengaluru

New-age medical diagnostics chain TrueMedix recently launched its operations with the inauguration of the startup's main branch office in Kodigehalli, Bengaluru, in the presence of the Minister of Health and Family Welfare and Medical Education, Government of Karnataka, Dr K. Sudhakar. The inauguration officially signals TrueMedix's beginnings as a National Reference Laboratory and drives the company into the spotlight amidst the medical diagnostics sector's shift towards quicker testing and reporting methods driven by next-generation technology. TrueMedix aims to spearhead this trend as it works with various partners in the ecosystem, including clinics, micro labs, nursing homes, hospitals, medical colleges, research organizations, corporates, and NGOs. TrueMedix has one processing centre in Shimoga, and 40 collection centres in all 36 districts of Karnataka, and in other neighbouring districts of states like Kasaragod, Hosur, Hindupur, Anantapur, Solapur, and Kolhapur. The company already has plans to increase this number and envisions processing over 10 million annual tests and serving in excess of 10,000 laboratories and hospitals.

IIT Kanpur receives Rs 2 Cr for seeding health technology innovations

Indian Institute of Technology (IIT) Kanpur alumnus Ajay Dubey and his wife Rooma Dubey have contributed Rs 2 crore for seeding health technology innovations. A Memorandum of Understanding (MoU) was signed between Prof. Abhay Karandikar, Director, IIT Kanpur, and Ajay Dubey on December 6, 2022 at IIT Kanpur. Ajay Dubey and Rooma Dubey have contributed towards instituting the 'Rooma & Ajay Dubey Healthcare Innovation & Ideation Programme' (HII Programme) with an aim to fund and nurture innovations in health technology, and build an ecosystem to nurture startups founded by students in the healthtech domain. The programme will expose students to various problem statements and motivate them to come up with technology solutions, and develop technological ideas for the betterment of the healthcare system.

New WHO brief sets out actions needed to improve lives of people with epilepsy

A new technical brief published by the World Health Organization (WHO), 'Improving the Lives of People with Epilepsy,' sets out the actions required to deliver an integrated approach to epilepsy care and treatment, which better meets the multifaceted needs of people with epilepsy. To ensure people with epilepsy get the diagnoses, care and treatment they need, the new brief sets out the case for tackling the burden of epilepsy through better integration in primary healthcare systems. It outlines concrete actions, grouped under the 11 dedicated levers first introduced by the Operational framework for primary healthcare to address the treatment gap, strengthen services and promote a person-based, human rights approach that meets the multifaceted needs of people with epilepsy. According to Dévora Kestel, WHO Director for Mental Health and Substance Use, given that epilepsy has significant personal, health, economic and social inclusion consequences for people living with the disorder and for their families and communities, the response should not be anything less than integrated, comprehensive and engaging all of society.

WHO recommends new name for monkeypox disease

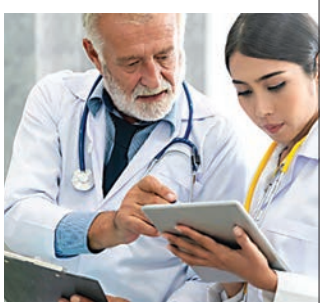
Following a series of consultations with global experts, the World Health Organisation (WHO) will begin using a new preferred term "mpox" as a synonym for monkeypox. Both names will be used simultaneously for one year while "monkeypox" is phased out. Assigning names to new and, very exceptionally, to existing diseases is the responsibility of WHO under the International Classification of Diseases (ICD) and the WHO Family of International Health Related Classifications through a consultative process which includes WHO Member States. Based on these consultations, and further discussions with WHO's Director-General Dr Tedros Adhanom Ghebreyesus, WHO recommends that the synonym mpox will be included in the ICD-10 online in the coming days. It will be a part of the official 2023 release of ICD-11, which is the current global standard for health data, clinical documentation and statistical aggregation.

India shows decline in malaria deaths: WHO

The World Health Organisation (WHO) has launched the 2022 edition of its annual World Malaria Report, emphasising the cumulative impacts the prolonged pandemic continued to weigh on the economies and health systems of malaria-endemic countries across the globe. As per the report, there were an estimated 247 million malaria cases recorded in 2021 in 84 malaria endemic countries. However, the rate of increase in malaria cases was slower than that observed between 2019 and 2020, when the spike in the rate was associated with the sudden disruptions to health service delivery brought on by the pandemic. The report states that the case incidence remained largely similar in 2020 and 2021. The WHO African Region continued to account for the largest burden globally, with four nations in the region responsible for over half of all malaria deaths. Over the past two decades, the WHO South-East Asia Region displayed a reducing trend in both the malaria cases and associated deaths – cases reduced by 76 per cent, from 22.8 million in 2000 to about 5.4 million in 2021.

UK awards £10M grant to improve health outcomes in India & Nepal

Experts from the Public Health Foundation of India (PHFI) and University of Leicester have been awarded a prestigious grant of nearly £10 million by the National Institute for Health and Care Research, UK to help improve the health outcomes and re-orient health systems to effectively address multiple long-term conditions (MLTCs) or multimorbidity in India and Nepal. The PHFI and University of Leicester will collaborate with the All India Institute of Medical Science (AIIMS), Jodhpur, Health Related Information Dissemination Amongst Youth (HRIDAY), Delhi, and Kathmandu Medical College (KMC), Kathmandu, thanks to the National Institute of Health and Care Research (NIHR) Global Health Research Centre for grant. Researchers will review existing evidence, generate new data as required and talk to people living with these conditions to identify the best care approach for people with multimorbidity in both countries. As part of the project, 17 places on master's degrees, 19 PhDs as well as 14 post-doctoral placements will be available in Leicester, Birmingham or Brunel, covering applied health research, implementation science, medical statistics, quality and safety in healthcare, health data science and diabetes.



Bangladesh to build rapid response capacities for influenza

Bangladesh has used lessons learnt during the COVID-19 pandemic to build emergency preparedness capacities by training rapid response teams (RRT) that can be deployed during any public health event due to influenza or any other respiratory pathogen. In total, more than 200 RRT members have been trained, including epidemiologists, clinicians, laboratory technicians, communication officers, anthropologists, logisticians, psychosocial support experts, data managers, & environmental experts among others. The trainings were developed and delivered by a group of epidemiologists & laboratory scientists from the Institute of Epidemiology Disease Control & Research (IEDCR) with direct field experiences in managing COVID-19, influenza & other respiratory pathogens. Key topics in the training package that were built on lessons learnt during the pandemic included: how to leverage the existing influenza surveillance system to integrate monitoring of other respiratory pathogens; how to establish an early warning & alert system and why it's important; how to use risk communications & community mobilisation in outbreak response; how to plan, prepare and carry out outbreak investigations; how to ensure biosafety & why it's important; & likely challenges & how to overcome them.

Japan contributes $1.3M to strengthen maternal healthcare in Afghanistan

The Government of Japan is contributing an additional $1.3 million to UNFPA's response to the escalating crisis in Afghanistan to boost life-saving reproductive health interventions for women, girls and youth. The new funding will support the continuation of services at 29 Family Health Houses in Helmand, strengthen the referral system for emergency maternal and newborn care, and support young people's access to reproductive health and

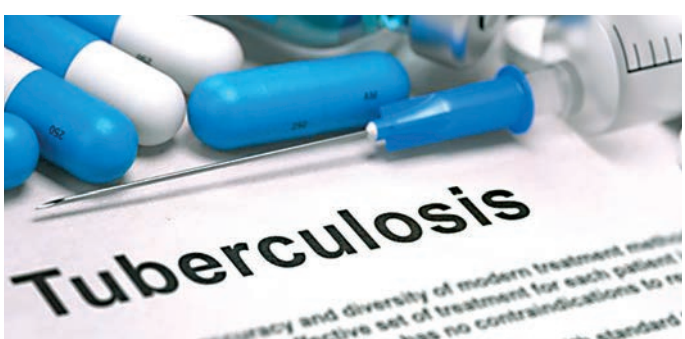
psychosocial support services and information. Japan's assistance will also support the provision of Mama and Baby Kits and medical equipment and supplies for mothers who have just delivered their babies. The new interventions aim to reach about half a million Afghans over a period of one year. The new funding brings to $2.2 million Japan's total contribution to the 2022 UNFPA Afghanistan Humanitarian Response, which requires $251 million to reach 9.28 million of the most vulnerable population in the country with humanitarian assistance.

Morocco explores medical manufacturing JV to serve African market

Moroccan Ministry of Investment, Convergence and Evaluation of Public Policies (MICEPP) as well as with the Moroccan Ministry of Industry and Commerce (MIC) have signed Memorandum of Understanding (MoU) agreements with US-based Mawi DNA Technologies (Mawi), a medical device company focusing on the development of innovative technologies for biological sample collection, to explore a joint venture with Mawi's local partner BIOTESSIA to establish a state-of-the-art manufacturing facility in Morocco to serve the African market. The new facility would help fulfill Africa's need for health sovereignty and accessibility, and Morocco was chosen as the site because it can also function as a launchpad to serve European markets. Mawi has developed iSWAB-Microbiome-EL, a product that is being extensively deployed worldwide for population-scale surveillance testing for infectious diseases, notably COVID-19 and its variants, due to its unique properties of viral inactivation, non-toxic formation, and enabling labs to skip the RNA extraction step, reducing costs and increasing testing throughput.

Viatris, MedAccess & TB Alliance agree to reduce price of MDR-TB drug by 34%

Viatris, a global healthcare company headquartered in the US, MedAccess, and TB Alliance have announced a new agreement to reduce the price of pretomanid, a drug used to treat multidrug-resistant (MDR) tuberculosis (TB), by 34 per cent. Pretomanid is part of two new treatment regimens with high efficacy and shorter treatment durations recently recommended by the World Health Organisation (WHO) as the preferred regimens for most drug-resistant tuberculosis patients. Pretomanid (Pa) is used in combination with bedaquiline (B), linezolid (L), and sometimes moxifloxacin (M) to form BPaL and BPaLM – six-month, all-oral treatment regimens, found to be effective at curing 89-91% MDR-TB patients. A volume guarantee to be provided by MedAccess to Viatris will see the ceiling price of pretomanid reduced to $240 Ex Works per six-month treatment course. It will help to bring both BPaL and BPaLM substantially closer to $500 per patient course.



Senegal joins CEPI in the fight against pandemics

The Republic of Senegal has joined the Coalition for Epidemic Preparedness Innovations (CEPI) in its mission to prevent future epidemics and pandemics. At a recently held ceremony in presence of President Macky Sall, an agreement was signed for a pledge of $1 million by the Republic of Senegal to support CEPI's pandemic preparedness plan, making Senegal the 35th country to join the Coalition. Senegal's investment in CEPI comes at a critical time as the global community continues to endure the repercussions of the COVID-19 pandemic and strives to ensure the world is better prepared to respond to future threats. Senegal's political and financial support to CEPI will bolster the organisation's efforts to reduce the risk posed by epidemics and pandemics by developing vaccines for known infectious disease threats (such as Lassa fever, Middle East Respiratory Syndrome and Nipah virus), and build on the scientific advances made during COVID-19 to prepare in advance for 'Disease X' – the threat of an unknown virus with pandemic potential.

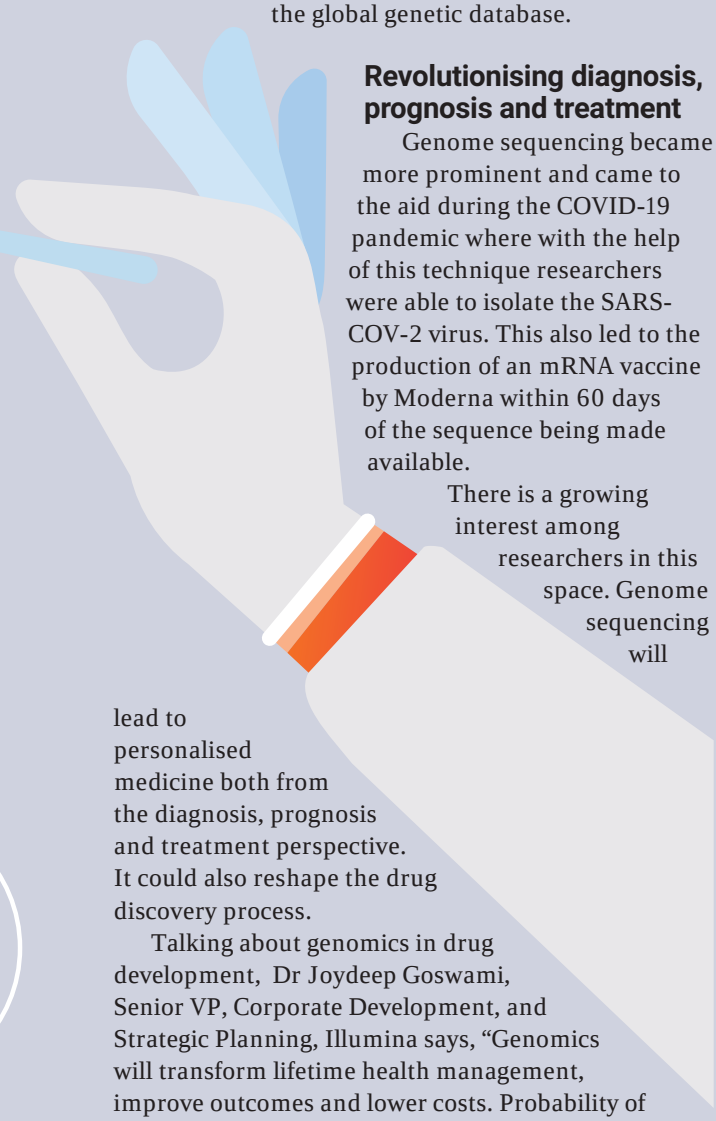
How genomics Can REVOLUTIONISE HEALTHCARE

A genomic revolution is taking place in India, where the value of genomic tests is being recognised in the prevention and diagnosis of diabetes, cardiovascular, cancer, carrier status, among others. Having the power to identify accurate preventive solutions to chart out treatment options for patients, predictive genomic testing is seen as the next major weapon in the arsenal of cutting-edge healthcare tech that can improve patient outcomes without relying on a curative approach. Let's learn more from industry leaders and experts in the field of leveraging genomics.

A recent study published by Mayo Clinic Proceedings indicates that nearly one in eight people who underwent predictive genomic testing found that they had a genetic risk for a health condition and may be able to manage it better with preventive care. Rising adoption of healthier lifestyles and increasing awareness of new healthcare programmes and advancements are expected to drive increasing demand for predictive genetic testing.

As per a Precedence Research analysis, the global gene therapy market was valued at $2.99 billion in 2021 and is expected to reach over $15.68 billion by 2030, which is poised to grow at a registered CAGR of 20.2 per cent from 2022 to 2030.

With a decrease in infectious diseases, there has been a rise in chronic illnesses. Treatments for chronic illnesses are focusing more on an individual's genetic makeup. Though India has 20 per cent of the world's global population, it only contributes to 0.2 per cent of the global genetic database.



Revolutionising diagnosis, prognosis and treatment

Genome sequencing became more prominent and came to the aid during the COVID-19 pandemic where with the help of this technique researchers were able to isolate the SARS-COV-2 virus. This also led to the production of an mRNA vaccine by Moderna within 60 days of the sequence being made available.

There is a growing interest among researchers in this space. Genome sequencing will lead to personalised medicine both from the diagnosis, prognosis and treatment perspective. It could also reshape the drug discovery process.

Talking about genomics in drug development, Dr Joydeep Goswami, Senior VP, Corporate Development, and Strategic Planning, Illumina says, "Genomics will transform lifetime health management, improve outcomes and lower costs. Probability of the drug molecule increases by 150 per cent when the drug target is supported by a genetically validated mechanism and cost per approval decreases by almost half, primarily through increased success rates. Genomics has the power to reshape drug discovery development."

Cost-effective genome sequencing in India

India has seen an increase in genome sequencing in recent years. Though lagging behind China and Korea in the Asia Pacific region, a lot of Indian startups and companies have started undertaking research in this new technique. Government bodies are also increasingly recognising the importance of these advancements and turning to genomic research to provide personalised healthcare for patients.

Earlier in 2022, Singapore and India entered into an agreement to collaborate on genome and bioinformatics research, while the Genome Institute of Singapore has embarked on mapping Asian genomes to investigate how illnesses can affect different groups, providing valuable insight for researchers. The success of genomics innovation relies on robust and agile digital infrastructure to support the entire research programme, from data processing and exchange to the ability to analyse and store increasing data volumes.

Sharing his views on need for genome sequencing, Murali Panchapagesa Muthuswamy, Chairman, Jananom; Chairman, Golden Jubilee Women's, Biotechnology Park and President, Council of Presidents of Association of Biotechnology Led Enterprise (ABLE), says, "We have to sequence a large number of genomes across ethnic groups among Indian populations and states from Northeast to South of India to get a decent representation. Credible bio markers and predictive and preventive models that are highly dependable will have to be developed. More efforts in this direction are needed and should be funded by government agencies since private bodies may not be able to afford 100k genome sequencing and million genome sequencing."

With support and initiatives from the government agencies many startups have come up in the last few years and have been offering many services using genomic sequencing.

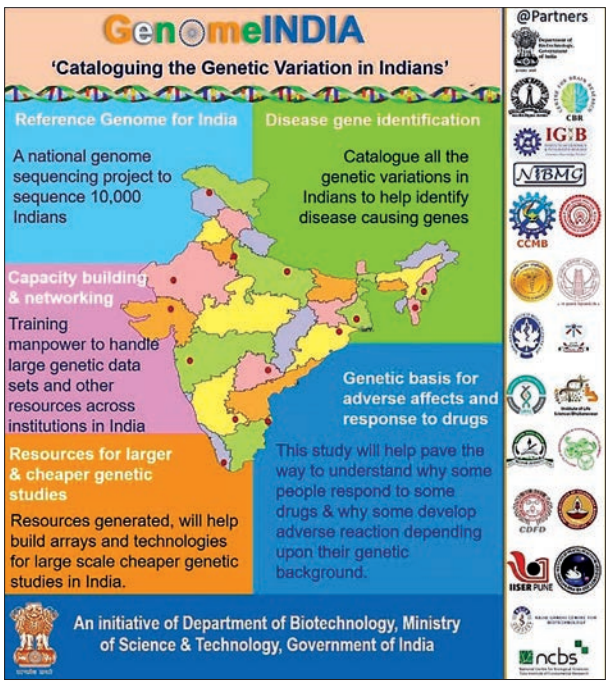
Bengaluru-based MedGenome has a state-of-the-art genetic lab where over 2,50,000 Exomes and Genomes are sequenced. It currently offers 1300 genetic tests and more than 9000 clinicians leverage the services. The company recently announced that it is offering Adaptive Biotechnologies' Next-Generation Sequencing (NGS)-based clonoSEQ Assay to assess minimal residual disease (MRD) in patients with multiple myeloma (MM), chronic lymphocytic leukaemia (CLL), and B-cell acute lymphoblastic leukaemia (B-ALL).

"Genomics will transform lifetime health management, improve outcomes and lower costs. Probability of the drug increases by 150 per cent when the drug target is supported by a genetically validated mechanism and cost per approval decreases by almost half, primarily through increased success rates. Genomics has the power to reshape drug discovery development."

- Dr Joydeep Goswami,
Senior VP, Corporate Development, and Strategic Planning, Illumina

"Technological advancements in next-generation sequencing & cheaper cost has led to an explosive growth of genomic data both from clinical & research studies. The affordability of these new technologies has led to significant growth in mainstream diagnostics in human cancer & rare disorder diagnostics."

- Ravi Gupta,
Vice President – Bioinformatics, MedGenome Labs



It has further unveiled VarMiner, an AI-enabled powerful variant interpretation software suite. The software will help clinicians, molecular geneticists, and genome analysts to interpret and report actionable variants. VarMiner supports various NGS Dx workflows like Germline Analysis where it covers all rare diseases, inherited cancers, Mitochondrial genome analysis, PGx and HLA analysis; Carrier/TRIO Analysis where it combines analysis of familial samples to detect De-novo and common inherited variants and reporting and somatic analysis, the comprehensive analysis of cancer genomes with support for liquid biopsy, haematology and solid tumour cases.

Hyderabad-based Mapmygenome India has opened its Genomics Experience Centre in Bengaluru. The new centre will enable customers to get access to distinctive services such as genetic tests, genetic counselling, blood tests, health screening tests, antibody tests and RT-PCR test for COVID-19.

The company has launched a cost-effective pharmacogenomics solution MedicaMap. MedicaMap gives a detailed report about the body's response based on genetic makeup. It covers over 165 drugs across 12 specialities like cardiology, oncology, psychiatry, and many more. MedicaMap generates user-friendly, thorough reports on the toxicity and efficacy of medicines. Mapmygenome has also created several educational channels including Genomics Gupshup, blogs and conducts several workshops and CMEs.

Oncology startup 4baseCare has announced a collaboration with AstraZeneca India, a global science-led biopharmaceutical company for advancing cancer care in India. Under this collaboration, the two organisations will support advanced-stage cancer patients with targeted therapy options using affordable genomic solutions.

In another instance, C2i Genomics, a cancer intelligence company based in the US, has announced a strategic partnership with Mumbai-based startup Karkinos Healthcare, to co-develop the MRD market in India. The partnership enables C2i Genomics to bring innovative cancer detection technology to drive R&D, future pharma partnerships and clinical use in India and supports the company's long-term goals to scale pharma R&D projects around the globe. C2i Genomics' SaaS solution utilises a cloud-based platform to perform cancer tumour burden monitoring on a global scale, utilising equipped labs and sequencing networks worldwide.

Bengaluru-based Clevergene Biocorp, a deep-tech genomics company has signed a Memorandum of Understanding with the Rajiv Gandhi Centre for Biotechnology (RGCB), to establish a state-of-the-art genomics centre at Thiruvananthapuram. The state-of-the-art genomics centre will house the latest DNA

Biotech startup partnerships for cell/gene therapy development in India
(As of Aug 16, 2022)

Date Announced	Deal type	Company	Investors	Investment Amount	Leading Pipeline Molecule	Indication
08-08-2022	Venture Financing (Series A Funding)	Eyestem	Biological E / Alkem / NATCO / Kemwell Biopharma	$6.4M	Eyecyte-RPE (Cell therapy —Preclinical)	Dry AMD
21-06-2022	Venture Financing (Series A Funding)	Immuneel Therapeutics	Eight Roads Ventures / True North / F-Prime Capital	$15M	IMN-003A (Gene-modified cell therapy — Phase II)	B-Cell Acute Lymphocytic Leukemia; B-Cell Non-Hodgkin Lymphoma
19-11-2021	Minority Acquisition	ImmunoACT	Laurus Labs	$7M	HCAR19 (Gene-modified cell therapy — Phase I)	B-Cell Acute Lymphocytic Leukemia

Source: GlobalData Pharma Intelligence Center

sequencing equipment like the Illumina NovaSeq and other allied infrastructure to support cutting-edge research in plant biotechnology, infections, cancer and other chronic diseases. The services of this high-throughput genomics centre will be open for use in research to other institutes and industries and will provide services like gene expression analysis, epigenetics and genome analysis including that of the COVID-19 virus.

Chennai-based LifeCell recently announced the addition of the 'NovaSeq 6000' sequencing system to their diagnostic technology platform. This development makes it one of the very few entities in India to have such exceptional capability which will enable more efficient and cost-effective genome sequencing. Following the successful implementation of Illumina's NovaSeq 6000 system, LifeCell will be able to leverage its technical expertise to improve scalability, support a varied range of applications, and simplify the workflow. Thus, this will provide high throughput speed and flexibility to carry out studies or testing which require processing a large amount of data, but in a faster and more economical way.

The company has also announced the launch of a revolutionary genetic test – Omega TB, in partnership with HaystackAnalytics, a genomics-based health-tech startup. The collaboration marks LifeCell's foray into the genetic testing industry for tuberculosis (TB) patients. The whole genome sequencing (WGS) test, designed by Haystack Analytics, aims to tackle the looming challenge of drug resistance. Apart from this, the test also helps in treating and preventing the spread of TB by providing a timely, affordable and accurate diagnosis.

Bengaluru-based Strand Life Sciences, a genomics-based research and diagnostics company, has launched Strand Genomic Wellness, a new line of genomic-based tests for preventive wellness. Launched at Bengaluru Tech Summit this year, the new offering can help individuals understand and manage their disease better. As the first offering of the programme, Strand has introduced the 'Genomic Health Insight' report to help individuals understand how their genomic variations might influence their risk for a broad range of diseases with 30-100 per cent heritability.

"We have to sequence a large number of genomes across ethnic groups among Indian populations and states from Northeast to South of India to get a decent representation. Credible bio markers along with predictive & preventive models that are highly dependable, will have to be developed."

- Murali Panchapagesa Muthuswamy,
Chairman, Jananom, and President, Council of Presidents, Association of Biotechnology Led Enterprise (ABLE)

"The main challenge in this industry now is that none of the equipment and reagents is made in India, and any NGS reagents made in India will reduce the pricing. One challenge that needs immediate attention is when you procure a new machine, and how to achieve RoIs quickly before the next model is released in the market.

- Ram Ramanujam,
Founder & CEO, Propinquity Genomics

"The future looks bright for genomics in India as the country has a large patient population. India needs to establish a supply chain for raw materials. The large patient population in established tertiary centres is likely to kick start any type of clinical therapy."

- Dr Roger Hajjar,
Head of Research & Development, Ring Therapeutics

"Consumer awareness of genomics is of course very low in India. There is also a lack of clarity on what genomics can or cannot help with. Genomics is a very high-complexity test with many nuances. Most tests take two or three days in the lab going through a multi-step process."

- Dr Ramesh Hariharan,
CEO and Co-Founder, Strand Life Sciences

Prominent global players in gene therapy market

- Dimension Therapeutics Inc.
- Taxus Cardium Pharmaceuticals Group Inc.
- Epeius Biotechnologies Corp.
- Shanghai Sunway Biotech Co. Ltd
- Applied Genetic Technologies Corporation
- Bristol-Myers Squibb Company
- American Gene Technologies
- BioMarin Pharmaceuticals Inc.
- Gensight Biologics S.A.
- Sibinono GeneTech Co. Ltd

Source: Precedence Research

CRISPR-Cas9 technology

Several approaches to genome editing have been developed. A well-known one is called CRISPR-Cas9. This new technology has generated a lot of excitement in the scientific community as it is faster, cheaper, more accurate, and more efficient than other genome editing methods. Researchers adapted this immune defence system to edit DNA.

"CRISPR-Cas has opened entirely new possibilities in biotechnology and biomedical gene therapies that have an impact on society and humanity. The field of CRISPR-Cas biology and engineering continues to grow at a rapid pace, with exciting new developments emerging almost weekly."

- Dr Emmanuelle Charpentier,
French microbiologist, Nobel Laureate in Chemistry 2020 and Scientific & Managing Director, Max Planck Unit, Science of Pathogens in Berlin

Researchers associated with the Tata Memorial Hospital in Mumbai and the Indian Institute of Technology, Bombay have developed India's first indigenously developed Chimeric Antigen Receptor (CAR) T-Cell therapy, a cutting-edge treatment for specific types of cancer patients. It has shown promising results. The therapy was tested on six paediatric patients of Acute Lymphocytic Leukaemia and 10 adults suffering from B-cell lymphoma as part of Phase I clinical trials by researchers. ImmunoACT along with Immuneel Therapeutics - backed by Biocon Biologics and top oncologist Dr Sidhartha Mukherjee - are two startups currently working to make CAR T-cell therapy available in India.

Recent launch of spatial transcriptomics and spatial proteomics have increased the confidence level of targeted therapies. Bengaluru-based TheraCUES Innovations has installed a technology platform from NanoString (GeoMx Digital Spatial Profiler (DSP) USA. Till a few years back, the cost of genome sequencing was huge. However, the costs have come down and are aiding researchers to take up more research activities.

Indigenisation, R&D and Governmental sops

Technological advancements in NGS and lower cheaper cost have led to an explosive growth of genomic data, both from clinical and research studies, according to Ravi Gupta, Vice President – Bioinformatics, MedGenome Labs. The affordability of these new technologies has led to significant growth in mainstream diagnostics in human cancer and rare disorder diagnostics. The last decade has also resulted in several large population-level sequencing including 1000 genome, Genome Asia, gnomAD, TopMed, Icelander, UKBiobank, Japanese and many others. COVID-19 genome sequencing is one of the best examples of how the new genomics tools have changed our lives. The genomics data is astronomical and needs a huge computing and storage power for quick turnaround."

Increasing economies of scale will reduce costs over time, but substantial R&D and indigenisation will

"Genomics has now become affordable and since germline mutations don't change over a lifetime, the value is very high. With access to genome sequencing, an average consumer can reduce the odds of disease and enhance longevity most cost-effectively."

- Anu Acharya,
CEO, Mapmygenome

"We need to bridge the gap between academia and industry. India has a unique advantage of skilled brain power. Bioinformatics training is now available free online and a readily available talent pool will further fuel the growth of the genomics industry in India."

- Dr Shibichakravarthy Kannan,
CEO, Oncophenomics

be required to get costs to the level needed for very large-scale democratisation.

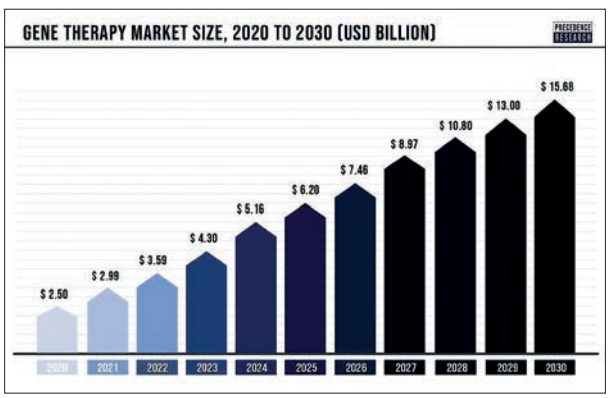
The pricing of gene therapies is a major issue in India. China and Korea have an advantage over India in volume processing. With the Indian government making the regulatory process much easier during the COVID-19 outbreak, a similar sop will be a win–win situation for the gene therapeutics market. Setting up labs and the availability of the right talent pools should be taken care of.

Anu Acharya, CEO, Mapmygenome, expounding on the cost-effectiveness of genome sequencing mentions, "The costs have come down dramatically from a few billion dollars to less than 100 dollars. That is more than what we saw in Moore's Law. Genomics has now become affordable and since germ-line mutations don't change over a lifetime, the value is very high. Streamlining new technologies, big data, and machine learning in genomic-based tests can have a massive economical impact on the healthcare system. With access to genome sequencing, an average consumer can reduce the odds of disease and enhance longevity most cost-effectively."

Says Gopalakrishna Ramaswamy, Founder and CEO, TheraCUES Innovations, "In a majority of developed countries, many genomic tests are paid by insurance/state health providers. However, in India, the patient has to pay. Though some insurance companies are bringing specific products based on disease, we need to have general acceptance for payment from insurance for tests, as it indirectly helps insurers in providing targeted therapies."

Learning curve hurdles

Awareness seems to be the primary challenge around genomic tests. Once consumers and clinicians become aware of the value of genomic testing, they become strong advocates for them. Most genomic tests are deemed difficult to understand by clinicians and efforts must be undertaken to make the process easier and make the entire process actionable. Another challenge is in the space of reimbursement.



Speaking about challenges Dr Ramesh Hariharan, CEO and Co-Founder, Strand Life Sciences, says, "Consumer awareness on genomics is, of course, very low in India. There is also a lack of clarity on what genomics can or cannot help with. Genomics is a very high-complexity test with many nuances. Most tests take two or three days in the lab going through a multi-step process. That results in a lot of data that has to be analysed and placed in the context of available literature. This is very different from a biochemistry test where a sample goes into a machine and the result comes out. There are many parameters and many sources of error. Inadequate attention to these parameters can yield garbage."

In a similar vein, Ram Ramanujam, Founder & CEO, Propinquity Genomics, says, "The main challenges in this industry now is that none of the equipment and reagents is made in India, and any NGS reagents made in India will reduce the pricing. One challenge that needs immediate attention is when you procure a new machine, and how to achieve RoIs in a quick time before the next model is released in the market. With evolving genomics enterprises in the world and emerging multi-scale biology and multi-omics with integrated biology, R&D must be incentivised in industry. As far as the R&D costs are concerned, sops from the Department of Biotechnology and Department of Scientific and Industrial Research (DSIR) will help new product development."

DBT initiatives

Department of Biotechnology, Ministry of Science and Technology, Government of India's R&D programme on human genetics, genome analysis and precision medicine seeks to address the burden of certain diseases by understanding the mutation spectrum of diseases having a genetic basis, developing cost-effective diagnostic methods for genetic diseases, implementing prenatal and newborn screening programmes, developing personalised medicines regimens and development of affordable therapies for these diseases.

The objective of the programme is to understand the role of genetic and genomic components in human health and disease, and the cross-talk of these components with environmental factors, lifestyle and cultural practices, by facilitating cutting-edge research involving individuals, families and populations. It further seeks to translate the understanding for the improvement of human health by promoting the development and dissemination of genomic methodologies and tools for prediction, diagnosis and prevention of disease, and for developing affordable therapeutic interventions. The programme leads to building capacity in human genetics and genomics by promoting training on technology platforms and methodologies for genome analysis in relation to human health and disease.

Priority Areas

1. Precision Health: Predictive, Preventive, Personalised and Participatory healthcare using genome, microbiome and exposome profiling, and improved diagnosis and therapeutics

2. Rare Genetic Disorders: Affordable Diagnostics and Therapeutics

3. Mutation spectrum of genetic and complex diseases in the Indian population

4. Genetic Epidemiology of Multifactorial Lifestyle Diseases

5. Translational Research: Developing basic genomics research discoveries to candidate health applications including affordable diagnostics, prophylactics and therapeutics

Major Programmes and Initiatives

1. DBT- Unique Methods of Management of Inherited Disorders (UMMID) initiative

Intending to address the burden of inherited disorders, the Department launched the DBT- Unique Methods of Management of Inherited Disorders (UMMID) initiative. In the first phase of the UMMID initiative, the Department has supported:

- NIDAN Kendras (National Inherited Disorders AdministratioN Kendras) for providing comprehensive clinical care including diagnosis, management, multidisciplinary care, counselling, prenatal testing at five government hospitals spread across four states of the country
- Training Centres for providing training to the clinicians working in government hospitals in Biochemical Genetics, Cytogenetics, Molecular Genetics, Clinical Genetics and Comprehensive clinical care
- Screening of 10,000 pregnant women and 5,000 neonates per year for diagnosis of inherited genetic diseases in each of the following seven aspirational districts: Mewat (Haryana); Yadgir (Karnataka); Haridwar (Uttarakhand); Washim & Nandurbar (Maharashtra); Ranchi (Jharkhand); and Shrawasti (Uttar Pradesh)

GenomeIndia: Cataloguing the Genetic Variation in Indians is a pan-India initiative focused on Whole Genome Sequencing of representative populations across India. The goal of the initiative is to carry out whole genome sequencing and subsequent data analysis of 10,000 individuals representing the country's diverse population. This would help build an exhaustive catalogue of genetic variations for the Indian population and aid in the designing of genome-wide association chips for the Indian population which will cost-effectively facilitate further large-scale genetic studies. Furthermore, it would also open new vistas for advancing personalised medicine regimens in the country paving the way for predicting health and disease outcomes and modulating treatment protocols based on the genome sequences. Besides, it would help in identifying the population groups which are more susceptible to various risk factors for certain diseases and would thus be instrumental in designing appropriate intervention strategies for such population groups.

Source: dbtindia.gov.in

The future

The future for genomics looks bright. In recent years, there has been steady progress in the advancement of newer sequencing technologies with never-before-seen features. Relying on able manpower, the right investments in research and timely government support, India is poised to set new benchmarks in the genomics space.

Talking about the growth of genomics in the country Dr Shibichakravarthy Kannan, CEO, Oncophenomics rightly points out, "You don't need a million dollars to start a genomics lab anymore. Anyone can start sequencing for as little as $10,000. The democratisation of such newer sequencing technologies will facilitate more research programmes and fast-track translation into commercially viable products. We need to bridge the gap between academia and industry to make this happen. India has a unique advantage of skilled brain power. Bioinformatics training is now available free online and a readily available talent pool will further fuel the growth of the genomics industry in India."

Speaking at the Bengaluru Tech Summit 2022 on opportunities for genomics research, Dr Roger Hajjar, Head of Research and Development, Ring Therapeutics, mentioned that the future looks bright for genomics in India as the country has a large patient population. India needs to establish a supply chain for raw materials. A large patient population in established tertiary centres is likely to kick-start any type of clinical therapy. The task ahead is enormous and there is a need to take stock of how much storage and processing speed is required. In this regard, more technological innovations in this space are expected to become game changers. BS

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"The penetration of genetic testing still remains abysmally low in a country like India"

The pandemic taught us important lessons, which goes beyond masks, sanitizers and lock down. It re-emphasised the need for molecular diagnostics with genomics playing a central role. With this view in mind, Agilent has recently opened a state-of-the-art diagnostics and genomics Centre of Excellence at Manesar with an investment of Rs 2.48 crore. The lab is housed within the ten acre Agilent campus and has been built over an area of 4500 sq ft. During an interaction with BioSpectrum India, Dr Samir Vyas, Country General Manager, Agilent Technologies shares about the new centre and the growth of the genomics market in India. ***Edited excerpts;***

« **Dr Samir Vyas,** Country General Manager, Agilent Technologies

What are the key diagnostic areas that Agilent will be exploring through this new centre?

As we continue our focus on fighting cancer, this lab will play a key role in training scientists and researchers on the latest technologies in cancer research and early cancer detection. Our diverse portfolio of products, including our state-of-the-art clinical interpretation software and our class-leading library prep chemistries, will support clinical researchers as they work to understand and advance genomics testing in India for cancer.

Will you be hiring new talent for the facility? What would be the skill set required?

The genomics lab will serve as a customer training and development centre. The scientists conducting customer training will be well versed in the latest genomics tools after spending a few years in the lab themselves unravelling complex biological processes.

Which key equipment/technologies are being installed at the centre?

The genomics lab is the first investment that Agilent has made in this space. The lab showcases Agilent's latest innovation and products for next generation sequencing (NGS). Agilent's NGS based precision oncology solutions help biopharma & clinical researchers accelerate cancer detection & diagnosis. Adding to this workflow, the Agilent Magnis NGS Prep System, a benchtop automated system with an on-board wizard, that allows assays to be set up in under five minutes, enabling molecular pathologists to profile samples for various genetic aberrations using a single, cost-effective, & efficient platform. The facility also houses Agilent's Microarray platform used for copy number analysis. Agilent arrays are extensively used in cytogenetic laboratories for prenatal & postnatal research. Over the next few years, we plan to invest further by adding another laboratory focused on Agilent's pathology solutions. Our customers would then have access & training in a broad range of cancer research and diagnostic tools, including fluorescence in situ hybridization (FISH), immunohistochemistry (IHC), cytogenetics, as well as other molecular pathology techniques and NGS-based solutions.

How do you foresee the growth of the genomics market in India?

Post COVID, the market for genomics is experiencing an upward trend which we expect to grow rapidly in the next couple of years.

What are the major plans in store at Agilent India in 2023?

Improving the human condition remains our mission. The penetration of genetic testing still remains abysmally low in a country like India with a population of 1.5 billion people. By opening this new Agilent genomics lab in India, we intend to increase awareness, in addition to training scientists on the latest innovations.

How much growth is expected in FY 22-23 for the India business?

India remains a very compelling market for Agilent. We are focused on it and firmly believe in the potential for continued high growth. We have therefore been making huge investments in India, not just in infrastructure but also in product registration and hiring exceptional employees. With these things in place, we expect to grow even more than the market growth rate. BS

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TOO MUCH OF A GOOD THING...

Thinking long term to ensure that huge amounts of vaccines are not wasted, manufacturers need to have a far-sightedness and not just go on a production spree.

During the first half of 2021 vaccine manufacturers were on a spree to launch their products anticipating that public apprehension will remain the same in 2022 as it was there in 2019 when COVID-19 struck. Three years down the line it is a different story altogether. Indian manufacturers Serum Institute of India (SII) and Bharat Biotech have now decided to stop manufacturing COVID-19 vaccines altogether due to hesitancy among the general public.

During the recently held annual general meeting of the Developing Countries Vaccine Manufacturers Network (DCVMN) in Pune, Adar Poonawala, CEO, SII, was quoted saying "To be honest, I am fed up with COVID vaccines."

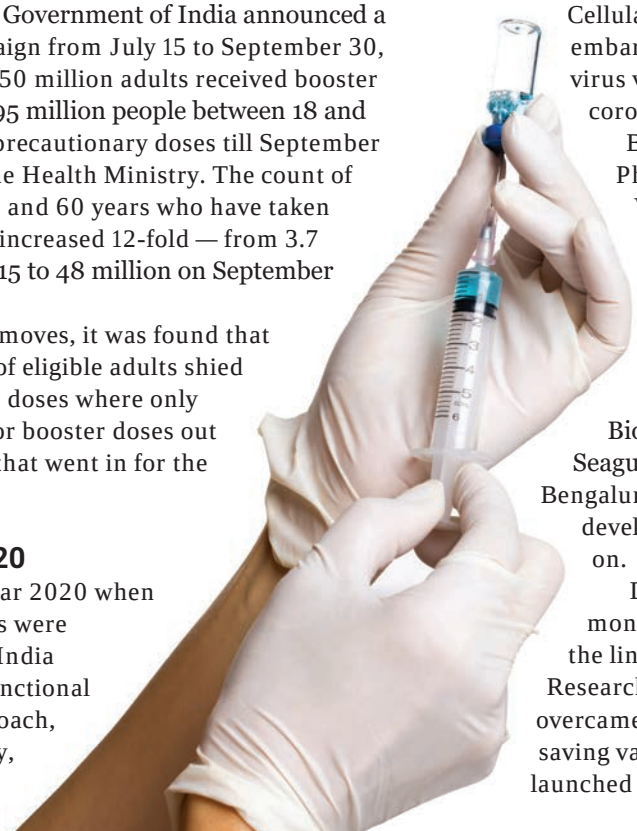
The COVID-19 vaccination drive began on January 16, 2020, with much fanfare and in 2022 it all fizzled out. The Government of India announced a free booster campaign from July 15 to September 30, 2022. More than 150 million adults received booster doses. More than 95 million people between 18 and 45 years received precautionary doses till September 29, according to the Health Ministry. The count of people between 45 and 60 years who have taken their boosters has increased 12-fold — from 3.7 million up to July 15 to 48 million on September 29.

Despite all the moves, it was found that large proportions of eligible adults shied away from booster doses where only 95 million opted for booster doses out of the 515 million that went in for the second dose.

Way back in 2020

It was in the year 2020 when 30 vaccine projects were initiated in India. India adopted a cross-functional collaborative approach, globally and locally, wherein currently 30 vaccine projects are afoot against COVID-19.

Apart from SII, Bharat Biotech, companies like Biological E., Panacea Biotech, Premas Biotech etc. took part in vaccine development activities. Vaccine manufacturers also teamed up with the academia and government to accelerate indigenous development of the COVID-19 vaccine. Indian Council of Medical Research (ICMR) and Hyderabad-based Bharat Biotech have partnered to develop a fully indigenous vaccine for COVID-19 using the virus strain isolated at ICMR's National Institute of Virology (NIV) in Pune. In the form of another industry-academic tie-up, the Indian Institute of Technology Guwahati (IIT-G) collaborated with Ahmedabad- based pharmaceutical company Hester Biosciences for vaccine development against COVID-19. Researchers from the Hyderabad-based Centre for Cellular and Molecular Biology (CCMB) embarked upon developing an inactivated virus vaccine for the dreaded novel coronavirus.



Besides IIT Kanpur; Gennova Pharmaceuticals, Pune; Auro Vaccines, Hyderabad; Christian Medical College, Vellore; IIT Delhi; IIT Kharagpur; Central Drug Research Institute, Lucknow; National Institute of Immunology, New Delhi; International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi; Seagull Biosolutions, Pune; Mynvax, Bengaluru etc. all took part in the vaccine development activities. And the list goes on.

Despite all the initiatives and a lot of money being invested, two years down the line, all the enthusiasm has been lost. Researchers burned the midnight oil, and overcame regulatory hurdles, to launch life saving vaccines. Whether the vaccines were launched or did they see the day of light

remains a mystery. And with no taker, it dealt a final blow to the initiatives.

A worrying trend

A lot of money was invested to manufacture the vaccines besides building capacity. Anticipating a huge demand then, the two major vaccine manufacturers are now on a move to eradicate the vaccines.

Bharat Biotech's Covaxin was sold for Rs 400 per dose to the government and Rs 1200 for private hospitals whereas AstraZeneca's Covishield was sold at Rs 300 per dose to government hospitals and Rs 600 per dose to private hospitals.

A whopping amount of 50 million doses of Covaxin produced by Bharat Biotech is set to expire in 2023 due to poor demand. The production has already stopped.

SII has already stopped the production of Covishield in December 2021. Poonawala also mentioned that the company will dump at least 100 million doses after the products expire.

The Government of India has decided against procuring more COVID vaccines as of now. The health ministry is surrendering Rs 4,237 crore of the 2022-23 budget allocation for inoculation purposes, to the finance ministry.

It may be noted that the same companies were also moving ahead to launch vaccines for children. There was a general perception of fear among the public with health experts mentioning that COVID may turn fatal for children. Here also, the vaccine manufacturers failed to make their mark. The entire concept of children getting vaccinated against COVID has lost somewhere with the government not commenting either on what is the future of the vaccines that were to be administered.

According to the COWIN website, Covovax, Corbevax and Covaxin are available for children.

Recently, there was news about Bharat Biotech producing Covaxin in a hurry due to political pressure. The allegations were, however, refuted both by the Government of India and also by the company.

And no one is talking about ZyCov-D, the world's first DNA –based vaccine that was developed by Cadila Healthcare in partnership with the Department of Biotechnology. Russia's Sputnik vaccine is priced at around Rs 1145 per dose.

The mRNA vaccine for COVID-19 was touted as a game changer. Pune-based Genova Biopharmaceuticals, a subsidiary of Emcure Pharmaceuticals, has announced that its mRNA vaccine – GEMCOVAC-19 - has received the Emergency Use Authorization (EUA) from the office of the Drugs Controller General of India (DCGI). Nothing much has happened on this front.

"With reduction in infection levels, there has been less interventions by the government.This has also led to idle capacity. It's time for the organisations not to dismantle the production facility but to look forward to R&D in the area of preventive medicine, develop newer vaccines and try maximum usage of the production capacities."

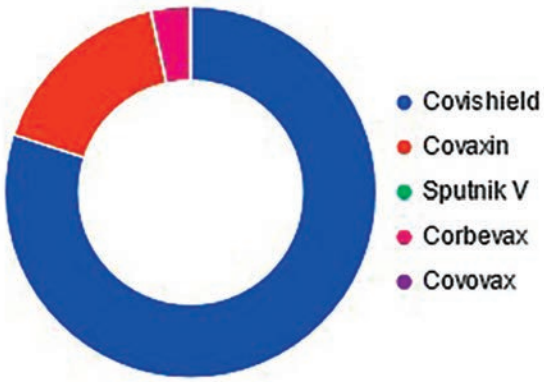
- Ashok Bhattacharya,
Global Health Care Consultant & Growth Enabler and Former Executive Director / Country Manager of Takeda Pharmaceuticals India

"Over-dependence on government for technical, financial, administrative and distribution (without scientific and serological follow up) led to inconsistency in the vaccine dosage (varying from one to three in short period of time) which further led to confusion and low confidence in public on the vaccine. This may be due to lack of data, follow-up services and to produce omni-potent vaccines."

- Dr (Prof) Ajay Gambhir,
Chairperson, Vaccine India and Ex National Technical Advisory Group on Immunisation (NTAGI) member

According to Dr (Prof) Ajay Gambhir, Chairperson, Vaccine India and Ex National Technical Advisory Group on Immunisation (NTAGI) member, "The industry got full support of the international agencies, governments, Drug Controller General of India (DCGI), NTAGI, World Bank, Bill & Melinda Gates Foundation (BMGF) and other agencies. However, their over-dependence on government for technical, financial, administrative and distribution (without scientific and serological follow up) led to inconsistency in the vaccine dosage (varying from one to three in short period of time)

Vaccination By Type



Covishield	:	174,46,92,627
Covaxin	:	36,14,38,038
Corvevax	:	73781,576
Sputnik	:	NA
Covovax	:	NA

Source: cowin.gov.in

Total registrations for COVID-19 vaccine

Age	Total registrations
12-14	4,20,74,546
15-17	6,30,82,409
18-44	63,30,92,213
Age 45+	37,01,95,298

As on Dec 2, 2022 Source: cowin.gov.in

which further led to confusion and low confidence in public on the vaccine; over-dependence on the vaccine to curb and control the pandemic, in which we failed to earn confidence of public and academia. This may be due to lack of data, follow-up services and to produce omni-potent vaccines .Also led to the failure to address the serious adverse events, both in youth and elderly and win public confidence."

He went on to add, "As pandemic weaned off, the role and scope of the vaccine also weaned off by the government due to less availability in poor countries and ineffectiveness in the rich countries also due to vaccine hesitancy in most of the countries. Few countries were producing and storing most of the vaccines, while the other countries did not even get the single dose for their healthcare workers and essential workers first vaccine. This led to global and regional disparity, questions of equity, equality along with availability and affordability came at the international level. So, the role of vaccines after the pandemic was over, became questionable as the industry was unsuccessful in delivering cheap vaccines to masses and poor countries."

Echoing similar views, Ashok Bhattacharya, Global Health Care Consultant & Growth Enabler and Former Executive Director / Country Manager of Takeda Pharmaceuticals India mentions, "We have witnessed that Serum Institute was under tremendous pressure to make Covishield available not only across the country but also in many other countries across the globe. Bharat Biotech had to respond to higher demands. High investments were made to increase the manufacturing capacity. The demand was significantly high and considering the magnitude of high infection rates coupled with government pressures for higher stock, the demand projections were more leading to higher production and inventory levels. With reduction in infection levels, there has been less interventions by the government.This has also led to idle capacity. It's time for the organisations not to dismantle the production facility but to look forward to R&D in the area of preventive medicine, develop newer vaccines and try maximum usage of the production capacities."

What next?

Vaccine manufacturers need to go back to the drawing board to take stock of what went wrong. Manufacturing millions of doses without anticipating what is in store for the future was a wrong decision by the manufacturers not only in India but also abroad.

The government also started the 'Har Ghar Dastak' campaign to propel the vaccination drive in November 2021. In May 2022, the second part of the campaign was launched to propel the vaccination drive in school, however, the public response was less.

We may come across many more diseases, more serious than COVID-19. Before launching any new vaccines, companies need to understand the future sentiments and anticipate the future outlook before joining the fray to launch a large number of vaccines.

The lesson learnt is that vaccine manufacturing plants should be decentralised and each country/ continent should have its own vaccine manufacturing process, depending upon the local needs. There must be sharing of data and technology amongst all countries- poor or rich during the pandemic. Adverse Event Following Immunization (AEFI) should be monitored, informed, counselled to win public confidence. Latest data must be shared with the public and made available to academia to contest any false claim or mis-information. Free vaccination drives by the government for a longer period may have made the matter less serious. BS

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Industry Expectations Riding Higher Than Ever

Certain reforms in Budget 2023-24 can be a game-changer for the life sciences sector. Like last year, the pharma, healthcare and med tech sector is expecting certain other reforms that can provide an impetus to the sector. Putting forth their recommendations, industry experts and associations are looking ahead to this year's budget.

The much anticipated Union Budget 2023-24 is knocking on the door and there are high aspirations from the finance ministry. The life sciences industry is hopeful that the government will consider certain recommendations being put forth by various healthcare and pharma companies and promote the growth of the sector.

Despite the Union Budget 2022-23 allocating Rs 86,200 crore to the Ministry of Health and Family Welfare, the industry is crying for more budgetary allocation from the finance ministry. However, certain sections within the sector were critical of the allocations made across the sector during the last year's budget.

More support from government

India is known as the 'pharmacy of the world' and the right investments in R&D will help in propelling the sector forward. Indian pharma manufacturers were able to provide life-saving medicines at affordable prices to countries during the COVID-19 outbreak.

Dr Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance (IPA), urges, "The budget should outline supportive policies, simplified regulations, and simple goods and services tax (GST) norms to aid in the development of the pharmaceutical industry. Measures to facilitate the ease of doing business will increase investment and contribute to the industry's long-term growth."

He goes on to add that following the 'Vasudhaiva Kutumbakam' principle, the industry is poised to shift from Make in India to Discover and Make in India.

The government should take the growth story of the Indian pharmaceutical industry to an all-new high. This calls for building upon the manufacturing and research capabilities of the pharma sector with a focus on self-sufficiency in active pharmaceutical ingredients (APIs) and value creation through cutting-edge R&D.

Speaking in a similar vein, Saransh Chaudhary, President, Global Critical Care, Venus Remedies and CEO, Venus Medicine Research Centre (VMRC) says, "The government should announce incentives and grants for cost-intensive research, particularly in critical care segments. All the material procured by pharma firms for R&D purposes should be exempted from both GST and customs duty. Strategic measures should be announced to capitalise on emerging opportunities for global value creation. Offering incentives to domestic API manufacturers on one hand and bringing about a reduction in GST and import duty on APIs on the other is the need of the hour. "

Similar to the pharma sector, the healthcare sector also needs some budgetary push to sustain itself in the long run. Experts also point out the need to focus on affordable healthcare with the help of digital technologies.

Emphasising training, skills and capacity building

The healthcare sector, particularly the hospital, doctors and nurses were overburdened during the COVID-19 pandemic. Considering the pandemic which wreaked havoc and now with Omicron BF.7 spreading across certain parts of the world, the budget should focus more on prevention. Emphasis should be made on providing formal training to doctors and enhancing skills to boost the sector. The budget also needs to pay attention to building capacity for intensive care, upgrading the infrastructure at primary healthcare etc.

Dr Alok Khullar, CEO, Gleneagles Global Health City, Chennai explains, "Healthcare sector needs to be considered as a priority and an essential service. Various subsidies and benefits should be given on land rates and other necessities such as electricity, as it will pave for accessible and affordable healthcare with better infrastructure and high-quality treatment improving access to care and better patient outcomes."

Apollo Hospitals has classified its expectations

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"Healthcare sector needs to be considered as a priority and an essential service. Various subsidies and benefits should be given on land rates and other necessities such as electricity, as it will pave for accessible and affordable healthcare with better infrastructure and high-quality treatment improving access to care and better patient outcomes"
- Dr Alok Khullar,
CEO, Gleneagles Global Health City, Chennai

"Stable policy frameworks and incentives to help the healthcare sector remain viable-investment via FDI, expanding reach, investing in technology and innovation, reinforcing patient safety and adding to the skilled professionals of India."
- Dr Shravan Subramanyam,
President, NATHEALTH

into three categories, all of which addressed two key concerns. The three categories are incentivising health-seeking behaviour, promotion of healthcare infrastructure and capacity building and GST. Apollo wants mandatory health insurance introduced to ensure universal healthcare access, enhancement of health insurance premium exemption, increase in tax exemption on preventive health check-ups and expansion of the Pradhan Mantri National Dialysis Programme to all the districts.

Dr Sangita Reddy, Joint MD, Apollo opines that there should be no capital gains tax incidence at the time of setting up a Real Estate Investment Trust (REIT)/Business Trust as well for individual investors on the income distribution by the REIT/ Business Trust. She mentions, "We are in favour of the provision of 150 per cent depreciation on new investment and infrastructure and permit depreciation charges over an accelerated time frame. An import duty relief for life-saving equipment; and a three-year extension for claiming Export Promotion Capital Goods (EPCG) credits given that the COVID years impacted international travel is recommended."

While exhorting about the GST, Apollo recommends that the government may levy 5 per cent GST on the composite service and allow input credit. It also wants a GST waiver for supplies of goods and services between the head office and branch offices.

Highlighting the need of enhancing the role of the private sector in increasing the capacities of healthcare professionals to address the shortage

of healthcare professionals NATHEALTH has emphasised GST reforms, transitioning to a new Income tax regime and health financing.

Dr Shravan Subramanyam, President, NATHEALTH, shares, "It is imperative to build infrastructure capabilities so that people have greater access to quality and critical healthcare services. Viability gap funding by the government is essential to set up hospitals in Tier-II and Tier-II cities, encouraging increased investment in healthcare infrastructure. Uniform adoption of the Ayushman Bharat Digital Mission is another imperative which calls for clearly defined delivery models for innovative modules developed by private players. We are also witnessing a significant impact on the cost of running the business which will affect the sustainability of MedTech organisations. If all payment backlogs both for providers and suppliers under insurance and public procurement are cleared, it would significantly improve the availability of healthcare infrastructure. As we prepare for the post-pandemic era, stable policy frameworks and incentives to help the healthcare sector remain viable- investment via Foreign Direct Investment (FDI), expanding reach, investing in technology and innovation, reinforcing patient safety and adding to the skilled professionals of India."

Reducing import dependence

The med tech industry has been vocal about strengthening the finances of medical device manufacturers. The sector believes in creating

"We are in favour of the provision of 150 per cent depreciation on new investment & infrastructure & permit depreciation charges over an accelerated time frame. An import duty relief for life-saving equipment; & a three-year extension for claiming EPCG credits given that the COVID years impacted international travel is recommended."
- Dr Sangita Reddy,
Joint MD, Apollo

"If the government implements even 70 per cent of the recommendations recently made by the Parliamentary Committee on Health, we can see a reversal on the import dependence and growth of the domestic industry which will bring in affordable wider access to medical devices leading to better healthcare delivery."
- Rajiv Nath,
Forum Coordinator, Association of Indian Medical Device Industry

"A separate budget of $1-5 million needs to be allocated for the promotion, advertising and marketing of the Indian medical device industry globally. This will help strengthen 'brand India' and get greater acceptability of India-made medical devices in overseas markets."
- Pavan Choudary,
Chairman and Director General, Medical Technology Association of India ((MTaI)

"PPP model can be leveraged to scale up diagnostics infrastructure in the form of centres of excellence for infectious disease or NCD management in tier II & III cities."
- Narendra Varde,
MD, Roche Diagnostics India & Neighbouring Markets

Key Budget Expectations

- Supportive policies, simplified regulations, and simple GST norms
- Formal training to doctors and enhancing skills
- Various subsidies and benefits should be given on land rates
- Promotion of healthcare infrastructure and capacity building
- Universal healthcare access
- Enhancement of health insurance premium exemption
- Increase in tax exemption
- Import duty relief for life saving equipment
- Three-year extension for claiming Export Promotion Capital Goods credits
- 5 per cent GST on composite service and allow input credit
- Exemption of free medical device samples from TDS
- Standardised regulations governing the accreditation of labs

a suitable environment for R&D by redesigning financial models.

The Association of Indian Medical Device Industry in its pre-budget recommendations wants the government to end the 80-85 per cent import dependence and an ever-increasing import bill of over Rs 63,200 crore. It urges the government to consider shifting from an 8 Digit HS Code to a 10 Digit HS Code as done by the US and Europe to give more granular data for enabling better analysis and policy making.

It further goes on to add that the government should protect the manufacturing base in India by increasing basic custom duty on the import of medical devices to at least 10 to 15 per cent from the current 0-7.5 per cent duty though WTO Bound rate is mostly 40 per cent; the GST needs to be a flat 12 per cent for all medical devices and trade margin monitoring.

Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry (AiMeD) says, "If the government implements even 70 per cent of the recommendations recently made by the Parliamentary Committee on Health, we can see a reversal on the import dependence and growth of the domestic industry which will bring in affordable wider access to medical devices leading to better healthcare delivery."

For a country that relies heavily on imports to meet its healthcare needs, an additional tax threatens to not only dent the access to advanced medical equipment coming to India but will also leave patients bearing the brunt of these additional costs adding to the inflationary spiral.

As Pavan Choudary, Chairman and Director General, Medical Technology Association of India ((MTal) points out, "A separate budget of $1-5 million needs to be allocated for the promotion, advertising and marketing of the Indian medical device industry globally. This will help strengthen 'brand India' and get greater acceptability of India-made medical devices in overseas markets which will further the government's vision of 'Make in India for the world'. It will also help in the promotion of India as a destination for manufacturing and R&D in MedTech." Lastly, Choudary recommends that the free medical device samples must be exempt from TDS.

Burden of high-cost diagnostics

Similar to the med tech sector, driving down the cost of diagnostics should be crucial. Expanding the number of diagnostic facilities will eventually raise the standards. Says Narendra Varde, MD, Roche Diagnostics India & Neighbouring Markets, "Free package of basic diagnostics in public healthcare facilities would not only lessen the burden on the poor and the vulnerable but also make them available to middle-class sections who are struggling financially because of the high cost of healthcare diagnostics. The PPP model can be leveraged to scale up diagnostics infrastructure in the form of centres of excellence for infectious disease or NCD management in tier II & III cities." He also opines on the need for greater and standardised regulations governing the accreditation of labs.

Expecting a proactive budget

Every year, the life sciences sector comes up with certain recommendations, however, which of these comes under the ministry's notice remains a big question. Considering all the above recommendations, it can be understood that the life sciences sector is looking ahead for certain big reforms. A lot of discussions are the need of the hour where the finance ministry needs to sit with the sector and look in depth about what needs to be done to overcome the situation where India can hold its head high in healthcare with its large population base.

With COVID-19 again in news across China and US, Japan is concerned, India needs to take decisive steps to ensure that a fruitful budget presents a win-win situation for both the government and industry at large. A proactive budget focusing on healthcare is an all around industry consensus. BS

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"India's regulatory system is developing well and is going to be at par with the best in the world"

With an aim to provide superior technological medical facilities, Fujifilm India has launched various campaigns to educate and spread awareness of chronic illnesses. The company has been able to install more than 50,000 medical devices across the country. Besides, it has a focus to expand strategic key products in the medical division, photo imaging, image capturing and graphic arts division. Chander Shekhar Sibal, Executive Vice President & Head of Medical Division at Fujifilm India reveals more about the company's India plans in an interaction with BioSpectrum India. ***Edited excerpts;***

« **Chander Shekhar Sibal,** Executive Vice President & Head of Medical Division, Fujifilm India

Recently you have expanded your product portfolios in pulmonology and cancer care segments etc. How optimistic are you when it comes to launching products in the Indian market? How much revenue could be gathered from these new products?

Fujifilm India has always been at the forefront of healthcare innovation. We have recently launched a new slim video bronchoscope called EB-710P. With the launch of the new bronchoscope EB-710P, we are expanding our pulmonology portfolio. The aim is to provide superior technological medical facilities that can help save lives and encourage patients to become more engaged in their care. In line with our vision to provide the best-in-class technology, we aim to never stop innovating and working towards making India a healthier place to live in.

We have equipment like Full Field Digital Mammography, Computed Tomography (CT) scanners, MRI and Ultrasound Systems for the early detection of cancers.

Fujifilm has recently opened health screening centres in India. What are the long-term goals for this development?

Fujifilm's commitment is aimed at spreading awareness about the importance of regular medical tests to eliminate the chance of chronic health ailments and highlighting the significance of timely health checkups for people of all ages to prevent diagnostic delays. We have been launching campaigns to educate and spread awareness on the same and will be moving forward along the same lines.

On the same lines, we have launched two NURA health screening centres in Gurugram and Bengaluru in partnership with Dr Kutty's Healthcare to focus on cancer and lifestyle disease screening in India. We are aiming to launch another centre in Mumbai soon. With the addition, we will be offering screening in a total of three NURA sites.

We have also collaborated with leading hospitals such as Paras Healthcare and Manipal Hospitals, amongst others. Through the partnerships, Fujifilm supplies a wide range of high-end and sophisticated medical devices including AI-based machines to the network of hospitals.

We have successfully installed more than 50,000 medical devices across India, ranging from top metropolitan cities to remote areas such as Leh, Ladakh, Northeast India, and across Jharkhand and Bihar, amongst other regions.

Since 2008, Fujifilm has striven to bring the best of its medical imaging and solutions systems to India for the betterment of the country's health. We are available with our CR, DR, and Imagers in the smallest of small villages of India for digitising the X-Rays. With this milestone, we hope to continue the legacy of innovation and never stop innovating and providing the best-in-class products and services.

Are you planning to hire more talent in India? Please elaborate.

The sentiment in the healthcare industry is very positive and we are working to develop the availability of high-quality health infrastructure products and solutions across the country. In the process, we are gradually upscaling our manpower as well as hiring people in service, application and product sales so that we can expand our geographic horizons and exceed customer expectations in the fields of service and application.

How is Fujifilm assisting in the TB elimination target of 2025? What strategies have been chalked out?

In line with the government's call to achieve the Sustainable Development Goal (SDG) targets related to TB by 2025, five years ahead of global targets, Fujifilm India aims to raise awareness on TB.

Fujifilm is a diamond member of the Corporate TB Pledge (CTP), which is being implemented by the International Union Against TB and Lung Disease (The Union) as part of USAID supported iDEFEAT TB project. The Corporate TB Pledge initiative was jointly launched in 2019 by the Government of India and USAID to galvanise corporate support in the fight against TB. More than 230 corporate partners have joined the Corporate TB Pledge initiative.

We have launched the "Never Stop: Screening to Reduce Diagnostic Delays" campaign aimed to create awareness of regular screening for tuberculosis. With the campaign, we ran a mobile screening van across 27 cities in North India and screened over 721,000 people at the mobile van and shared a total of 8,104 X-ray reports in six months.

We have also launched the second phase of the campaign aiming to increase awareness on TB as a curable disease and promote screening and early diagnosis among tea sector workers, difficult-to-reach people residing in rural and urban areas including the tribal population in selected districts of Gujarat, Kerala and Assam.

Under the campaign, Fujifilm India will support three mobile handheld X-ray machines and the implementation of the project in community settings. With the campaign, we aim to reach more than 5 million people and screen around 30,000 of them by using handheld X-ray machines. The project will also facilitate TB testing of identified presumptive cases. In association with International Union Against TB and Lung Disease (The Union), the project aims to demonstrate a model for promoting early diagnosis of TB by utilising newer solutions in community settings. Fujifilm will also offer door-to-door awareness and provide mobile digital X-ray services along with Qure.ai's computer-aided radiology software application designed with deep learning for the intervention.

How challenging is the regulatory market in India for Fujifilm? What are your expectations from the Indian government?

The regulatory system in India is at a nascent stage compared to global standards, however, it has made giant leaps in the recent past. As far as Fujifilm India is concerned, we are not facing any challenges as of now and our mission is to work together with the regulatory bodies for a robust ecosystem. India's regulatory system is developing well and with The Atomic Energy Regulatory Board (AERB) and Central Drugs Standard Control Organization (CDSCO), it is going to be at par with the best in the world. Our expectation from

the government is to make the regulations at par with global standards so that a high-quality healthcare ecosystem can be created in India.

What more plans are in store for the Indian market for the next five years, in terms of investment and product launches?

India is witnessing a fast-economic growth. Under these circumstances, we are focusing on expanding strategic key products in the medical division, photo imaging, image capturing and graphic arts division.

Indian Medical Devices Industry is Asia's fourth-largest market and one of the top 20 in the world. According to a forecast by the Indian Brand Equity Foundation (IBEF), India's medical device market will expand at a 35.4 per cent compound annual growth rate (CAGR), with a market value of $11 billion in 2020 and $50 billion by 2025. Imports, on the other hand, currently supply the majority of the medical device market in the country, accounting for 80 per cent of total sales.

We are witnessing a promising future for ourselves in the Indian market. Each category that Fujifilm has a presence in is driven by a long-term commitment towards our customers and partners. Our growth drivers are coming from new-age customers who are well aware of what they want and are quality conscious.

What is the future of the technology-driven medical devices market in India? Please highlight the challenges and investments associated with it.

The Indian healthcare sector will experience rapid growth in the coming years due to increased government initiatives and public awareness of health issues. India is well on its way to becoming a major global player in the medical sector, as it has learnt from its challenges and is preparing for everything that may come. People are getting their regular annual health checkups and have become more aware and alert regarding minor health issues as well, especially after covid.

Therefore, it is inevitable that the industry for medical devices used in the examination/diagnosis of all minor and major health issues will also grow manifolds. In fact, in the last few years, the market for medical devices has expanded significantly and is essential to every stage of the healthcare continuum. Despite its important role in increasing healthcare access and affordability, several ecosystem constraints have resulted in a high dependence on it.

Fujifilm India has always been committed to bringing innovations to the healthcare sector. To deliver better healthcare services, we have begun integrating cutting-edge technologies like AI into our products. For instance, we have created specialised AI platforms like REILI to address the needs of patients right now. Through this, specialists can use technology like image processing and artificial intelligence to provide their patients with more accurate diagnoses. We have tied up with Qure.ai for proving TB Screening through a combination of X-Air and AI for early detection of tuberculosis.

Recently, we have launched a new software version of 'CAD EYE', a function that supports real-time detection of colonic polyps during colonoscopy utilising Artificial Intelligence (AI) technology. This updated and advanced function will be essential for colon polyp detection and characterisation, which will be achieved by utilising a type of AI called deep learning.

We have also made significant contributions to the field of radiography and mammography along with promoting the early detection of breast cancer. We are dedicated to providing our customers with cutting-edge solutions that are the utmost easy and convenient, assisting them with early/timely diagnosis and treatment. BS

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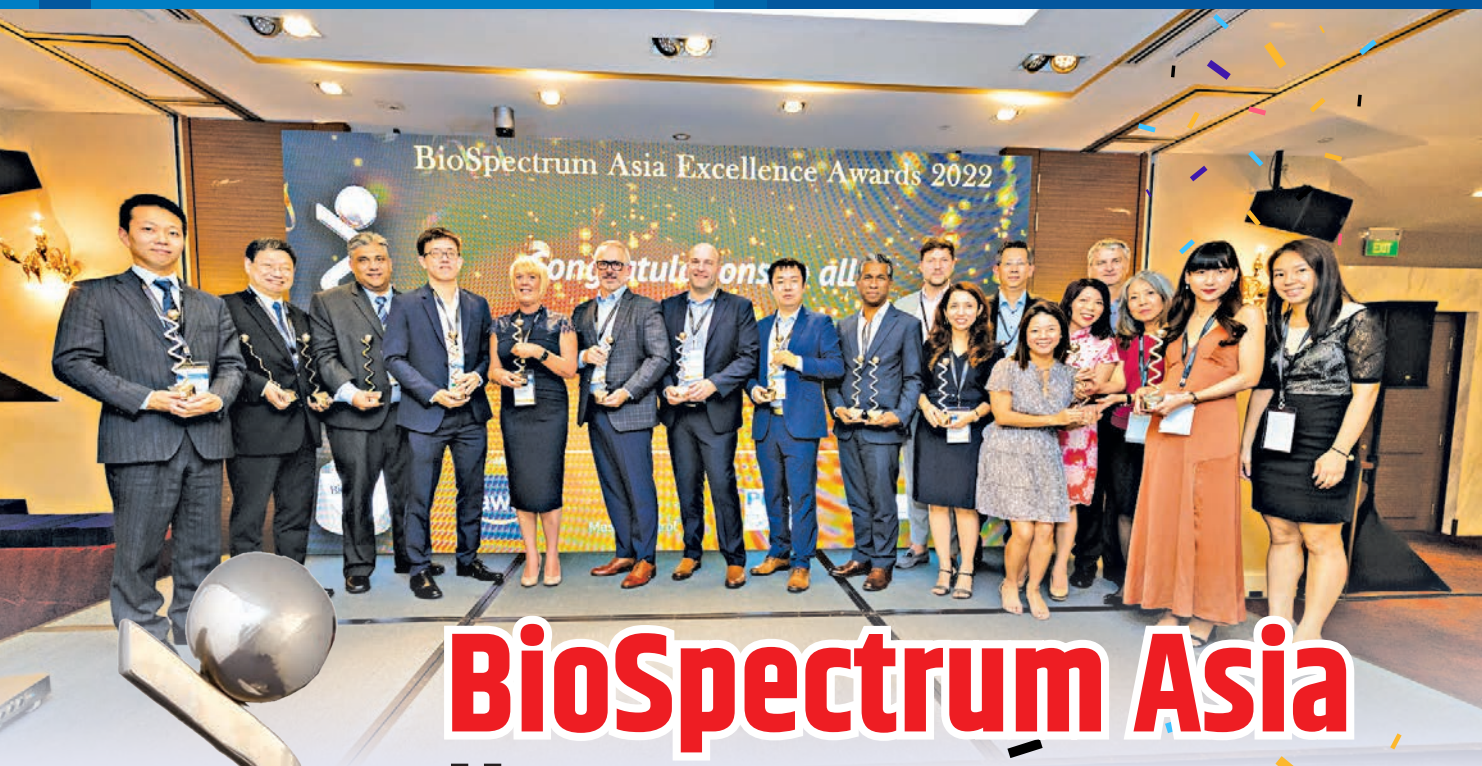

BioSpectrum Asia Honours Industry Stalwarts

Asia has, indeed, become the new hub for potential growth and innovation, with no signs of losing steam. To appreciate the Asian companies and individuals for their commendable performance and achievements during Calendar Year (CY) 2021, BioSpectrum Asia Excellence Awards 2022 ceremony was held at Lavender Ball Room, Hotel Fort Canning in Singapore on December 2, 2022.

These awards are an extension to observe and highlight the winners in the long battle to tackle the world's emerging health problems and find solutions. Since 2020 and 2021 were majorly affected by COVID-19, we saw the industry players relentlessly working towards developing novel solutions in the form of diagnostic tests, vaccines, monoclonal antibodies, drugs etc. to fight the emergency.

BioSpectrum Asia is playing the role of picking tomorrow's winners. Through these awards, we are nudging today's entrepreneurs to achieve greater glory, while honouring yesterday's key players who have laid the foundation for success.

The evening began with some networking amongst the industry experts which spanned across verticals such as pharma, medical technology, API development, bio therapeutics, venture capitalists etc. The networking session was followed by the awards ceremony, which began with a welcome note from Ravindra Boratkar, Publisher and Managing Editor, BioSpectrum Asia.

The BioSpectrum Asia Excellence Awards 2022 was divided into two segments- Jury and Editor's choice. The former segment had six categories associated with it- Startup of the year; Product of the year; Woman Entrepreneur of the year; Entrepreneur of the year; and Lifetime achievement award.

BioSpectrum Asia is an integrated B2B media platform for the life sciences industry in the Asia Pacific region to engage its readers from pharma, biotech, medtech industry segments through its products and services i.e. the monthly magazine, daily newsletters, and the website. Besides its sharp reportage focus on the APAC region, it is also a one stop information hub for the life sciences industry for its readers from the US and Europe as well. At present remarkable developments and ground breaking research are being done by the academia and industry within the APAC region. For instance, the world's first atlas of air-borne microbes for public health research has been developed by researchers from the Hong Kong Polytechnic University, or Japan has commercialised world's first test for early stage pancreatic cancer, or Australia has announced the world-first brain cancer clinical trials. And not to forget that Singapore has emerged as the global manufacturing hub for the life sciences industry. We saw companies such as GSK, Merck, Chugai, Smith & Nephew investing into newer facilities in the country this year. Asia is indeed playing a big role in taking the global life sciences industry to the next level and BioSpectrum Asia is at the forefront in identifying these achievements"

- **Ravindra Boratkar,** Publisher and Managing Editor, BioSpectrum Asia.

The latter segment focused on these categories- Top Company in Bioprocessing; Top Company in Manufacturing Technology and Equipment; Top Company in API development; Top company for Analysis, Testing, and Quality Control; Top Company in Packaging & Drug Delivery Services; Top Company in Supply Chain, Logistics, and Distribution; Top Company in Clinical Research-based Development; Best Vaccine efforts of the year and Special Recognition in Cell Therapy for the year 2022.

While the Jury awards had well-defined criteria for which BioSpectrum's editorial team brought together a six-member international jury to evaluate the shortlisted nominees, the Editor's Choice award winners were selected by the magazine's editorial team to turn the spotlight onto companies we believe will lead the way in the near future.

BioSpectrum Asia Excellence Awards 2022 jury comprised of Prof Patrick Tan, Executive Director, Genome Institute of Singapore; Prof Gagandeep Kang, Microbiology- Wellcome Trust Research Laboratory, Division of Gastrointestinal Sciences, Christian Medical College, Vellore, India; Clare Blain, Chief Executive Officer, Life Sciences Queensland Limited, Australia; Dario Heymann, PhD, Chief Research Officer, Galen Growth, Singapore; Dr Satya Dash, Founding & Former Head Strategy; Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology (DBT), Government of India and Founding CEO- BITS BioCyTiH Foundation, BITS Pilani, India; and Xinyi Tow, Director, Hello Tomorrow Asia Pacific, Singapore.

Sharing his experience as a jury member during the virtual meetings, Prof Patrick Tan, Executive Director, Genome Institute of Singapore said, "It has been a great privilege to serve as a jury member for the BioSpectrum Asia Excellence Awards. It was fascinating to see the tremendous diversity of the applicants, all of whom are committed to improving health for Asian populations."

In sync with this observation, Prof Gagandeep Kang, Microbiology- Wellcome Trust Research Laboratory, Division of Gastrointestinal Sciences, Christian Medical College, Vellore said, "Recognising excellence is critical for assessment of performance and potential of the biotechnology industry. It was a pleasure and a learning experience to serve on the jury for the Biospectrum Asia Excellence Awards, with transparent evaluation criteria and a panel with expertise from multiple domains. Since applications were across a range of categories and countries, it enabled an understanding of ecosystem level strengths and facilitators."

While Prof Patrick Tan and Prof Gagandeep Kang could not make it to the event, Dario Heymann, PhD, Chief Research Officer, Galen Growth and Xinyi Tow, Director, Hello Tomorrow Asia Pacific, made their presence felt by interacting with all the industry players at the event.

"The awards session is a literal revamp of what we have seen in the last few years happening in the life sciences ecosystem, especially seeing the APAC region expanding across the life sciences industry, catching up with the rest of the globe particularly with North

BioSpectrum Asia Excellence Awards 2022

Jury Award Winners for 2022

- Startup of the Year- Lunit Inc (South Korea)
- Startup of the Year - Special Jury Recognition - Hummingbird Bioscience (Singapore), Brain Navi Biotechnology (Taiwan), MiRXES (Singapore)
- Product of the Year -Allplex SARS-CoV-2 Assay by Seegene Inc (South Korea)
- Entrepreneur of the Year - Dr Alex Zhavoronkov, Founder and Chief Executive Officer, Insilico Medicine (Hong Kong)
- Woman Entrepreneur of the Year - Dr Parul Ganju, Co-Founder and Chief Executive Officer, Ahammune Biosciences (India)
- Lifetime Achievement - Prof Helen Marshall, Professor in Vaccinology in the Adelaide Medical School, and Deputy Director, Clinical and Translational Research for the Robinson Research Institute at University of Adelaide (Australia)

Jury members

- Prof Gagandeep Kang, Microbiology- Wellcome Trust Research Laboratory, Division of Gastrointestinal Sciences, Christian Medical College, Vellore, India
- Prof Patrick Tan, Executive Director, Genome Institute of Singapore
- Clare Blain, Chief Executive Officer, Life Sciences Queensland Limited, Australia
- Dario Heymann, PhD, Chief Research Officer, Galen Growth, Singapore
- Dr Satya Dash, Founding & Former Head Strategy; Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology (DBT), Government of India and Founding CEO- BITS BioCyTiH Foundation, BITS Pilani, India
- Xinyi Tow, Director, Hello Tomorrow Asia Pacific, Singapore

Editor's Choice Award Winners

1. Top Company in Bioprocessing for the Year 2022- Cytiva
2. Top Company in API Development for the Year 2022- Genovior Biotech Corporation
3. Top Company in Analysis, Testing, and Quality Control for the Year 2022- Veolia Water Technologies & Solutions - Sievers Instruments
4. Top Company in Packaging & Drug Delivery Services for the Year 2022- Catalent Inc.
5. Top Company in Supply Chain, Logistics, and Distribution for the Year 2022- DKSH
6. Top Company in Clinical Research-Based Development for the Year 2022- Agilex Biolabs
7. Best Vaccine Efforts of the Year 2022- AstraZeneca
8. Special Recognition in Cell Therapy for the Year 2022- I Peace, Inc.
9. Top Company in Manufacturing Technology and Equipment for the Year 2022- Cytiva

America and Europe. BioSpectrum Asia is doing a good job in bringing like-minded people together", said Dr Dario Heymann.

Concluding the enthralling banquet evening, Dr Milind Kokje, Chief Editor, Biospectrum Asia extended gratitude to the guests, winners, and jury members for their involvement, along with the programme partners – Amazon Web Services (AWS), Master Control, and Parenteral Drug Association (PDA) in shaping the event into a grand success.

In the coming pages we will be covering the profiles of the Jury award winners. BS

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Jury Award Winners

Entrepreneur of the Year 2022

L-R- Ravindra Boratkar, Publisher & Managing Editor, BioSpectrum Asia; Dr Shaun Lim, Investments, Pavilion Capital (receiving the award on behalf of Dr Alex Zhavoronkov); and Sophie Asker, Managing Director, GCI Health.

Woman Entrepreneur of the Year 2022

L-R- Ravindra Boratkar, Publisher & Managing Editor, BioSpectrum Asia; Dr Parul Ganju, Co-Founder and Chief Executive Officer, Ahammune Biosciences; and Sophie Asker, Managing Director, GCI Health.

Startup of the Year 2022- Special Jury Recognition

L-R- Ravindra Boratkar, Publisher & Managing Editor, BioSpectrum Asia; Dr Dario Heymann, Chief Research Officer, Galen Growth; and Dr Jerome Boyd-Kirkup, Chief Scientific Officer, Hummingbird Bioscience

Startup of the Year 2022- Special Jury Recognition

L-R- Ravindra Boratkar, Publisher & Managing Editor, BioSpectrum Asia; Dr Dario Heymann, Chief Research Officer, Galen Growth; and Dr Wallace Lin, Secretary General, Taiwan Bio Industry Organisation (receiving the award on behalf of Brain Navi Biotechnology)

Startup of the Year 2022- Special Jury Recognition

L-R- Ravindra Boratkar, Publisher & Managing Editor, BioSpectrum Asia; Dr Dario Heymann, Chief Research Officer, Galen Growth; and Dr Cheng He, Vice President, Research & Development, MiRXES

Product of the Year 2022

L-R- Ravindra Boratkar, Publisher & Managing Editor, BioSpectrum Asia; Christopher Hardesty, Partner, Pureland Global Venture; Lin Sheng Wong, Chief Executive Officer, Genomax Technologies (business partner of Seegene in Singapore)

Trivitron Healthcare signs MoU with Amity University to promote collaborative research

Trivitron Healthcare and Amity University & Institutions (AU) have signed a Memorandum of Understanding (MoU) to bridge the gap between academia and the medtech industry through joint research and training. This MoU will go into effect immediately and will remain effective for five years. As part of the MoU, Trivitron Healthcare and Amity University will synergise on multiple initiatives in cooperation for the joint research and training in the areas of Pharmacology, Immunology, Virology, Biotechnology, Healthcare Devices, Molecular and Stem Cell Research, Applied Sciences, New Born Screening, Next Generation Sequencing, Molecular/Serology and Advanced Diagnostics. Trivitron Healthcare and AU will also have collaborations in joint research, joint projects, dissertation projects for AU students at Trivitron, organising of joint seminars and conferences, joint publications, any collaborative efforts that both may deem fit from time to time, and Trivitron Healthcare will offer internships and projects to students from Amity University.

University of Birmingham and IIT-M launch study programme for biomedical engineering

The Indian Institute of Technology Madras (IIT-M) and the University of Birmingham, UK, are joining forces to launch Joint Masters' programmes that will see students studying in Birmingham and Chennai before receiving a single degree awarded by both universities. It is proposed to launch the first joint postgraduate programme next year before developing further study programmes in subsequent years. The partnership agreement was reached during a visit to Chennai, by Prof. Adam Tickell. Prof. V Kamakoti, Director, IIT Madras, and Prof. Adam Tickell, Vice-Chancellor and Principal, University of Birmingham, signed a collaborative Statement of Intent to explore study areas including data science, energy systems and biomedical engineering.

IIM Raipur inks MoU with Digital Health Academy for launching new online course

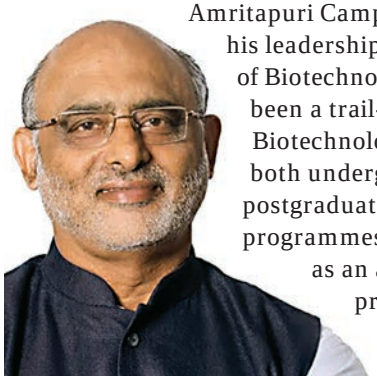
A Memorandum of Understanding (MoU) has been signed between Digital Health Academy (an SBU of Digital Health Associates) and the Indian Institute of Management (IIM) Raipur to start the first-of-its-kind online course on Digital Health. The Certified Digital Health Professional (CDHP) course will be a year-long, completely online course specifically designed for healthcare and management professionals. The CDHP course is designed for Physicians, Allied Healthcare Professionals, and professionals in healthcare administration and life sciences. The aim of this course is to enhance the competence level with regard to the use of digital tools across the continuum of care. Ideated in 2020 by Digital Health Academy, CDHP is the result of two years of research, brainstorming, and extensive consultation with around 54 global leaders. Through the CDHP course, Digital Health Academy wants to bridge the gap between the healthcare professional & application- oriented Digital Health. Segregated into three levels: Basic, Advanced and Professional, the course will cover the theoretical and practical implementation of digital health technologies.

Cadila Pharma names Ashraf Allam as Global COO

Ahmedabad-based Cadila Pharmaceuticals has appointed Ashraf Allam as the Global Chief Operating Officer (COO). Allam joined Cadila Pharma on November 30, 2022. He will be based at Bhat corporate office and will report to Cadila's Group Chairman and Managing Director Dr Rajiv Modi. An accomplished and well-regarded industry leader with more than three decades of experience, Allam was serving recently as the Chief Executive Officer (CEO) at the Public Investment Fund prior to joining Cadila Pharmaceuticals. He also serves as a board member for a number of US, European and regional Pharma, Biotech, Medical devices, Diagnostics, Self-medication and technology companies. In addition, he is also serving as senior executive advisor for global private equity funds and family offices both in the US, Europe and in the Middle East. Allam has a strong track record of holding senior positions at global multinational and privately-held companies such as Johnson & Johnson, Amgen, Eli Lilly, BMS and Mundipharma. He brings a great mix of leadership, inspiration, operational experience, technical breadth, and passion for patients.

Dr Bipin Nair steps in as vice chair of India AMR Innovation Hub's SIG

Amrita Vishwa Vidyapeetham's Life Science, School of Biotechnology, Dean Dr Bipin Nair has been appointed as the vice chair of one of the five Special interest Groups (SIG) of the India AMR Innovation Hub (IAIH), a national-level body engaged in research related to antimicrobial resistance. Dr Nair will be the AMR Environment Committee's vice chair, one of the five SIGs of IAIH. Additionally, four SIGs focusing on key areas are Human AMR, AMR in Human-animal- Agri Interface, AMR stewardship, and Surveillance & Public Health Preparedness. Antimicrobial resistance (AMR) has been identified by WHO as one of the top ten global healthcare threats that is presently claiming 700,000 lives per year. In 2004, Dr Nair took over as Professor and Chairman of the Centre for Biotechnology, Amrita Vishwa Vidyapeetham, Amritapuri Campus. Under his leadership, the School of Biotechnology has been a trail-blazer in the Biotechnology arena for both undergraduate and postgraduate academic programmes as well as an active PhD programme at the School.



MSD India appoints Bhargavi Kakunuri as Human Resources Lead

MSD has announced Bhargavi Kakunuri' s appointment as the HR Lead, India and member of the India Country Leadership Team, as well as the Asia Pacific HR Leadership Team. She will succeed Sameer Tamhane, who retired in November. In this role, Bhargavi will report to Noora Alsagoff, Head of Human Resources, MSD Asia Pacific, responsible for developing and implementing the HR strategy that drives innovation and business growth in India. She will lead the HR function across the enterprise to enable an agile learning culture, leverage talent opportunities in the market, promote managerial and leadership capability building, and bring impactful diversity, equity and inclusion initiatives to life. Bhargavi joins MSD from P&G India Consumer Health, where she led the annual business formulation exercise and focused on strengthening capabilities for the future while building a strong leadership succession pipeline and driving an engaged and high-performance culture. Diversity, equity, and inclusion have always been at the forefront of Bhargavi's priorities as an HR leader. She has executed many innovative initiatives to improve gender balance and create a culture of inclusion in her past organisations.

Shreehas Tambe steps in as Managing Director & CEO of Biocon Biologics

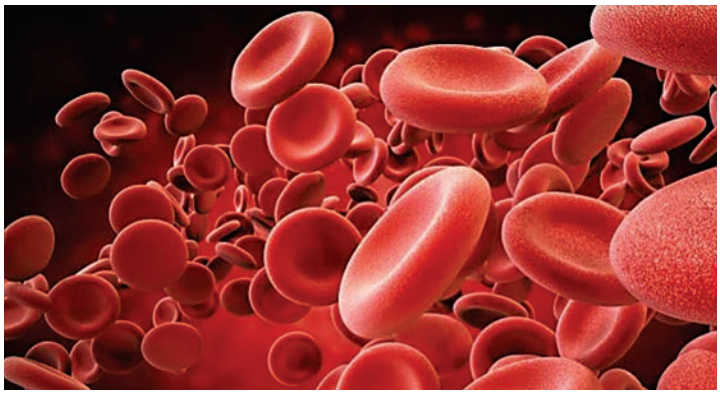
Shreehas Tambe, Deputy Chief Executive Officer (CEO) of Biocon Biologics, has been appointed as the Managing Director and CEO of the company from December 5, 2022. Tambe will lead Biocon Biologics in realising its goal of being a global biosimilars leader. As Deputy CEO of Biocon Biologics since March 2021, Tambe has played an important and very effective role in supporting Dr Arun Chandavarkar steer the company towards sustainable growth and build a strong foundation for the future. Both have also played an integral role in Biocon Biologics' historic acquisition of Viatris' global biosimilars business and the strategic alliance with Serum Institute Life Sciences (SILS), which will drive the company's future growth and create long-term value for all its stakeholders. Tambe has been with Biocon since 1997 and has held diverse leadership and operational roles. Over the past 25 years, he has helped build and shape Biocon's biosimilars business and spearheaded the Group's strategic capital investments, including its first overseas facility in Malaysia.

AstraZeneca India appoints Dr Sanjeev Panchal as Country President & MD

AstraZeneca Pharma India has announced a change in its leadership with the appointment of Dr Sanjeev Panchal as Country President & Managing Director (MD), with effect from January 1, 2023. Dr Panchal has been with AstraZeneca for 19 years and began his career in India back in 2003 as a Brand Associate. Over time, he progressed through several positions in India, Indonesia, Asia Pacific and the International region, based in Singapore and the UK. He is currently the Country President for AstraZeneca Malaysia, where he has been instrumental in transforming the business, by driving new launches, innovative patient centric partnerships and Market Access strategies, guiding an inclusive and diverse team to achieve double digit growth outpacing the market. Dr Panchal played a critical role in supporting the government in combating the pandemic through AstraZeneca's COVID-19 vaccine and long-acting monoclonal antibodies, as well as leading the Corporate Affairs strategy and sustainability initiatives. He is a science graduate (BSc) with Post Graduation and Doctorate in Business Administration (PhD). Dr Panchal will be assuming the new role starting January 2023 and will be taking forward the commitment of the organisation in the country.

StanPlus appoints Shalabh Dang as CRO

StanPlus, Hyderabad-based medical emergency response platform, has announced the appointment of Shalabh Dang as its Chief Revenue Officer to expand StanPlus' business verticals and footprint across India and international markets. Dang will be responsible for driving and implementing strategic partnerships with hospitals, corporates, and other channels to boost revenue growth and support the company's mission of creating a 911 model for Indian healthcare. Dang comes with over two and a half decades of cross-domain experience. In his previous role, he was leading the international and domestic sales and collections at Fortis Healthcare as their Group Sales Head. He has also worked with leading companies like Philips, Vodafone, and TATA Teleservices, amongst others. He has been rewarded with the Top 100 Global Healthcare Leader Award, Dubai in the year 2019 by IFAH.



Study reveals recommended anticoagulant therapy for COVID-19 patients

The AustralaSian COVID-19 Trial (ASCOT) has pinpointed the most efficient level of blood thinning treatment needed for patients hospitalised with COVID-19, in a study published in the New England Journal of Medicine Evidence and presented at the American Society for Hematology conference. Patients in hospitals with COVID-19 are at increased risk of blood clots (or thromboses), which in turn may contribute to development of organ failure. Almost all these patients will receive some degree of blood thinning medication. In an international study, the ASCOT team conducted a randomised clinical trial to test different levels of anticoagulation (or blood thinning) in more than 1,500 patients in Australia, New Zealand, India and Nepal. They found that an intermediate level of anticoagulation had an 86 per cent probability of being better than low dose anticoagulation. A higher therapeutic dose did not show any benefit.

CELLINK opens Centre of Excellence for 3D bioprinting in India

Sweden-headquartered CELLINK, the global leader in developing 3D bioprinters, and the Indian Institute of Science (IISc), Bengaluru have opened the doors to the first 3D bioprinting Centre of Excellence (CoE) in the Indian subcontinent. Housed in the Centre for BioSystems Science and Engineering (BSSE) at IISc's Bengaluru campus, the CoE will provide access to 3D bioprinting systems, enabling researchers to accelerate their work across critical applications with the ultimate goal of improving health outcomes. The CoE was inaugurated by Dr Ashwath Narayan CN, Minister of Electronics, Information Technology – Biotechnology, Science and Technology, Higher Education, Skill Development, Entrepreneurship and Livelihood in the Government of Karnataka; Prof. Govindan Rangarajan, Director, IISc; and Tomoko Bylund, CELLINK's Head of Sales – APAC. The event was also attended by Dr Vishal US Rao, Group Director and Dean, HCG Cancer Centre, Bengaluru.

IET develops SARTHI to enhance national disease surveillance initiative

The Institution of Engineering and Technology (IET), in partnership with Siemens Healthineers India, the Centre for Health Research and Innovation (CHRI) and Capgemini, has developed a digital platform to enhance the national disease surveillance initiative. The platform is called Social Analytics for Rapid Transformation in Health for India (SARTHI), which leverages publicly available digital data to track mentions of three disease conditions – Dengue,

Malaria and Chinkungunya. SARTHI assimilates data available in the public domain across digital channels like online news broadcasts, forums, blogs, twitter, facebook, instagram and reviews to track mentions of the three disease conditions. The platform looks at granular data and can trace the origin of the information down to district and street locations. SARTHI has huge implications for the real time tracking of disease conditions in India and will lay the foundation of creating a model for predicting disease outbreaks, thereby helping to improve the preparedness of public health infrastructure.

Barcode Biosciences brings Gene synthesis (End-to-End) to India

Dr Ramprasad Kuncham,
Managing Director & Chief Executive Officer, Barcode Biosciences

Barcode Biosciences (BBS), a fast-expanding Bengaluru-based genomic company, has come forward and succeeded in synthesising artificial genes in its inhouse facility and become the **FIRST Biotech Company** to initiate the End-to-End gene synthesis in India at commercial scale. Since inception in 2018 with two employees, the company was able to process 1000 – 1500 DNA Sanger sequencing samples per month. Today, BBS with its state-of-the-art technologies, has catapulted to become one of the fastest growing genomic companies in India with over 60 employees, a large network of clients pan India, and overseas. Currently, they are processing over 2000 samples per day and also offering versatile genomic services. Dr Ramprasad Kuncham, Managing Director & Chief Executive Officer, Barcode Biosciences talks about gene synthesis, its scope, value addition, company's growth, and the other services that BBS is offering in India.

What is the main objective behind initiating a gene synthesis unit in India?

At this moment in time, the Indian scientists will have to depend on other developed countries for their gene synthesis needs as there are no in-house gene synthesis operations in India. In consequence, during the recent global pandemic of COVID-19, the Indian scientists (especially those who were looking for novel drug candidates viz; mRNA vaccines/ heterologous proteins/viral spike proteins) had faced many challenges in getting their desired synthesised genes in time. Now companies and scientists look towards a post-COVID future when gene synthesis will be deployed to tackle a variety of other investigations/ studies.

With a mission to settle the current gap and to accelerate the advanced genomic research in India, also to firmly echo the Make-in-India initiative which has come from the government, BBS has come forward and established an indigenous in-house gene synthesis unit in Bengaluru.

By nature of its operations, BBS is housing the great infrastructure, progressive technology and expertise that are required for the gene synthesis. Leveraging on this, our scientist group could manage the end-to-end steps in gene synthesis under one roof without having dependency on any third-party agencies. Therefore, we were able to cut short the turnaround time (TAT) for synthesizing a gene than the current TAT in the market.

With all the inspiration from the legacy of Dr Har Gobind Khorana, the one who paved the way to synthesise a gene, today BBS has turned out to be the first organization in India to start in-house gene synthesis at a commercial scale.

Please share more details about the process of gene synthesis? What are its applications?

Gene synthesis refers to chemically synthesising a desired gene of interest base-by-base with desired/ custom sequence utilising oligonucleotides. Various scientific methods are available to assemble these generated stretches of double-stranded DNA which, further usually cloned into a plasmid vector.

As the gene synthesis technologies keep getting advanced, scientists over the world were able to modify/synthesise various types of genes in search of answers for many unanswered questions across the science disciplines including virology and vaccine designing, therapeutic antibody engineering, cancer biology, neurosciences, agriculture, environmental health sciences and the list goes on.

For instance, through gene synthesis scientists can efficiently clone the synthetic therapeutic genes into custom viral vectors to optimise expression and specificity of gene delivery. The scientists can also engineer novel enzymes that fight cancers.

Countries can improve their crop yield and reduce vulnerability to the plant diseases that may disrupt food supplies and contribute to global hunger.

Further applications include detecting and breaking down environmental pollutants in the soil, air and water; building designer metabolic circuits using interchangeable synthetic parts; generating novel biological functions and systems with CRISPR and

other gene editing technologies; and using codon-optimised genes to rapidly express recombinant protein for structure determination in gene-to-protein pipelines etc.

What are the latest advances being made with gene synthesis?

Today, scientists are equipped to quickly synthesise any newly identified viral genes that are crucial for developing a potential vaccine candidate to fight against the future novel pathogens that are of global threat (pandemics), thus accelerating vaccine development around the globe.

To give you an example, gene synthesis is the technology that is behind two of the biggest "products" of the past year: the mRNA vaccines from Pfizer and Moderna. This duo has developed a mRNA vaccine as soon as the Chinese C.D.C. first released the genomic sequence of SARS-CoV-2 to public databases in January 2020, they were able to synthesise the gene that corresponds to a particular antigen on the virus, which is called the spike protein. This meant that their vaccines, not like the traditional vaccines which teach the immune system to recognise a virus by introducing a weakened version of it, could deliver genetic instructions prompting the body to create just the spike/antigenic protein, to be recognised and attacked during an actual viral infection.

The global gene synthesis market size is projected to reach $872.3 million by 2028, from $353.7 million in 2021, at a CAGR of 13.6 per cent during 2022-2028.

Please tell us more about the work being done at BBS?

As I quoted earlier, BBS is equipped with cutting-edge technologies and high throughput laboratories, manned by highly qualified professionals with over 17+ years of experience, dedicated and stringent measures to avoid cross-contamination, robust processes to enhance the quality of services and products. With an excellent track record, BBS has become the most reliable and affordable genomics services provider in India.

Barcode Biosciences' core focus is genomics R&D, with highly experienced PhDs working through the complexities of genomic services, and bespoke projects like, chicory identification in coffee, protozoan identification in drinking water, adulterants in spices, cereals and herbs, identification of origin of cultivation, cattle genotyping, halal testing, authenticity of honey, cereals, spices and many more.

BBS has different business verticals, offering versatile services, products, which are marketed independently through divisions namely **Genomic Synthesis** (Cloned genes and gene fragments,

modified and unmodified oligonucleotides, probes, SiRNA oligos, molecular beacons etc.); **Genomic Information** (Sanger sequencing, microbial identifications, plant, animal, insect barcoding, genotyping, fragment analysis, primer walking, gene expression etc.); **Food Genomics** (DNA authenticity of spices, cereals, plants, fruits, animals, birds, eggs, fish, prawns etc., GMO testing, food adulterants, basmati authenticity etc.); I**nfectious disease testing** (COVID-19 RT PCR, COVID-19 Surface testing) ; and **Molecular Biology products** (Offering a wide range of genomic isolation kits, RNA isolation kits, DNA ladders, PCR Master mix, enzymes, plastic ware, glass ware, chemicals, and pipettes etc.)

BBS has been awarded as the exclusive distributing partner for Andhra Pradesh, Goa, Karnataka, Kerala, Puducherry Territory, Tamil Nadu, Telangana, Odisha, Madhya Pradesh and Maharashtra by NimaGen, Netherlands.

We offer complete NimaGen portfolio and exclusively BrilliantDye™ Terminator Cycle Sequencing Kits, NimaPOP, 10x CE Running Buffers, AmpliClean™ Cleanup Kit Magnetic Beads, ExS-Pure™ Enzymatic PCR Purification Kits, Orange-500/600 DNA Size Standards (500 bp and 600 bp), Seq-DI™ Formamide solutions, EasySeq™ 16S rRNA Bacterial ID Kits, EasySeq™ 18S and Cyp51A rRNA Fungal ID Kits, IDseek® forensic kits and all other NimaGen products.

What are the major future plans of BBS?

The current success in gene synthesis has given us confidence and encouragement to invest more into Research and Development. With our highly passionate team and cutting-edge technologies, BBS is always striving to contribute to solve the existing unsolved long due problems and also to equip the global scientific community to handle the future unforeseen global pandemics/natural calamities. In the near future, BBS is going to expand its operations and services into European countries to explore new markets and challenges. In the long term, we would like to offer high quality genomic and analytical services across the globe and aim to become the global leader. ■

West introduces Gamma Irradiated Flip-Off seals in India

West Pharmaceutical Services has recently expanded its seal offerings by launching Gamma Irradiated Flip-Off seals in India and Asia Pacific markets. Designed and developed to deliver consistent machinability, maintain container closure integrity, and support a safe, convenient user experience, West has launched Gamma Irradiated Flip-Off seals to help pharmaceutical and biopharmaceutical manufacturers protect their products from external contamination while protecting drug quality. Using precision technology, these seals deliver consistent quality which can be the ideal solution for those who are faced with operational challenges to consistently achieve reproducible and effective container integrity of pharmaceutical products. Produced at West's Sri City manufacturing facility in Andhra Pradesh, the Gamma Irradiated Flip-Off seals are brought to meet the growing demands from India and the Asia Pacific markets.

Agilent unveils new customer experience centre in US

Agilent Technologies has announced the opening of a new Customer Experience Center (CEC) in Lexington, MA, in the US, focused on solutions from Agilent genomics and diagnostics product portfolios. The facility will serve as a regional hub for Agilent representatives to showcase and demonstrate both product capabilities and complete workflow solutions to customers. Hands-on training, education, assay development, and optimisation are critical to a laboratory's success. Scientists are looking for suppliers to support their discovery work and product and solution development efforts. The new Agilent CEC delivers an immersive experience for pathologists, clinicians, and researchers to increase their confidence in using Agilent products to meet the unique needs of their lab. The facility is strategically located where Agilent has a high concentration of genomics and pathology customers who can easily access the CEC. The new CEC boasts an efficient layout to demonstrate workflows for next-generation sequencing (NGS) and pathology in clinical and research applications. It also provides a location for novel application development and collaborations.

Freudenberg Medical launches HelixFlex TPE Tubing for Indian pharma market

Freudenberg Medical, a US-based manufacturer of medical and pharmaceutical devices, components, and tubing, has launched HelixFlex, a high-purity thermoplastic elastomer TPE tubing designed for use in biopharmaceutical fluid transfer applications. This is an expanded product offering from Freudenberg, adding to its existing pharma product portfolio of silicone tubing and components for bioprocessing, drugs and vaccine manufacturing, filling and sampling, peristaltic

pumping, lab, and medical device applications. TPE tubing is ideal for pharmaceutical bioprocessing applications because it can be welded to existing tubing lines, and heat-sealed to allow for easy, fast, and safe fluid transport in biopharma processes. TPE tubing from Freudenberg also offers many different sterilization options including autoclave, gamma irradiation, x-ray, and e-beam. Additionally, TPE tubing is a more environmentally friendly option than silicone and can be recycled. HelixFlex is produced in a certified cleanroom and material certification and traceability is included in every package.

Prejex joins hands with Polybond to make needle-less injections in India

Prejex, a spin-off of Germany-based Prejex GMBH, has entered into an agreement with Polybond, headed by Adit Rathi of Rathi Group to manufacture needle-less injections. The partnership has enabled shifting of the manufacturing capabilities of the German company from Berlin to Pune, for global distribution. The Prejex-Polybond factory will make needle-less injections for the entire world. Prejex's New Drug Delivery System (NDDS) via needle-less injections is a cutting-edge innovation that the medical world has long been waiting for. Prejex provides a solution to a variety of issues that professionals face in day-to-day operations. Syringes and disposable needles are major contributors to toxic waste and their disposal cost is sky-rocketing.

Trypanophobia (fear of needles) is a common factor leading to the reluctance of patients in drawing blood and receiving vaccines or intravenous fluids. A broad spectrum of applications can be covered using these needle-less injections including diabetes, oncology supportive care, biosimilars, vaccines etc.

PerkinElmer launches industry-first ready-to-use viral vector assays

PerkinElmer has launched ready-to-use Adeno-associated Virus Vectors (AAV) Detection Kits to support researchers working on gene therapies for a variety of serious diseases. The high-throughput viral assays are designed to help researchers quickly and easily characterise viral vector particles being produced to enable decision-making for safe and efficient gene transfer. The validated and fully automatable assays are built on PerkinElmer's proprietary AlphaLISA technology which requires no separation and are the only optimised, no-wash AAV detection assays currently available on the market. The new offering provides researchers expanded options to measure viral titers beyond ELISA and other wash-based systems, which can be time-consuming and limited in assay range. Designed to streamline gene therapy research and development workflows with an easier-to-use and more high throughput method, each of the seven kits detects specific serotypes to target different cell types in the body for gene therapy application.

Thermo Fisher unveils TrueMark Infectious Disease Research Panels

Thermo Fisher Scientific has announced the launch of the TrueMark Infectious Disease Research Panels designed to enable rapid and accurate detection and categorisation for investigating microorganisms that cause respiratory, vaginal, urinary, gastrointestinal, and sexually transmitted diseases. To effectively study outbreaks and determine disease etiology where pathogens are similar, analytically sensitive panels are needed to support laboratory research. TrueMark Infectious Disease Research Panels are analytically sensitive, real-time polymerase chain reaction (PCR) syndromic panels for the analysis of a wide range of infectious disease pathogens. Leveraging real-time PCR technology, the predefined and customisable panel options allow researchers to choose from more than 90 different bacterial and viral strain assays to generate results within four hours from taking the samples. The assays use pre-spotted and dried down TaqMan plates, which are designed to enable easy set-up and increased accuracy. Testing can be done from nasopharyngeal swabs or nasopharyngeal aspirate, vaginal, genital and lesion swabs or urine samples.

Neutralising Pain with Neuromodulation

It sounds simple when we say that 'pain' is a message from the body to the brain that something is not right, but for anyone who has experienced serious pain, including chronic pain, there's nothing simple about it. Though research has made strides in understanding pain, it remains a complex and individualised challenge for those coping with injuries, illnesses and disease.

The International Pain Society and Global Health Community has stated that "failure to treat pain is viewed worldwide as poor medicine, unethical practice, and an abrogation of a fundamental human right." A recent survey conducted by the World Health Organisation (WHO) in 15 centres across Asia, Africa, Europe and the US has revealed prevalence of chronic pain among 33 per cent of the population. Surveys from India across eight cities have unveiled the prevalence of chronic pain in 13 per cent of our population, which is huge.

Unlike most 'known' illnesses, chronic pain does not get the recognition it deserves. Every patient is different and the type, amount and frequency of pain is unique to the individual, and thus the condition can be difficult to understand and manage. The interplay between physical sensation and the pain experienced by an individual is difficult for another to perceive.

Studies have shown that chronic pain is a common problem in ageing populations, with varying levels of functional and psychological impairment. Because of the increasing demand for public healthcare services and the lack of awareness of pain management in the society, many patients fail to receive the right treatment.

Adding on, chronic pain can be continuous or episodic. It comes in many different forms, making it extremely difficult to classify. Sometimes it directly relates to specific illnesses like chronic inflammatory disease or cancer, while at other times it has no clear identifiable biological origin. More commonly though, chronic pain arises from nervous system dysfunction.

As a result, neuromodulation and neurostimulation are becoming expanding areas of medicine for chronic pain management. While doctors have used neurostimulation for pain since the 1960s, neurostimulation devices and protocols are now evolving in the quest to offer robust pain relief without side effects. While neuromodulation works by either actively stimulating nerves to produce a natural biological response or by applying targeted pharmaceutical agents in tiny doses directly to the site of action, neurostimulation devices involve the application of electrodes to the brain, the spinal cord or peripheral nerves.

One of the most common neurostimulation techniques for chronic pain is spinal cord stimulation, in which lead wires with electrodes are placed in the epidural space between the vertebrae and the spinal cord. Connected to these leads is a small pulse generator placed under the skin, similar to a pacemaker. A handheld controller can be used to change stimulation parameters.

An example of neuromodulation is the intrathecal pump, which is a device designed to deliver a desired medication directly into the spinal fluid surrounding the spinal cord. This technique allows a drug to be administered in much smaller doses, because it does not have to be metabolised through other body systems before reaching the target area.

Besides neuromodulation and neurostimulation based techniques, new and emerging targets like the dorsal root ganglion, as well as high-frequency and patterned stimulation methodologies such as burst stimulation, are paving the way for better clinical outcomes. As we look forward to 2023, neural sensing, novel target-specific stimulation patterns, and approaches integrating bioengineering into neuromodulation and clinical medicine, are likely to make a significant impact. Moreover, select biomarkers may influence and guide the use of neuromodulation and help objectively demonstrate efficacy and outcomes.

However, this space is hugely dominated by international medical technology players where India would need to make its place very soon by developing indigenous solutions. BS

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