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the business of Bio & Health Sciences

PUNE ▪ Volume 22 ▪ Issue 7 ▪ July 2024

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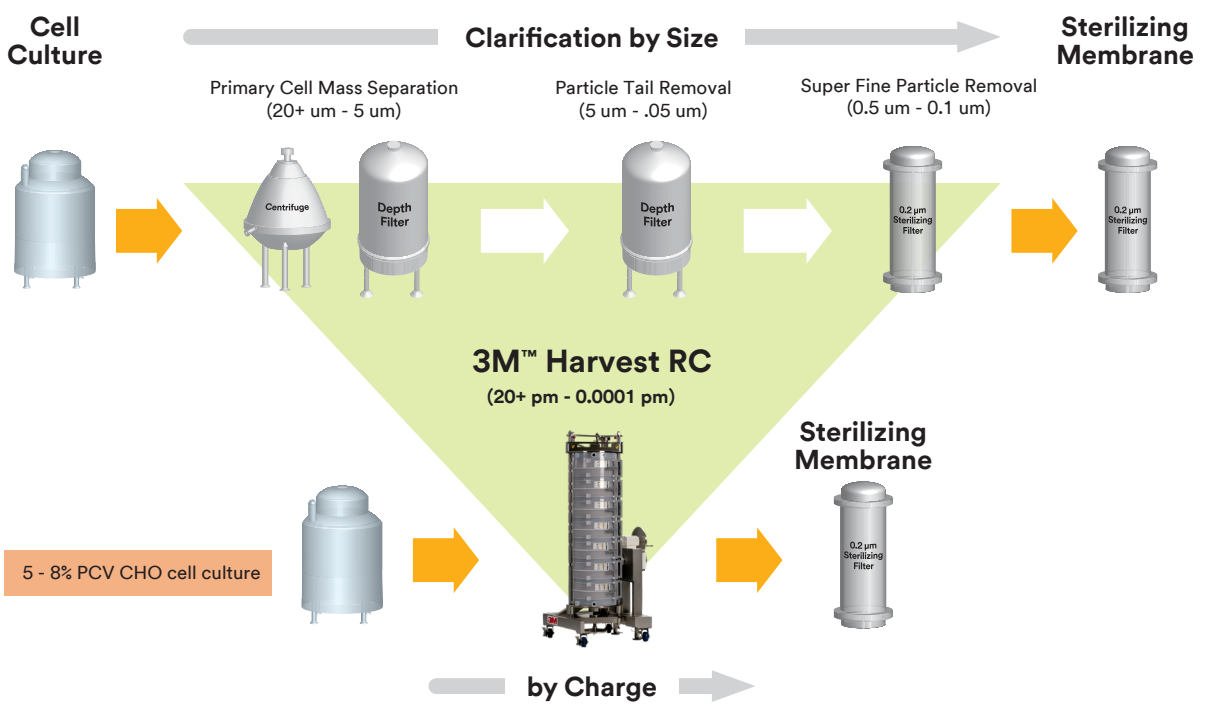

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Feedback/ Acknowledgement

Addressing the patenting landscape for emerging technologies and ensuring guidelines for these emerging fields such as deep tech can encourage responsible innovation and attract investment.

- Prof. Ajay Sood, New Delhi

Thank you BioSpectrum India for the interview feature on Lindström in the June edition, and for highlighting our focus on sustainability, operational excellence, and customer satisfaction, all crucial in the biopharma and pharmaceutical industries.

- Manas Kumar, New Delhi

The Indian market for laboratory and analytical instruments is steadily growing. As new regulations demand highly sensitive and advanced technology products, there's a growing replacement market.

- Shailendra Chavan, Mumbai

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Letter from Publisher

Ravindra Boratkar
Publisher &
Managing Editor,
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Dear Readers,

India's medtech market is expected to grow at a rate of 28 per cent per annum and reach $50 billion by 2030 and has enormous potential. India ranks among the top 20 global markets for medical devices and is the fourth-largest market in Asia. Net imports for 2022-23 stands at $4.101 billion. Imports have increased dramatically, mostly from the US, China, and Germany. But through local manufacturing, India's strong policy environment offers chances for exports and lower reliance on imports. In the past year, exports have surpassed imports in both consumables and disposables.

Continuing the momentum and supporting this niche space, the Department of Pharmaceuticals rolled out 'MediTech Stackathon 2024', on May 7 in a bid to harness the collective expertise of stakeholders to ultimately propel the industry towards unparalleled heights of innovation and self-reliance. Our team has covered a story, with inputs from the industry captains, about how the Indian medtech industry is prepping for the big leap.

Experts worldwide are adopting novel research approaches in the molecular design of vaccines, and vaccine technology platforms. New vaccine platform technologies could dramatically shorten the period from research to development, clinical trials, and vaccination. India is seeing increasing interdisciplinary research, and a rise in cutting-edge technological interventions in fundamental and translational research. The time is ripe for boosting out-of-the-box R&D approaches in vaccinology.

Our correspondent has covered an article on India's efforts in the development of next-generation vaccines, particularly during COVID-19, reflecting its commitment to leveraging innovation and collaboration to address public health challenges. With a focus on mRNA and viral vector vaccine platforms, India has made significant strides in expanding its vaccine portfolio and contributing to global vaccination efforts.

The average cost to develop a new drug is approximately $2.6 billion, according to a study by the Tufts Center for the Study of Drug Development. Pharma companies are using pivotal technologies such as generative AI, AI/ML, and data analytics, which offer unprecedented opportunities to revolutionise drug development and boost efficiency. An expert article, in this edition, points out that the integration of research data in the pharma landscape is a critical step in leveraging these technological advancements that will impact drug efficiency, cost reduction, regulatory harmonisation, and global competitiveness.

The Government Institute of Medical Sciences (GIMS) of Greater Noida in Uttar Pradesh became the first public hospital-based medical incubation centre in the country. Our team interacted with the head of the centre who talked about how the centre will revolutionise healthcare innovation by providing a platform for medical startups and researchers to develop groundbreaking solutions.

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

Thanks & Regards,

Ravindra Boratkar,
Publisher & Managing Editor

MediTech Stackathon 2024 to Drive Explosive Growth

India's medtech industry holds immense potential, with projections estimating a growth rate of 28 per cent annually, reaching a size of $50 billion by 2030. Currently, India is the fourth largest market for medical devices in Asia and among the top 20 globally. Net imports for 2022-23 stands at $4.101 billion with import coverage ratio of 0.45. The sector has witnessed a surge in imports, driven primarily by countries like the US, China, and Germany, however, India's robust policy ecosystem presents opportunities for exports and reducing import dependence through domestic manufacturing. Exports have overtaken imports in consumables and disposables during last year. The industry now needs to continue with the momentum in other pillars of the medtech sector. Against this backdrop of immense potential, the Department of Pharmaceuticals launched Meditech Stackathon 2024, which seeks to harness the collective expertise of stakeholders to propel the industry towards unprecedented heights of innovation and self-reliance. With optimal support and participation from all stakeholders, initiatives like Meditech Stackathon will take the Indian medtech industry to the next levels to become self-reliant.

22

"The Stackathon aims to taper import dependence and position India as a frontrunner in medical technology on the global stage"

Himanshu Baid,

Chairman, National Medical Technology Forum (NMTF), Confederation of Indian Industry (CII) & Managing Director, Poly Medicure Ltd.

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Top Video

Dr Ravinder Singh Rao, a structural heart disease expert in India, explains why TAVI is an ideal surgery option for high-risk patients in digital era.

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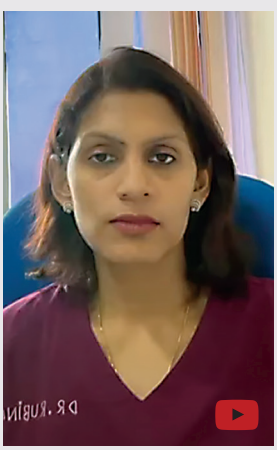

Dr Rubina Shanawaz, Senior Consultant Obstetrics and Uro Gynaecology, Fortis Hospital, Bengaluru shares her views on the advantages being offered by robotic technology in gynaecology-based surgical procedures.

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Double Edged Decision

In recent times two issues have emerged which are at the crossroads of pharmaceuticals and nutraceuticals. The first is a proposal to bring nutraceuticals under the purview of the Central Drug Standard Control Organisation (CDSCO). The second is, not permitting nutraceutical production at the same facility where pharma products are manufactured.

Nutraceuticals and health supplements are considered foods and hence regulated by the Food Safety and Standards Authority of India (FSSAI) since 2006 when a comprehensive food law was enacted. The government initiated a proposal to shift them from the FSSAI to CDSCO. In another development, the Drug Controller General of India (DCGI) decided to take action against pharma units which were manufacturing nutraceuticals, health supplements and drugs in the same facility.

However, the government deferred the action against such companies following the industry's request to reconsider the decision.The Federation of Pharma Entrepreneurs (FoPE) pointed out to the DCGI that any such action would affect exports and domestic market, especially for small and medium units. Regarding the proposed shifting of nutraceuticals to CDSCO for regulatory purposes also, the nutraceutical industry was upset over the proposed move.

In both the cases, the government has appointed two separate committees of five members each to examine whether nutraceuticals manufacturing should be allowed at the pharma production site and whether nutraceuticals should be governed by CDSCO for better regulation. While the first committee has an industry representative as a member, the second committee comprises only officials and surprisingly no stake holder is a member.

As per the existing revised Schedule M rules of the Drugs and Cosmetics Act 1940, a facility approved for drug manufacturing cannot be used to produce other products. However, exceptions were approved to some older plants, which were established prior to December 2001. This exception was then extended to all manufacturing units in 2007 following the Drug Consultative Committee's decision. However, DCGI discontinued this exception in February.

Although the immediate reasons for such a change are not clear, it is obvious that for any such change to take place adequate time will have to be provided for the pharma units to set up separate manufacturing facilities for nutraceutical manufacturing.

The industry feels that although the authorities' viewpoint of avoiding cross contamination between pharma and nutraceuticals can be acknowledged, there cannot be a blanket ban. The decision should be left to individual competent officers to decide on a case-to-case basis. Norms to allow nutraceutical production already exist. The expert officers can verify whether the norms are being observed or not. They can also check the possibility of cross contamination on the basis of the type of drugs that are being produced and accordingly allow (or disallow) nutraceutical production at the pharma production facility.

The reason for bringing nutraceuticals under pharma regulator is cited as some companies are seeking FSSAI approval for their health supplements despite their therapeutic usage and for the ingredients which are akin to drugs. Some are claiming disease management and disease risk reduction. This situation is creating confusion and could turn risky.

Still, the industry feels that shifting nutraceuticals from the FSSAI to the CDSCO is not a solution. If some companies are misrepresenting their products, there are provisions to take action against them. There is a clear distinction between the two. By bringing nutraceuticals under CDSCO, consumers will have to go to doctors even for nutraceutical prescriptions, it will affect the online sales and if nutraceuticals sales go down even farmers will be affected.

Although the intentions of authorities for both moves are not doubted and in fact appreciated, they will have to take into consideration the stakeholders' views. More than bureaucracy, the issue should be left for the experts to decide on. Any move when initiated with the stakeholders' approval, at least to some extent, possibility of its smooth sailing and success is always more. BS

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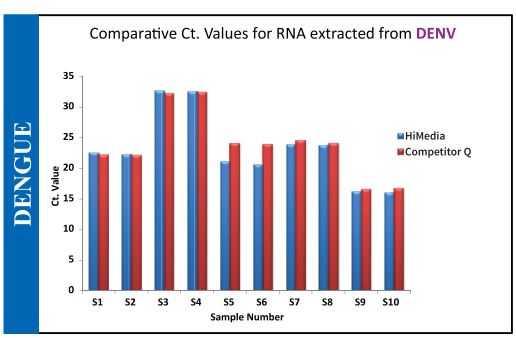

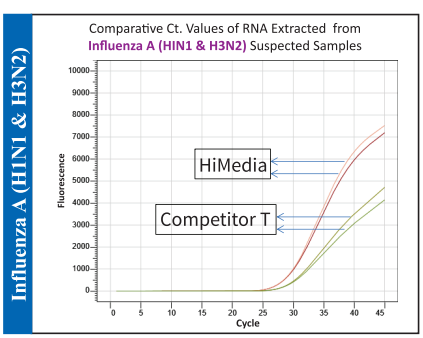

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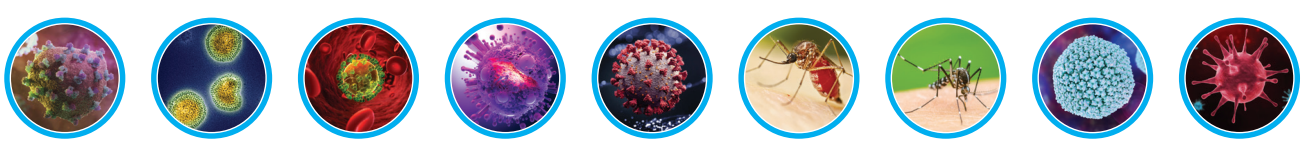

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DCGI approves Orchid Pharma's Cefepime and Enmetazobactam antibiotic combination drug

Orchid Pharma, based in Chennai, has received Drugs Controller General of India (DCGI) approval for the manufacturing and marketing of its invented New Chemical Entity Active Pharmaceutical Ingredient (API), Enmetazobactam. DCGI has also granted permission to manufacture and market Finished Dosage Form (FDF) of Cefepime and Enmetazobactam as a dry powder injectable. This formulation is indicated for

the treatment of complicated Urinary Tract Infections (cUTI) including acute Pyelonephritis, Hospital-Acquired Pneumonia (HAP) including Ventilator-associated pneumonia (VAP), and Bacteremia when it is associated or suspected to be associated with either complicated urinary tract infections or hospital-acquired pneumonia. This new Combination Drug provides a powerful treatment option against a range of severe infections caused by resistant bacteria, addressing a critical need in combating antimicrobial resistance.

Govt seeks Google's support for greater collaboration in digital tool

Apurva Chandra, Union Health Secretary, leading the India delegation, met with Dr Karen DeSalvo, Chief Health Officer, Google at a side-event of the 77th World Health Assembly of WHO, held recently in Geneva. The purpose of the meeting was to discuss ongoing engagement between Google Research and the Union Health Ministry in making digital health tools more accessible to people. At the outset, the Union Health Secretary appreciated the ongoing engagement between the two organisations. He expressed the need for exploring possible collaboration in areas such as Artificial Intelligence (AI) and sought Google's support to the Ayushman Bharat Digital Mission (ABDM), building more digital health tools like Automated Retinal Disease Assessment (ARDA) and make them ABDM enabled, and in spreading awareness about ABDM among the student community as well as startup community. The google team highlighted the existing engagement of Google Research with India's National Health Authority (NHA). Google Research has been engaged with NHA since 2022, when Google's AI model for diabetic retinopathy screening (ARDA) was listed on ABDM's website under the Open Call for Expression of Interest (EoI) for creating a digital health ecosystem for India.

Health Ministry to set up mental health assistance helpline for armed forces

A Memorandum of Understanding (MoU) has been signed between the Ministry of Health and Family Welfare (MoHFW) and the Ministry of Defence (MoD) to facilitate collaboration between the two ministries in operating a special cell of Tele MANAS, the National Telemental Health Helpline of MoHFW, as a pilot project for a period of two years at the Armed Forces Medical College in Pune. Recognising the unique stressors faced by the Indian military, the need for tele-mental health services in the Armed Forces has become evident. The operational environment, cultural challenges, and specific stressors related to regional conflicts necessitate a specialised approach to mental healthcare in Armed Forces. With the signing of the MoU, the mental health and well-being of Armed Forces personnel and their families will be addressed and the Armed Forces beneficiaries will have direct access to specialised care, ensuring that their unique mental health needs are addressed promptly and effectively.

Ayush Ministry takes initiative to propel ayurveda research in collaboration with pharma

The Central Council for Research in Ayurvedic Sciences (CCRAS), an autonomous body under the Union Ministry of Ayush, has launched 'PRAGATI- 2024' (Pharma Research in AyurGyan And Techno Innovation). It offers a very useful opportunity for collaborative research in the field of Ayurveda. The primary goal is to utilise research outcomes and technologies developed by CCRAS; establish robust networks for collaborative research in quality control, drug standardisation, product development, and validation; identify potential industrial partners with in-house R&D facilities; explore opportunities for capacity building for researchers in drug manufacturing and product development; and assist Ayurveda professionals in initiating startups and incubating centres, promoting entrepreneurship in Ayurvedic pharmaceutics.

Inaugural Women Leadership in STEM programme to drive impact in gender equality

Grand Challenges India, the Biotechnology Industry Research Assistance Council (BIRAC), supported by the Department of Biotechnology, Ministry of Science and Technology, Government of India, and the Bill & Melinda Gates Foundation, along with WomenLift Health, have launched the inaugural 2024 Women Leadership in STEM (WLS) programme to drive impact in gender equality in STEM (Science, Technology, Engineering, and Mathematics) leadership in India. The Women Leadership in STEM offers a pathway for advancing gender equality in STEM in India, underscoring a commitment to elevating the power and influence of mid-career women in STEM fields by equipping them with essential tools, structured mentorship, coaching, peer support, and leadership skills for high impact. The inaugural 2024 WLS cohort comprises 20 leading women scientists from public and private research institutions across India, including the Indian Institute of Science Education and Research (IISER) Tirupati, the Indian Institute of Technology (IIT) Kanpur, the Indian Council of Medical Research (ICMR), and the Council of Scientific and Industrial Research (CSIR).

DAHD focuses on digitalisation of animal vaccine cold chain

The Department of Animal Husbandry & Dairying (DAHD), Ministry of Fisheries, Animal Husbandry & Dairying has signed a Memorandum of Understanding (MoU) with the United Nations Development Programme (UNDP) India on Digitalisation of Vaccine Cold Chain Management, Capacity Building, and Communication Planning. The vaccine cold chain management process will be monitored with the help of new age technology and artificial intelligence through the Animal Vaccine Intelligence Network (AVIN) developed by UNDP. Through this partnership with DAHD, UNDP will support and strengthen India's first animal vaccine supply chain management system ensuring communities and animals are protected and further mitigating the risks at the human-animal-environment interface. UNDP and DAHD will jointly work on Strengthening Animal Health with One Health approach. Currently, DAHD is supplying FMD (Foot and Mouth Diseases) vaccine worth approximately Rs 900 crore this year and aims to cover 50 crore large animals and 20 crore small animals in FMD vaccination programme.

Nephro Care India plans to raise Rs 35-40 Cr through IPO

Nephro Care India, a leading multi-speciality healthcare provider in East India, is planning to raise Rs 35-40 crore through an initial public offering (IPO), subject to NSE Emerge approval. This strategic move will allow Nephro Care to expand its operations across India. The company plans to use the net proceeds from the IPO to establish a multi-speciality hospital named 'Vivacity Multi Speciality Hospital' in Madhyamgram, Kolkata, West Bengal. The remaining capital will be used for general corporate purposes. The new hospital, a unit of Nephro Care, will reportedly include 100 inpatient beds, including a 30-bed critical care unit with ICU, HDU, RTU, and NICU facilities. Vivacity will offer treatment services in various disciplines, including cardiology, medical oncology, gastroenterology, gynaecology, and an advanced renal transplant unit, making it the most advanced facility of its kind in East India.

Tata Capital injects $20M in Orbicular Pharma

Tata Capital Healthcare Fund II (TCHF II), the healthcare focused private equity fund of Tata Capital Ltd., has invested an amount of $20 million in Orbicular Pharmaceutical Technologies for an undisclosed equity stake. Orbicular, a Hyderabad-based specialty pharmaceutical company, excelling in developing complex generics for global pharmaceutical markets, will utilise the capital for accelerating the development of product pipeline. The specialty generics industry (market size $60+ billion) is rapidly expanding, driven by increasing demand for cost-effective alternatives to complex and high-cost branded medications. Orbicular has developed a robust pipeline of niche products in the specialty generics space positioning them as an ideal partner for global generic players targeting regulated markets.

KKR invests in Infinx Services

KKR, a leading global investment firm, and Infinx Services, an artificial intelligence (AI)-driven healthcare revenue cycle solutions provider, have announced the acquisition of a significant minority stake in Infinx by a KKR-managed fund. Through this investment, KKR will leverage its extensive experience in the global healthcare and technology sectors to accelerate Infinx's growth, expand the company's network, and support bolt-on acquisitions. Norwest Venture Partners, an existing shareholder, also participated in the transaction. Co-founded in 2012, Infinx is a provider of innovative, data-driven revenue cycle management solutions for the healthcare sector, with a particular focus on the US market. Infinx's Healthcare Revenue Cloud platform supports end-to-end revenue cycle business functions utilising AI, automation, payer integration, and workforce management. Recent reports have valued the US healthcare market at approximately $4.3 trillion, representing over 18 per cent of US GDP.

Aurigene Pharma announces opening of biologics facility in Genome Valley

Aurigene Pharmaceutical Services, a Dr. Reddy's Laboratories company, inaugurated its biologics facility spread across 70,000 sq ft in Genome Valley, a bio cluster, located in Hyderabad. The facility is designed to serve customers with process & analytical development and small-scale manufacturing of antibodies and other recombinant proteins for preclinical and early phase clinical requirements. The process and analytical development laboratories are now operational while the commissioning of manufacturing capacity will be completed later in 2024. The state-of-the-art facility is equipped with best-in-class equipment and control systems, supported by an experienced talent pool that will ensure seamless transfer to large-scale commercial manufacturing facilities. The new facility is complementary to the company's current discovery capabilities and infrastructure, which primarily focuses on recombinant proteins including monoclonal antibodies (mAbs), bi- and multi-specifics, immune-fusion molecules, antibody drug conjugates and other complex proteins. The newly opened Genome Valley facility will deliver robust, compliant and economically viable cell lines, process development solutions and supporting analytical methods in support of customers seeking to rapidly enter and progress through clinical development.

Syngene launches platform for rapid, enhanced protein production

Bengaluru-based Syngene International, a leading global contract research, development and manufacturing organisation (CRDMO), has announced the launch of its new protein production platform. The platform, using a cell line and transposon-based technology in-licensed from Swiss biotech services company, ExcellGene, coupled with Syngene's clone selection and development processes, promises significant improvement in efficiency and precision. The new platform accelerates enhanced protein production, enabling quicker preclinical and clinical development as well as product launches, thereby reducing time to market. It streamlines clone selection and enhances operational productivity. It also supports a wide range of biomolecules including monoclonal antibodies, biosimilars, bispecifics, antibody-drug conjugates and other recombinant proteins. This versatility facilitates integration with both perfusion and fed-batch manufacturing processes.

Torrent Pharma inks agreement with Takeda to commercialise novel gastrointestinal drug in India

Ahmedabad-based Torrent Pharmaceuticals has entered into a non-exclusive patent licensing agreement with Takeda to commercialise Vonoprazan in India. Vonoprazan is a novel potassium-competitive acid blocker (P-CAB), used for the treatment of acid related disorders - Gastroesophageal Reflux Disease (GERD). Torrent will market Vonoprazan under its own trademark, Kabvie. As per a 2019 study published by Indian Journal of Gastroenterology, prevalence of GERD in the Indian population is around 8.2 per cent, with a higher prevalence of around 11.1 per cent in urban population. According to AWACS MAT April 2024 data, the Indian market for treatments used in GERD is valued at Rs 8,064 crore, growing at 8 per cent CAGR over the last 4 years. Currently treatments such as Pantoprazole (Proton Pump Inhibitors) are used to treat GERD. Availability of P-CABs such as Kabvie will make accessible new and effective treatments of GERD for the Indian population.

Enzene unveils new Discovery Services Division

Enzene Biosciences, Pune-based contract development and manufacturing organisation (CDMO) known for its flagship fully-connected continuous manufacturing platform (EnzeneX), has announced the launch of a new Drug Discovery Division. This further expands the CDMO's breadth of services to the biotech industry and complements its EnzeneX equipped biologics manufacturing site, which will open later this summer in the US. Enzene is introducing its new discovery arm to provide end-to-end integrated discovery services in response to the rapidly growing industry demands. The discovery offerings will include antibody services (target validation, discovery and engineering), reagent production ranging from custom peptides & proteins to advanced modalities like plasmids, RNA and exosomes, and multi-platforms assays services. While financial details remain undisclosed, the new Discovery Division will be located at Enzene's Pune facility, with new state-of-the-art discovery laboratories set to be operational by July and further expansions planned later in the year.

Canon eyes strengthening industrial and medical business in India

Highlighting India's crucial role in its global growth strategy, Japanese company Canon has announced its outlined plans for strengthening its core business segments of imaging, printing, and surveillance, along with growing presence in the Semiconductor, Flat Panel Display business and the medical industry. Reaffirming the brand's commitment to India, these announcements were recently made during Canon's strategy meet in Mumbai, attended by key global leadership. With respect to healthcare, Canon has a comprehensive portfolio of advanced medical products and solutions from diagnostic imaging systems and healthcare IT solutions. With India as a key market, Canon further focuses on bolstering the rapidly growing medical business. The brand has established a strong footprint in the digital imaging industry, as an end-to-end solutions provider, having diversified into new markets, broadening its product range and asserting its leadership across customer segments. Canon Medical Systems India is a subsidiary of Canon Medical Systems Corporation in Japan.

Wipro collaborates with Centre for Brain Research at IISc for AI-driven health behaviour innovations

Wipro has announced a collaboration with the Centre for Brain Research (CBR), an autonomous, non-profit research organisation, hosted at the Indian Institute of Science (IISc), Bengaluru. This partnership will focus on harnessing the power of artificial intelligence (AI), machine learning (ML), and big data analytics to develop new technologies that will provide precision support towards the prevention and management of long-term health disorders. Wipro's research & development (R&D) team, part of Lab45, will design and develop a personal care engine, an AI that will take into account an individual's health history, desired health state, and other behavioural responses, to promote healthy ageing, positive lifestyle changes, and psycho-social wellbeing to meaningfully improve an individual's health over time. The personal care engine will focus on reducing and managing the risk of cardiovascular disease and correlated neurodegenerative disorders, by using AI to personalise its interaction with users, optimising for their long-term health and wellbeing. Wipro will test the engine through a digital app-based trial in collaboration with CBR at IISc.

DocPlix raises Rs 1.2 Cr for market expansion

Lucknow-based health-tech startup DocPlix has raised Rs 1.2 crore in a Bridge Round led by Inflection Point Ventures. The funds raised will be utilised for product development, artificial intelligence (AI) integration, and market expansion. This will involve enhancing their electronic health record (EHR) system, incorporating advanced AI capabilities to improve decision support and patient care, and expanding their market reach to bring their innovative healthcare solutions to bigger clinics and hospitals. The company is experiencing rapid growth with its ever growing customer base and a renewal rate of 93 per cent. DocPlix plans to expand globally, starting with the USA in late 2024, aiming to enter lucrative and technologically advanced markets to further amplify its impact in the healthcare sector.

RNT Health Insights receives US FDA breakthrough device designation for early gastric cancer detection tool

Chandigarh-based RNT Health Insights, a clinical stage medical diagnostics startup, has announced that the US Food and Drug Administration (FDA) has granted Breakthrough Device Designation for their Early Gastric Cancer detection tool. The innovative solution is designed to detect lesions present in the upper gastrointestinal tract indicative of Early Gastric Cancer, as well as gastric malignancy, inclusive of gastric atrophy, nodules, polyps, masses and growths present in the stomach, in real-time during standard endoscopy examinations. RNT Health Insights' Early Gastric Cancer detection technology can be used in real-time during endoscopic procedures to detect these pathologies, and currently displays a detection accuracy of 96 per cent in accordance with the preclinical validation conducted. With the Breakthrough Device Designation, RNT Health Insights will benefit from an expedited review pathway to obtain the necessary permits for marketing their device. The company anticipates this will accelerate the timeline for bringing their innovative tool to market, ultimately benefiting patients and healthcare providers.

Innominds, SCIINV Biosciences unveil AI-driven solution to combat AMR

Innominds, a US-based digital transformation and product engineering company, has announced its partnership with Hyderabad-based startup SCIINV Biosciences to introduce AMRx, an advanced AI/ML-driven digital diagnostic tool designed to combat the growing threat of antimicrobial resistance (AMR). This innovative tool promises to revolutionise the detection and treatment of antibiotic-resistant infections without the need for traditional cultures. AMRx leverages patient clinical history to accurately predict UTIs, identify causative organisms (Enterobacteriaceae), and determine antibiotic resistance or susceptibility patterns without the need for traditional cultures. By reducing unwarranted clinical investigations, AMRx saves valuable time, effort, and resources. This efficiency is particularly beneficial in resource-limited settings. AMRx can be deployed as a clinical decision support tool, aiding healthcare professionals in making appropriate empirical antibiotic prescriptions, thereby enhancing the accuracy and effectiveness of treatment.

IOTA Diagnostic receives CDSCO approval for cervical cancer screening test

IOTA Diagnostic, Ahmedabad-based medtech startup, has announced a significant milestone with the recent approval of its groundbreaking M-Strip device by the Central Drugs Standard Control Organization (CDSCO). The M-Strip is an indigenously built novel advancement for cervical cancer screening which empowers women to mark themselves safe by self-sampling in the comforts and privacy of their homes. This revolutionary

method for cervical cancer screening using menstrual blood, follows a study conceptualised by Dr Somesh Chandra, the principal investigator, which was carried out in collaboration with Sterling Accuris, a leading diagnostic chain in northwest India. Vaibhav Shitole, the founder of IOTA Diagnostic, alongside Dr Somesh Chandra, a renowned oncologist from Ahmedabad and Rajiv Sharma from Sterling Accuris are the inventors and Co-Filers of the patent for the M-Strip device. Recently, the company was granted a design patent for the device by the Indian Patent Office.

Pristyn Care joins hands with Ortho Sport to establish CoE for sports injuries

Gurugram-based startup Pristyn Care, a leading healthcare provider, has partnered with Ortho Sport to establish a state-of-the-art Centre of Excellence (CoE) for Sports Injuries. This collaboration aims to deliver top-tier sports injury treatments and rehabilitation programmes, featuring cutting-edge technology and expert care. The new centre, spanning 4,000 square feet, is designed to provide the latest in sports therapies. It will offer a comprehensive Athlete Rehabilitation Programme, addressing the specific needs of athletes recovering from injuries. The facility is equipped with the latest advancements in sports medicine to ensure optimal recovery and performance enhancement. The centre will utilise advanced surgical tools such as the ACL REPAIR with internal brace, ACL RECONSTRUCTION QuadPro Harvester, internal brace and FiberTag TightRope Implants, AUTOCART Cartilage transplant, ensuring the highest standards of care and precision. In addition to the physical centre, Pristyn Care has introduced a new WhatsApp integration, allowing patients to securely share MRI scans directly through the messaging platform.

UP opens first government hospital-based medical incubation centre in Greater Noida

First public hospital-based medical incubation centre in Uttar Pradesh has been officially opened at the Government Institute of Medical Sciences (GIMS), Greater Noida. This centre is set to revolutionise healthcare innovation by providing a platform for medical startups and researchers to develop groundbreaking solutions. The mission is to foster collaboration and drive advancements that will transform patient care and the overall healthcare ecosystem. This Medical Incubation Centre has been developed in partnership with Stanford University's Biodesign, ensuring cutting-edge innovation and collaboration. This incubator at GIMS will enhance accessibility to clinical mentoring, validation testing, and much more, driving medical innovation to new heights.

MediTech Stackathon 2024 to Drive Explosive Growth

India's medtech industry holds immense potential, with projections estimating a growth rate of 28 per cent annually, reaching a size of $50 billion by 2030. Currently, India is the fourth largest market for medical devices in Asia and among the top 20 globally. Net imports for 2022-23 stands at $4.101 billion with import coverage ratio of 0.45. The sector has witnessed a surge in imports, driven primarily by countries like the US, China, and Germany, however, India's robust policy ecosystem presents opportunities for exports and reducing import dependence through domestic manufacturing. Exports have overtaken imports in consumables and disposables during last year. The industry now needs to continue with the momentum in other pillars of the medtech sector. Against this backdrop of immense potential, the Department of Pharmaceuticals launched Meditech Stackathon 2024, which seeks to harness the collective expertise of stakeholders to propel the industry towards unprecedented heights of innovation and self-reliance. With optimal support and participation from all stakeholders, initiatives like Meditech Stackathon will take the Indian medtech industry to the next levels to become self-reliant.

India's medtech sector has shown a promising growth trajectory over the past decade. It is a fast-growing industry today, holding strong potential for technological innovations and making unique industrial transformative strides. Being the world's second most populous country with a rising number of diseases, effective healthcare delivery to improve health outcomes is important. While India hosts an impactful healthcare professionals' ecosystem and is home to an excellent pharmaceutical domain, there is a wide gap in healthcare delivery to patients. The development and incorporation of medical devices and technology in healthcare can be a key factor in bridging this gap.

In the past few years, new dedicated policies and initiatives have been introduced to boost the growth and development of India's medtech sector. Some of the significant ones from the recent past include the National Medical Devices Policy from April 2023, the Production Linked Incentive (PLI) Scheme for medical devices, under which new medical device manufacturing parks will be developed to foster indigenous manufacturing of medical devices; and, in August 2022, the Department of Pharmaceuticals reconstituted the National Medical Devices Promotion Council (NMDPC) under the Chairmanship of the Secretary of the Department of Pharmaceuticals.

Continuing the momentum and supporting this niche space, the Meditech Stackathon initiative launched on May 7, 2024 by the Department of Pharmaceuticals (DoP) in collaboration with the Confederation of Indian Industry (CII) is an important one. During the launch of the Meditech Stackathon, Dr Arunish Chawla, Secretary of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers emphasised the importance of policymakers and industry coming together to draw up a sturdy policy stack for the growth of the medical devices industry in the country. The Meditech Stackathon is 'designed to catalyse transformative change within India's burgeoning medtech sector by undertaking a comprehensive value chain analysis of select medical devices'. It will serve as a platform to bring together policymakers, industry players, healthcare professionals, and experts to strategise the growth of India's medical devices sector.

Prospects and obstacles

The World Health Organisation (WHO) defines a medical device as 'any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose.' Such a multi-faceted industry spanning several segments, the medtech sector can present its fair share of challenges and opportunities. Streamlining industry operations and establishing strong market growth could enable better accessibility of quality healthcare and affordability to a larger proportion of India's population. Medical technology innovation can be a significant tool to make this possible by lowering the cost of the product or delivery.

The key focus of the Stackathon will be to identify critical challenges and opportunities and carry out a comprehensive value chain analysis of the various segments of the medtech industry. In addition, the Stackathon initiative will also focus on targets of reducing import dependence and building a strong and self-sufficient domestic manufacturing of medical devices.

Dr Arunish Chawla, during the launch of Meditech Stackathon, highlighted the critical need to focus on quality to ensure that India becomes globally competitive. Through the Stackathon, Dr Chawla said, the participants will delve into the complexities of different product segments within the medical devices industry to gain insights into their unique challenges and opportunities, analyse and map value chains across various segments of the medical devices industry to identify key stakeholders, processes, and dependencies, identify critical issues hindering the development of the medical devices industry, such as import dependence, regulatory hurdles, and technological gaps.

Regulatory landscape

Focussing on the quality of medical devices and related regulatory frameworks will be instrumental in increasing the market penetration and trust factor at the consumer end for indigenously manufactured medical devices and equipment. Gauging the ground reality through primary and secondary healthcare providers, and driving effective and continuous dialogue between the key stakeholders – from doctors to industry leaders and policymakers – would be crucial in ensuring the highest quality and safety standards are met in the medical devices sector. Initiatives like Meditech Stackathon could help streamline regulatory policies and quality standards and provide a simultaneous boost to domestic production of innovative medical devices; a factor that can prove crucial for the holistic growth of India's medtech sector.

This is especially important in view of

reports around India being at the receiving end of refurbished medical devices and equipment. According to recent reports, the Patient Safety and Access Initiative of India Foundation (PSAIIF) has filed a writ petition, in the nature of a Public Interest Litigation (PIL). The PIL arises from concerns regarding the laxity in the regulatory framework concerning the quality, safety and efficacy assessment of second-hand or used medical devices, which are compromising the standard of health services in the country. The cause of action also arises in view of refurbished medical devices posing an inherent safety risk to the life of the general public at large. Some of the overseas multinational companies are importing refurbished/ reconditioned medical devices, such as robotic surgical systems. The cause of action in the nature of a PIL inter alia also arises from the risks associated with India being made a dumping ground for such pre-used/refurbished/reconditioned medical devices.

A wholly indigenously operating medtech company, Gurgram-based SS Innovations has been developing cutting-edge, first-in-India robotic surgical systems, with a dedicated goal of making advanced robotic surgeries cost-effective and accessible to a global population. SS Innovations is also driving innovations in Telesurgery. Dr Sudhri Srivastava, Founder and CEO of SS Innovations shared his views on how the Meditech Stackathon can address issues of domestic manufacturers and increase the overall trust in Indian brands in the medtech sector. "The whole initiative of 'Make in India' must become a reality. We continue to import a majority of devices, nearly 80 per cent. Refurbished devices and equipment are imported. Government should take actions in the direction of discouraging imports in general, especially in reducing imports of refurbished equipment."

Stressing the fact that India not having the kind of technology yet increases dependence on this kind of import, Dr Srivastava added, "The only way to address these issues is to build the technologies in India by fostering innovations. Innovations take time and money and boosting investments in the sector will be the key to encouraging advanced medical technologies in India. He added that the government's help to the medtech sector in this regard would also be needed to reduce the duty on some imported devices to make affordable healthcare delivery accessible to a larger percentage of our population. He also emphasised that there is a huge need for the right kind of governmental support to build an enabling and holistic infrastructure in the medtech sector to achieve a

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- Dr Sudhir Srivastava,
Founder, Chairman & CEO, SS Innovations International

"The right laws are in place to prevent import of refurbished and outdated devices, but their implementation is the main problem. Meanwhile there is a bias among healthcare professionals in using indigenous medical devices even now. India is a leader in technological advancements, and domestic manufacturing of advanced, technology-heavy medical devices needs to be boosted."

- Prof. Dr Somashekhar SP,
Chairman – Medical Advisory Board, Aster DM Healthcare (GCC & India) and Board of Director, SS Innovations International

"As we navigate the evolving landscape of medtech in India, harmonising Indian regulations and standards with global best practices will be the keystone which will not only attract international investment in the sector but will also enable Indian manufacturers to get greater acceptability of their products in global markets, furthering the 'Make in India' objective of the government and keeping India aligned to global supply chains."

- Pavan Choudary,
Chairman, Medical Technology Association of India (MTaI)

collective goal of equitable healthcare, especially in rural areas.

Speaking about how initiatives like Meditech Stackathon can help address such issues, Prof. Dr Somashekhar SP, Chairman – Medical Advisory Board, Aster DM Healthcare (GCC & India) and Board of Director, SS Innovations International shared that the right laws are in place to prevent import of refurbished and outdated devices, but their implementation is the main problem. He also added that there is a bias among healthcare professionals in using indigenous medical devices even now. Further elaborating on the 'Make in India' initiative, he opined that India is a leader in technological advancements, and domestic manufacturing of advanced, technology-heavy medical devices needs to be boosted.

Sharing his views Pavan Choudary, Chairman, Medical Technology Association of India (MTaI) said, "As we navigate the evolving landscape of medtech in India, harmonising Indian regulations and standards with global best practices will be the keystone which will not only attract international investment in the sector but will also enable Indian manufacturers to get greater acceptability of their products in global markets, furthering the 'Make in India' objective of the government and keeping India aligned to global supply chains. We feel that domestic and international trends will together help carve out key policy recommendations that will be instrumental in furthering the medtech industry in India."

'Make in India' ventures

Aligning to initiatives such as 'Atmanirbhar Bharat' and 'Make in India', supported by the government's schemes such as the Production Linked Incentive (PLI), global medtech leading companies have taken strides in advancing their footprints in India aligning with the direction of domestic manufacturing and overall indigenous advancements in medical technology in India.

Dublin headquartered medtech leader, Medtronic, has significant operations in India, including manufacturing facilities. Over the past few years, Medtronic has introduced plans for advancing medical technology in the Indian market. In 2020, the company opened a Medtronic Engineering & Innovation Center (MEIC) in Hyderabad to support their global operations; and in May 2023, Medtronic announced an investment of approximate Rs 3,000 crore ($362.8 million) to expand the MEIC centre in India. The MEIC is Medtronic's largest R&D centre outside the USA. Additionally, in 2023, Medtronic announced a partnership with Qure.ai to integrate artificial intelligence (AI) for advanced stroke management in India. In 2021, Medtronic India introduced a surgical robotics experience centre in Gurugram to help clinicians with robotic-assisted surgery technology

In 2022, Wipro GE Healthcare, announced the launch of its new manufacturing facility in Bengaluru, under the Indian government's PLI Scheme. The new facility was launched to further boost local manufacturing of medical devices in India. The company has invested around Rs 100 crore in this facility. Wipro GE Healthcare has also launched its next-generation Revolution Aspire CT (Computed Tomography) scanner in 2022, an advanced imaging solution designed and manufactured end-to-end in India.

With the government emphasising early diagnosis of Non-Communicable Diseases (NCDs) and self-reliance, through 'Ayushman Bharat', there is an increased demand for advanced medical devices. The Revolution Aspire CT aims to address this need and enable access to quality medical equipment across India, including tier 2 and tier 3 cities. Commenting on this development of end-to-end manufacturing in India, Dr Devi Shetty, Founder and Chairman of Narayana Health said, "Access to healthcare has been deeply asymmetric in India and innovative medical technology products will help bridge this gap. We are witnessing this change with cutting-edge, locally manufactured, and affordable products such as the Revolution Aspire CT scanner helping democratise the market, taking quality healthcare to tier 2 cities and beyond. It is critical for all health centres, big and small, to have access to quality diagnosis."

Additionally, earlier this year Wipro GE Healthcare strides towards further strengthening a 'Make in India' initiative. The company signed an MoU with IISc, Bengaluru to advance medtech innovation from India – 'for India and the world'. The company also announced an investment of over Rs 8000 crore in manufacturing output and local R&D over the next five years.

In 2020, Siemens Healthineers announced an investment of $179.7 million for a period of five years till 2025 to establish an innovation hub in Bengaluru. The innovation hub will focus on the design and development of entry-level products. Expanding its manufacturing footprint in India, it has launched a new production line of Computed Tomography scanners approved under the Government of India's PLI scheme. Additionally, the company also inaugurated an MRI facility at Bengaluru, under the Government of India's PLI scheme. In 2022, Stryker inaugurated

a neurovascular research lab at Stryker's Global Technology Centre (SGTC) in Gurugram to develop innovative solutions for brain stroke.

Expressing his views on how the Meditech Stackathon initiative is poised to boost the medtech industry, Falgun Jani, Business Head – India, Freudenberg Medical said, "Meditech Stackathon is a much needed and timely initiative that will definitely help to propel the growth of India's medtech industry. Thoughtful selection of 8 chosen medical device segments will encourage more collaborative activities amongst various stakeholders that are involved either directly or indirectly with these segments. Such initiatives will help foster domestic manufacturing, reducing import dependence, and positioning India as a frontrunner in the global medtech arena. Some of the important aspects are the analysis of import-export dynamics & supply chain of these devices, the formation & implementation of industry-friendly policies, and streamlining of the regulatory framework. Through close collaboration and concerted efforts, the initiative aims to address critical challenges, stimulate innovation, and unlock the full potential of India's medtech industry."

A robust domestic market

Increasing penetration of medical technology into the Indian healthcare ecosystem to grow the medtech market can be a key factor in the overall development of this fast-growing sector. Frugal innovations across the value chain in areas of product development, technology, marketing, business modelling, service delivery, etc. to increase market penetration and drive the growth of the indigenous market.

Given that the Stackathon initiative is designed to drive transformative change in India's growing medtech sector, catering to the needs of domestic businesses to boost market growth will be a crucial factor.

Speaking about factors that can help to create and drive strong market demand for innovative medical devices within India, Amit Gandhi, Founder & CEO of Insight Tribe, said that government initiatives like incentivising domestic manufacturing can help in creating a more robust ecosystem for innovative devices and potentially lower costs for consumers. In line with this crucial factor, he added, "Innovation tailored to Indian needs by developing cost-effective, yet high-quality, medical devices suitable for the Indian market will be crucial for wider adoption. A focus on innovation in devices for the prevention, diagnosis, and management of India's specific

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Founder and Chairman, Narayana Health

"Going forward from the industry we requested Department of Pharmaceuticals to organise segment wise workshops to build on the Stackathon findings, bridge the gaps and strengthen the value chain analysis to decide on the production linked and research linked incentive schemes, which will give a major boost to domestic manufacturing in India, making us more Atmanirbhar, and joining forces with the Government of India towards a 'Viksit Bharat."

- Dr Rajiv Chhibber,
Vice President External Affairs,
Sahajanand Medical Technologies

“The Stackathon aims to taper import dependence and position India as a frontrunner in medical technology on the global stage”

Himanshu Baid, Chairman, National Medical Technology Forum (NMTF), Confederation of Indian Industry (CII) & Managing Director, Poly Medicure Ltd.

The Confederation of Indian Industry (CII) in collaboration with the Department of Pharmaceuticals, Government of India is organising the Meditech Stackathon 2024. In an interaction with BioSpectrum India Himanshu Baid, Chairman, National Medical Technology Forum (NMTF), Confederation of Indian Industry (CII) & Managing Director, Poly Medicure Ltd. shared his views on current challenges and opportunities India’s medtech sector presents, and how the Meditech Stackathon is set to address these challenges and boost the growth of this industry. Edited excerpts;

How will Meditech Stackathon help to bridge the gaps in the Indian medtech sector’s regulatory standards and compliance framework?

The Meditech Stackathon, a ground-breaking initiative by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers in collaboration with CII, serves as a pivotal platform to address regulatory gaps within India’s medtech sector. By fostering collaboration between industry experts, policymakers, and regulatory bodies, this initiative facilitates dialogue and ideation to enhance regulatory standards and compliance frameworks. Through workshops, and panel discussions, participants identify key challenges, propose innovative solutions, and establish best practices to ensure the safety, efficacy, and quality of medical devices.

By harnessing collective expertise and leveraging technology-driven approaches, the Stackathon accelerates progress towards a robust regulatory ecosystem, ultimately fostering growth, innovation, and trust within the Indian medtech industry.

How can the Stackathon initiative serve to create and drive a strong enough market demand for innovative medical devices within India?

The Meditech Stackathon aims to stimulate market demand for innovative medical devices by convening focused groups to address critical aspects of the industry. These groups, spanning various sectors such as Cancer Therapy, Imaging, and Critical Care, meticulously analyse segment-specific medical devices, import-export dynamics, duty structures, and their implications on the value chain. Prior to the workshop, group leads and members engage in extensive virtual discussions and preparatory work to ensure comprehensive insights. Despite persistent challenges like cost competitiveness, quality assurance, and regulatory hurdles, the Stackathon serves as a catalyst for collaboration and innovation.

What will be the priority areas of focus for the Meditech Stackathon?

The Stackathon represents a pioneering initiative poised to drive transformative change in India’s growing medtech sector. It prioritises a thorough value chain analysis of key medical devices, engaging industry leaders, policymakers, and experts. By addressing critical challenges and promoting domestic manufacturing, the Stackathon aims to taper import dependence and position India as a frontrunner in medical technology on the global stage. Priority areas of focus include enhancing innovation, streamlining regulatory processes, ensuring quality assurance, and promoting accessibility and affordability of medical devices. Through collaborative efforts and strategic interventions, it endeavours to propel the growth and advancement of the Indian medical device industry.

How can Meditech Stackathon target the upliftment and advancement of the different levels of businesses - startups, MSMEs, and SMEs in the medtech sector?

It plays a pivotal role in advancing and uplifting startups, MSMEs, and SMEs in the Indian medtech sector. Recognising their significance as the backbone of the industry, the Stackathon provides a platform for these businesses to highlight identified gaps to policymakers and other key stakeholders. Through this collaborative effort, they can advocate for conducive policies that support domestic manufacturing, export growth, and reducing import dependence. Furthermore, startups, MSMEs, and SMEs contribute to innovation, agility, and localised solutions in the medtech industry. Their role is crucial in addressing diverse healthcare needs, especially in underserved regions.

What hurdles and opportunities do you foresee in the development and streamlining of a holistic infrastructure needed for boosting India's medtech sector growth?

Developing and streamlining a holistic infrastructure for boosting India's medtech sector growth presents both challenges and opportunities. Hurdles include navigating complex regulatory frameworks, ensuring compliance with international quality standards, and addressing infrastructure gaps, particularly in rural areas. Additionally, fostering a culture of innovation and entrepreneurship requires investment in research and development, as well as building a skilled workforce capable of driving technological advancements.

However, there are significant opportunities to capitalise on India's demographic dividend, abundant talent pool, and growing healthcare needs. Leveraging digital technologies, such as telemedicine and artificial intelligence, can enhance healthcare delivery and accessibility, especially in remote areas. Moreover, strategic collaborations between industry, academia, and government can spur innovation, facilitate technology transfer, and attract investment. By focusing on these opportunities and addressing challenges proactively, India can position itself as a global hub for medtech innovation, driving economic growth and improving healthcare outcomes nationwide. BS

"Innovation tailored to Indian needs by developing cost-effective, yet high-quality, medical devices suitable for the Indian market will be crucial for wider adoption. A focus on innovation in devices for the prevention, diagnosis, and management of India's specific disease burdens/ health conditions, will be a particularly attractive factor. Also, encouraging the use of locally sourced materials and components can further reduce manufacturing costs & create a more sustainable supply chain."

- Amit Gandhi,
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Business Head – India, Freudenberg Medical

India's medtech sector is a fast-growing industry poised to achieve exponential progress. Several policies and initiatives are in place or expected to be introduced, and key stakeholders at all levels of the medtech sector seem to be carrying the torch forward to see India through to the pinnacle of a global medtech hub. The government's help through initiatives like the Meditech Stackathon and a robust policy and regulatory framework will be instrumental in orchestrating this progress.

disease burdens/health conditions, will be a particularly attractive factor. Also, encouraging the use of locally sourced materials and components can further reduce manufacturing costs and create a more sustainable supply chain."

"Growing public awareness about health issues and preventive care will create a market for innovative devices for early detection and treatment. An untapped rural market, where expanding healthcare access to rural areas, presents a significant opportunity for affordable and portable medical devices", said Amit Gandhi.

He further added that a rising disposable income, increased insurance penetration, and increased health awareness; in addition to important government initiatives are some factors that can accelerate a strong market demand for innovative medical devices within India. He said, "As insurance coverage expands, patients become more open to considering advanced medical procedures that were previously cost-prohibitive. Some insurance plans cover the cost of certain medical devices, such as pacemakers or insulin pumps. This makes these devices more accessible to patients, further stimulating the medtech market."

Harmonious to this, leveraging on the opportunities presented by the development and streamlining of a holistic infrastructure needed for boosting India's medtech sector growth can also aid in driving the sector's growth and expansion.

Sharing his views on how the Meditech Stackathon initiative is poised to boost the medtech industry, Dr Rajiv Chhibber, Vice President External Affairs, Sahajanand Medical Technologies, said, "The Meditech Stackathon is a much-needed step as India grows to become a net exporter in the long run, and also significantly reduce import dependency in high-end medical devices. The fact that Dr Arusnish Chawla emphasised the necessity of anchoring the policy stack on a solid foundation, encompassing precise economic classifications such as HSN and NIC Codes, meticulous assessment of tariffs and taxes at each stage of the value chain gives an impetus to manufacturers and helps them to overcome obstacles within the medtech domain including the need for standard harmonisation, supply chain, raw material and even post market surveillance and streamlining the regulatory landscape so that better and ease of doing business can be enhanced, side by side, making India a net exporter in earmarked devices."

Further adding on what needs to be priority areas of focus for the Meditech Stackathon, Dr Chhibber said that the industry had highlighted the imperative of identifying and mitigating policy arbitrage, spanning price, quality, taxation, incentive structures, and regulatory frameworks that need to be relooked at when discussing Ease of Doing Business. With optimal support and participation from all stakeholders, initiatives like Meditech Stackathon are set to make this a reality in the coming years, as India continues to grow its global standing as a leading country in Science and Healthcare innovations and technology. "From the industry we requested the DoP to organise segment-wise workshops to build on the Stackathon findings, bridge the gaps and strengthen the value chain analysis to decide on the production-linked and research-linked incentive schemes, which will give a major boost to domestic manufacturing in India, making us more Atmanirbhar, and joining forces with the Government of India towards a Viksit Bharat", added Dr Chhibber.

All in all, India's medtech sector is a fast-growing industry poised to achieve exponential progress. Several policies and initiatives are in place or expected to be introduced, and key stakeholders at all levels of the medtech sector seem to be carrying the torch forward to see India through to the pinnacle of a global medtech hub. The government's help through initiatives like the Meditech Stackathon and a robust policy and regulatory framework will be instrumental in orchestrating this progress. A growing medtech sector fuelled by innovations and collaborations could bridge the gaps between critical healthcare delivery, including accessibility and affordability, in India. It remains to be seen how this eventuates. BS

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Setting Bigger Targets for Next-gen Vaccines

New vaccine platform technologies could dramatically shorten the period from research to development, clinical trials, and vaccination. Reimagining R&D approaches in vaccine design and vaccine immunology may hold the key to significantly elevate the health impact of vaccines. Experts worldwide are adopting novel research approaches in the molecular design of vaccines, and vaccine technology platforms. India is seeing increasing interdisciplinary research, and a rise in cutting-edge technological interventions in fundamental and translational research. The time is ripe for boosting out-of-the-box R&D approaches in vaccinology. Let's explore further.

The National Institute for Allergy and Infectious Diseases (NIAID), one of the 27 institutes and centres that make up the National Institutes of Health (NIH) of the US, referred to next-generation vaccines as those with enhanced breadth of protection to variants, improved durability, and enhanced ability to block infection/transmission relative to currently approved vaccines. The Coalition for Epidemic Preparedness Innovations (CEPI), a global partnership working to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic, describes vaccine technology platforms as technologies that are essential for rapid responses to emerging viral threats.

Essentially, vaccine platform technologies are systems that use the same basic components as a backbone but can be adapted for use against different pathogens by inserting new genetic or protein sequences. Rational vaccine design, developed using

suitable vaccine technology platforms, could thus present significant advantages in immunisation. Creating such an unprecedented disease agnostic vaccine technology platform can empower the world to be ready for future pandemics. Studies have shown that next-generation vaccines can enable a higher spectrum of protection against multiple variants, increased durability, and minimal safety concerns due to side effects while increasing their immunogenicity.

Each vaccine's utility or efficiency is determined by its formulation, adjuvants, and mode of action. The efficacy of the vaccination depends on numeral properties like the generation of antibodies, memory cells, and cell-mediated immunity.

Studies on COVID-19 immunisation have shown that next-generation vaccines hold promise in generating long-lasting, broad immunity against virus variants. Since the launch of the first COVID-19 mRNA vaccine, continuous developments in improving mRNA vaccine technology for the SARS-COV2 virus are underway all over the globe. Research approaches from reverse vaccinology and immunoinformatics to continuous-replicating mRNA carrying the antigen of interest are being used to develop new vaccine platforms and improve the current lot of next-generation vaccines. For the larger goal of enhanced immunogenicity, researchers are exploring new antigenic epitopes, the role of immune cell subtypes, and unique adjuvant or delivery vehicles to generate better immune responses.

Approaches such as exploiting the role of mRNA modifications in attuning their immunogenicity, stability, and translational efficiency are important examples. Research into mRNA modifications has yielded multiple candidate mRNA therapeutics undergoing clinical or preclinical trials, as well as effective SARS-CoV vaccines. The COVID-19 mRNA vaccine highlights that using structurally modified mRNA allows for increased dose tolerance and may be better for eliciting a rapid antibody response. The new mRNA COVID-19 vaccine of Moderna, mRNA-1283, designed for multiple SARS-CoV-2 strains found to offer improved neutralising antibody response in individuals more than 65 years of age.

A team from the Yong Loo Lin School of Medicine at the National University of Singapore and Monash University, Australia has engineered a COVID-19 vaccine using a novel vaccine platform to fuse the receptor binding domain of the spike protein of the SARS-COV-2 virus to Clec9A antibody (an antibody against the receptor on dendritic cells presenting antigen to T and B cells to generate immune response). This construct showed long-lasting immunity till 21 months in a preclinical study after only a single dose. This would be a promising approach against waning immunity and a useful strategy for adults above 60 years by eliminating the need for repeated boosting.

The platform of the vaccine, number of doses for immunisation, the production capacity, and vaccine storage condition are all important for the rapid development of the vaccine from laboratory to clinical trials and approval. In addition, vaccine designs that can reduce safety concerns hold the advantage of crossing regulatory hurdles and approval stages in a reasonably short period. Moreover, a focus on next-generation vaccines and novel delivery methods, such as intranasal vaccines, may exhibit more effective and user-friendly vaccination strategies. This can prove crucial in India, owing to factors like the emergence of tropical infections, an overall vaccine hesitancy, a large population to vaccinate, and enabling wide-spread accessibility of vaccines, especially in rural areas.

Fostering an ecosystem for R&D in vaccinology could aid in directing focus toward vaccine discovery, vaccine design, and formulation, as well as vaccine administration methods. Experts across different verticals in this field are now making efforts to build an infrastructure to deliver effective but economical vaccines. This could help to achieve a better sense of preparedness for emerging diseases as well as an all-round improvement of the health impact of vaccines, particularly in the cases of HIV, dengue, malaria, and tuberculosis, which have been outsmarting scientists for decades. In addition, some at-risk groups show even low responses to the vaccines or the existing vaccine have severe side effects and need further development of suitable or more immunogenic vaccines (e.g., for elderly individuals or infants).

Given this scenario, enhancing efforts in the development of next-generation vaccines can hold a promise in protection against emerging and re-emerging infections.

"To enhance fundamental research in vaccinology in India, a multifaceted approach is necessary. Though India is at the forefront of vaccine manufacturing, there is a pressing need to climb the value chain and become a leader in vaccine research and innovation", said Dr Pragya Yadav, Director in Charge, National Institute of One Health, Nagpur and Scientist 'F' and Group Leader, Maximum Containment Laboratory, Indian Council of Medical Research-National Institute of Virology, Pune.

A report on 'Cost Modeling Vaccine Manufacturing' by Merck sheds light on a comparative analysis of the new-generation vaccine development.

Comparison of different vaccine modalities

Modality	Development Speed	Flexibility	Production Duration (batch) *	Cost per Dose (USD)	Stability	Selling Price (USD)	Biosafety Hazard to Personnel	Facility Complexity	Adjuvant
Inactivated vaccine	++	+	+++	++	+++	+	High	High	Yes
Protein subunit vaccine	+	++	++	+	++	++	Medium	Medium	Yes
Virus-like particles (VLP) vaccine	+	++	++	+	++	++	Medium	Medium	Yes
mRNA vaccine	+++	+++	+	+++	+	+++	Low	Low	No

*** Production duration per batch in this model study in days.**

Source: 'Cost Modeling Vaccine Manufacturing: Estimate Production Costs for mRNA and other Vaccine Modalities' report by Merck

Next-gen vaccines in India

Nucleic acid vaccines, viral vector-backbone-based vaccines, and protein subunit vaccines are vaccine platforms being explored for new-generation vaccine developments in many countries. The advent of the COVID-19 pandemic brought the mRNA technology to the forefront. Beyond Pfizer and Moderna, who were pioneering leaders in bringing mRNA vaccine platform to the community, the indigenously developed 'GEMCOVAC-19' vaccine is the only third mRNA vaccine to be approved for COVID-19 in the world, and is the very first mRNA vaccine developed in India in June 2023. Developed by Pune-based Gennova Biopharmaceuticals in collaboration with Department of Biotechnology (DBT), this Omicron-specific mRNA (booster) vaccine 'GEMCOVAC-OM' is thermostable, which does not require ultra-cold chain infrastructure used for other approved mRNA-based vaccines, making it easy for deployment pan India. It is delivered intradermally using a needle-free injection device system.

Upon Drug Control General of India (DCGI) approval for 'GEMCOVAC-OM' for Emergency Use Authorisation (EUA), in June 2023, Dr Jitendra Singh, Union Minister (Independent Charge), Ministry of Science and Technology, commended the efforts of the DBT said, "I take great pride in DBT fulfilling its mission yet again, enabling technology-driven entrepreneurship through creating this indigenous mRNA-platform technology. We have always supported technology-driven innovation towards the creation of a 'future-ready' technology platform in line with the Prime Minister's vision of Aatmanirbharta." He added, "Infrastructure to deploy vaccines in India, including LMICs, at 2-8°C exists today & this innovation is tailored for the existing established supply-chain infrastructure. The vaccine does not need ultra-low temperature conditions for transport and storage."

Dr Rajesh S Gokhale, Secretary, DBT, and Chairperson, Biotechnology Industry Research Assistance Council (BIRAC) said "Strategic infusion of funds is essential to drive and create an ecosystem for technological innovation. DBT did just that when it provided support for the development of the nation's first mRNA-based platform technology in 2021-22 and development of GEMCOVAC-19'

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- Dr Jitendra Singh,
Union Minister (Independent Charge), Ministry of Science and Technology

"Strategic infusion of funds is essential to drive and create an ecosystem for technological innovation. DBT did just that when it provided support for the development of the nation's first mRNA-based platform technology in 2021-22 and development of GEMCOVAC-19' vaccine. This is a disease-agnostic platform and can be used to make other vaccines in a relatively short developmental timeline."

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vaccine. This is a disease-agnostic platform and can be used to make other vaccines in a relatively short developmental timeline."

Researchers at IIT-Delhi, led by Dr Jayanta Bhattacharya at the institute's Centre for Biomedical Engineering, developed a novel nanovesicle presenting spike protein on the surface of the dendritic cell-derived extracellular vesicles (DEVs) for use as a potential vaccine platform against SARS-CoV-2. Their research explored an approach to establish the immunogenic nature of DEVs and could demonstrate that a low dose of DEVs induces antibodies to inhibit SARS-CoV-2 infection in vitro. This warrants that with this approach, IIT Delhi researchers effectively developed a COVID-19 vaccine prototype using the body's own immune cells.

iNCOVACC, Bharat Biotech's intranasal vaccine for COVID-19, was designed and developed on a novel adenovirus vector. The vaccine demonstrated stimulation of a broad immune response and has the advantage of being non-invasive and needle-free with high compliance. Additionally, the vaccine design and development protocol allows for scalable manufacturing, to even meet global demand. The DCGI under the Central Drug Standards Control Organisation (CDSCO) has granted permission for the sale or distribution of iNCOVACC for immunisation against SARS-CoV-2 virus infection for the age group ≥18 years, for restricted use in emergency situations in public interest. The iNCOVACC vaccine is perhaps an all-round example of a rational vaccine design on a new-generation vaccine technology platform with intranasal delivery as compared to injections.

Speaking about the Indian scenario of next-generation vaccine development, Dr Pragya Yadav said "India's efforts in the development of next-generation vaccines, particularly during the COVID-19 pandemic, reflect its commitment to leveraging innovation and collaboration to address public health challenges. With a focus on mRNA and viral vector vaccine platforms, India has made significant strides in expanding its vaccine portfolio and contributing to global vaccination efforts."

"With a focus on improving efficacy, safety, and ease of administration, Indian researchers and companies have been exploring innovative vaccine platforms such as DNA vaccines, mRNA vaccines, and viral vector vaccines. One notable area of focus has been the exploration of mRNA vaccine technology. This cutting-edge platform, which has demonstrated remarkable success in the development of COVID-19 vaccines elsewhere, holds promise for India's vaccine portfolio - GEMCOVAC-19 by Genova

Biopharmaceuticals, and the viral vector vaccines - iNCOVACC by Bharat Biotech. India's strong manufacturing capabilities have further bolstered its position in the development of next-generation vaccines. The country's robust pharmaceutical industry and established infrastructure for vaccine production enable rapid scaling and distribution of advanced vaccine candidates. This manufacturing prowess has been instrumental in accelerating the availability of next-generation COVID-19 vaccines, thereby contributing to the global vaccination effort", she elaborated.

Zydus Cadila's ZyCoV-D, the world's first and India's indigenously developed DNA-based vaccine for COVID-19 is another significant milestone. It was developed by Zydus Cadila in partnership with the DBT, and implemented by BIRAC under the Mission COVID Suraksha. The vaccine received approval for EUA from the DCGI in August 2021, just over a year since the COVID-19 pandemic hit India. The plug-and-play technology on which the plasmid DNA platform is based can be easily adapted to deal with mutations in the virus, such as those already occurring. In addition, studies have shown, including Zydus's own analysis, that DNA vaccines are stable at higher temperatures, making storage and distribution easier.

A tetravalent dengue subunit vaccine, DSV4, developed by the International Centre for Genetic Engineering and Biotechnology (ICGEB) is a single-component, non-replicating '4-in-1' vaccine based on a virus-like particle (VLP) platform, produced using the methylotrophic yeast Pichia pastoris. In 2016, ICGEB transferred the dengue vaccine technology licence to Sun Pharma for further development. Process scale-up has been conducted in the Sun Pharma affiliated biotech company in Germany in 2019, and has been brought back to India for in-house development under the National Biopharma Mission, Government of India. A GMP facility of Sun Pharma is being established in Bangalore and efforts are being made to reach Phase 1 efficacy trials.

What does the future hold?

While India is a global leader in manufacturing vaccines, vaccine research, especially the development of next-generation vaccine technologies, are thus far relatively unexplored waters. Having an infrastructure for enabling rapid production of economical and safer vaccines in shorter time frames will allow our public health system to stay poised to fend off emerging diseases. Conventional vaccine development approaches have primarily involved live attenuated or inactivated whole pathogens. These approaches followed largely empirical design and developmental cycles. Additionally, attempts for R & D of traditional platforms of vaccines can take up to several years, which will fail to align with the expectations for fast response and control of epidemics and pandemics of an emerging or re-emerging pathogen.

Sharing her views on new research approaches in immunology-vaccinology that can be explored to enhance the scope of the field of vaccine research in India, Dr Pragya Yadav said "To elevate the landscape of vaccine research in India, adopting modern immunology-vaccinology research approaches is imperative. Systems vaccinology can be employed to integrate multi-omic data for a holistic understanding of immune responses, while nanotechnology promises to refine vaccine delivery and effectiveness. mRNA vaccine technology, proven during the COVID-19 pandemic, offers rapid adaptability to combat emerging pathogens. Reverse vaccinology and the exploration of novel adjuvants can bypass traditional cultivation challenges and enhance immune responses. T cell-based vaccines could provide a robust defence against elusive pathogens. Efforts to develop universal vaccines could provide broad-spectrum protection and mitigate future pandemics. Additionally, leveraging bioinformatics and computational modelling can expedite antigen prediction and vaccine development, positioning India at the forefront of global vaccine innovation."

Indian companies have entered into collaborations with global pharmaceutical firms and research institutions to leverage advanced technologies and expertise. The government is funding and providing regulatory support through DBT and the Indian Council of Medical Research (ICMR).

While next-generation vaccines can have their advantages, several major vaccine candidates that have evolved in India are based on traditional live attenuated and inactivated whole organism-derived approaches. These have proven to be immensely successful models for India, as chronicles of vaccines like MMR, OPV, and BCG, among others, have demonstrated for decades.

COVID-19 has resulted in an innovation surge in vaccine development globally and in India. While traditional vaccine development and delivery platforms have proven to be a successful model for India for many decades, it stands to reason that with pathogens evolving to adapt, it will be crucial for humans to evolve vaccine strategies to stay on top. BS

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"Our goal is to avoid dependence on imports and to promote a sustainable and robust industry"

Dr Krishna Ella,
President, Indian Vaccine Manufacturers Association (IVMA)

Dr Krishna Ella, Co-Founder and Executive Chairman of Bharat Biotech and Vice President of Indian Vaccine Manufacturers Association (IVMA) has been appointed as President of IVMA for a two-year period from April 20224. Building on the legacy of his predecessor, Adar C. Poonawalla, who held the position from 2019 to March 2024, Dr Ella in an exclusive interview with BioSpectrum shared his vision and priorities for the future of the Indian vaccine industry. ***Edited excerpts;***

What are your key priorities and objectives for advancing the mission of ensuring global access to life-saving immunisations?

Our priorities at IVMA are to transform the status of the Indian vaccine industry from a leader in Low and Middle-Income Countries (LIMCs) to a global vaccine leader across the world. The regulations that govern vaccine development and manufacturing are administered by several Ministries at the State and Central levels in India leading to inconsistencies. We wish to collaborate with government agencies to streamline the regulatory processes to be more transparent, streamlined, and enforceable.

How do you plan to continue the legacy of your predecessor and further strengthen the role of IVMA in advocating for vaccine equity and accessibility across different regions and demographics?

My predecessor Adar C. Poonawalla did an excellent job in highlighting the issues related to our industry and developing solutions to solve some of them. I look forward to carrying forward that legacy. With more than five decades of experience in the worldwide supply of vaccines, we wish to present India as a global vaccine leader. These supplies amount to 10's of billions of doses of vaccines, which helped save millions of lives and livelihoods worldwide. The Indian vaccine industry has been a steadfast partner in supplying high-quality vaccines at affordable prices, with public health as the top priority.

How do you plan to balance innovation, sustainability, and equity to drive the development and distribution of vaccines, particularly in underprivileged areas?

The Indian vaccine industry must innovate and develop novel vaccines. This is important as competition is building up within India and globally. Innovative and differentiated products are critical to our sustainability, maintaining our knowledge, expertise, and resources towards R&D and new products. Within India and in most LICs and MICs, vaccination coverages are healthy. However, vaccination rates need to be improved in countries facing conflicts and inadequate health systems. While vaccine innovation is highly sought after, especially for new infectious diseases, and improvement in product profiles for existing vaccines, the industry is uncertain if procurement agencies are willing to pay a premium for innovative vaccines. There are significant pricing pressures on the vaccine industry, driving most companies towards routine vaccines, instead of novel vaccines.

With a focus on fostering growth in startups, how do you plan to navigate challenges and seize opportunities to advance the vaccine manufacturing ecosystem in India under your leadership at IVMA?

We have a few startups in the vaccine industry but are constrained due to high CAPEX, long lead times for product development, and regulatory approvals. However, the ecosystem for vaccines and vaccinology is very well established in the country. There are several examples of collaborations between industry and academia, for vaccine development and manufacturing. A good sign for the vaccine industry is that several ancillary products, equipment, reagents, consumables, and services required for our industry are available within the country. One of our goals is to further increase the extent and maturity of the entire vaccine ecosystem, to avoid dependence on imports, and to promote a sustainable and robust industry. BS

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"GIMS will play a pivotal role in providing solutions for validation and trials for medtech startups in Uttar Pradesh"

On June 1, Uttar Pradesh got its first public hospital-based medical incubation centre, established by the Government Institute of Medical Sciences (GIMS) of Greater Noida. This centre has been set up with a purpose to revolutionise healthcare innovation by providing a platform for medical startups and researchers to develop groundbreaking solutions. Its mission is to foster collaboration and drive advancements that will transform patient care and the global healthcare ecosystem. In an interaction with BioSpectrum India Dr Rahul Singh, Head of Incubation, Centre for Medical Innovation at GIMS shared the USP of the Centre, its offerings to the healthcare startups and long-term road map of the Centre. ***Edited excerpts;***

« **Dr Rahul Singh,** Head of Incubation, Centre for Medical Innovation, GIMS, Greater Noida

GIMS Startup Centre for Medical Innovation is a public hospital-based incubator and the first-of-its-kind in UP. What was the objective of setting up this Centre?

The GIMS Startup Centre for Medical Innovation was established with the primary goal of addressing a significant challenge in India's healthcare sector: the heavy reliance on imported medical devices and the validation hurdles faced by domestically manufactured devices.

As the first public hospital-based incubator of its kind in Uttar Pradesh, our centre leverages the expertise and resources of a 630-bed hospital that serves over 50,000 patients every month. This unique setup allows us to bridge a crucial gap in the medical device development ecosystem.

Prior to the establishment of our centre, there was a noticeable disconnect between the end users of medical devices—primarily doctors and the innovators developing these technologies. Our incubator addresses this by enabling doctors to initially validate problem statements, ensuring that the solutions developed are practical and effective.

The GIMS Incubation Centre offers comprehensive clinical mentoring for startups through our Startup Clinic, which is accessible to anyone by appointment. Our focus is on fostering innovation in healthcare technology, particularly in rapidly advancing fields such as artificial intelligence and machine learning. By developing affordable and cutting-edge technologies, we aim to bring all stakeholders to the table, creating a collaborative environment for innovation.

We are currently in discussions with several IITs across the country to establish MoUs for clinical support, reinforcing our strength in clinical trials and efficacy testing. Our ultimate vision is to create medical technologies in India that can serve the world, with doctors incubating their research ideas into market-ready products.

Inaugurated by the Director General of Health Services, Government of India, our centre also holds the distinction of being a Stanford University Biodesign Centre in India.

We currently support 30 startups, primarily focused on medical devices. One of our standout startups, MATRI, which is developing a menstrual pain management device, has even progressed to the current season of Shark Tank, showcasing the potential and impact of our incubation efforts.

What are the unique features of this incubation centre and how will it foster research and medical innovations in the state of UP?

Our mission is to address the significant challenge of India's reliance on imported medical devices and the difficulties faced by domestically manufactured devices in the validation process. By providing a platform where doctors and innovators can work together, we aim to develop solutions that are both innovative and practically applicable, ultimately enhancing healthcare delivery in Uttar Pradesh and beyond.

What kind of infrastructure currently the incubation centre is having?

GIMS has allocated 15,000 square feet of space on the 4th floor of the hospital exclusively for the incubation centre. This comprehensive setup ensures that startups have access to all necessary resources in one location. An entire floor is dedicated to mentoring, with our expert faculty available during working hours to provide guidance and support. This ensures that startups have continuous access to clinical and technical expertise.

A fully equipped clinical trial unit is available, enabling startups to conduct essential clinical trials and validate their products under real-world conditions. The facility includes two meeting rooms and a conference room, providing spaces for collaborative discussions, presentations, and strategy sessions.

Also, there are co-working setups available for 30 startups, fostering a collaborative and dynamic environment. We support both physical and virtual incubation, with a physical capacity for 30 startups and the ability to mentor 100 startups virtually.

Our research wing is a standout feature, equipped with advanced facilities such as genome sequencing, BSL-2 and BSL-3 VRDL (Viral Research and Diagnostic Laboratories), and a molecular research lab. These state-of-the-art resources enable high-level biomedical research and development.

We have a world-class skill lab that provides practical training and development opportunities, ensuring that startups can build and refine their technologies with hands-on experience.

Our hospital and laboratories are accredited by the National Accreditation Board for Hospitals & Healthcare Providers (NABH) and the National Accreditation Board for Testing and Calibration Laboratories (NABL). This ensures that startups have access to facilities that meet the highest standards of quality and reliability.

Startups require funding at every stage. How does GIMS plans to financially support its incubatees?

GIMS has developed a comprehensive plan to financially support its incubatees, ensuring they have access to necessary resources at various stages of their development. Here's how GIMS facilitates funding and support for its startups:

GIMS has several venture capitalists (VCs) on its panel who act as mentors at the incubation centre. These VCs assist in screening startups and provide funding at different stages based on the startups' portfolios. Their involvement ensures that startups receive not only financial support but also strategic guidance tailored to their growth needs.

Startups at GIMS have access to several grants aimed at different aspects of their development. These include grants for sustenance, prototype development, marketing, conferences, and more. This broad spectrum of funding opportunities helps startups navigate the financial challenges of early-stage development.

Most importantly, startups with a registered address in Uttar Pradesh are eligible for specific grants. However, GIMS also accommodates startups from other regions, ensuring they receive necessary support through the incubation programme.

GIMS is a member of various associations such as ISBA (Indian Science and Technology Entrepreneurs Parks and Business Incubators Association), which helps in networking and provides access to funding platforms. This membership broadens the funding and support network available to GIMS startups.

Out of 15 startups, 9 have been selected for the Stanford University Biodesign programme, which offers mentoring and prepares them for funding opportunities.

GIMS startups are part of a funding programme run by Delhi Ecosystem, ISBA, KPMG, and SIDBI. Currently, 10 GIMS startups are participating in this programme, with 3 reaching the final round. This programme provides critical financial support and enhances the visibility of startups to potential investors.

GIMS employs a co-incubation model where other institutions provide additional funds to GIMS startups. For instance, IIT Mandi funded a GIMS startup through the NIDHI PRAYAS programme. This approach has resulted in 30 per cent of GIMS startups receiving funding or grants through collaborative efforts.

Also, GIMS assists other incubation centres in validating their startups' devices, reinforcing its role in the broader medical innovation ecosystem. This cross-incubation support helps in building a robust network of validated and market-ready medical devices. GIMS has submitted a proposal for the BioNEST fund from BIRAC, which includes plans for a cleanroom facility, a bio-bank, and a prototype facility for startups. This proposal aims to further enhance the infrastructure and resources available to GIMS startups.

Many private institutions are joining hands with GIMS, contributing to the funding and support ecosystem. These partnerships expand the financial and developmental resources available to startups.

By leveraging these diverse funding sources and collaborative models, GIMS ensures that its startups receive comprehensive financial support and mentoring, enabling them to thrive and innovate in the competitive healthcare sector.

Has the centre planned to focus on a particular disease for R&D and innovation?

Yes, the GIMS Startup Centre for Medical Innovation has strategically planned to focus on specific diseases for R&D and innovation, with a particular emphasis on disease prevention.

We are actively inviting applications from across India to leverage technology for the prevention of various diseases. This initiative aligns with our broader vision of utilising advanced technology to improve public health outcomes and reduce the incidence of preventable diseases.

We partnered with the Netherlands-based foundation NLR (No Leprosy Remains) on June 11, to launch a dedicated startup cohort focused on early detection and management of leprosy. This collaboration aims to develop and implement technologies that can significantly improve the early diagnosis and effective treatment of leprosy, ultimately striving towards the eradication of this disease.

We are initiating a dedicated cohort to address menstrual hygiene, recognising the critical need for innovation in this area to improve women's health and well-being.

Another focus area is non-communicable diseases (NCDs). By developing point-of-care (PoC) diagnostics and other innovative solutions, we aim to enhance the management and prevention of NCDs, which are a major health challenge globally.

Our vision also includes the development of advanced PoC diagnostic tools. These tools are crucial for early disease detection, timely intervention, and effective disease management, particularly in resource-limited settings.

The disease prevention cohort is already live, and we have received 25 applications to date. This enthusiastic response indicates a strong interest and need for innovative solutions in disease prevention.

Mentorship is key to the development of successful startups. How is GIMS planning to leverage its in-house medical fraternity to mentor the incubatees? Will there be external mentorship collaborations?

GIMS Centre for Medical Innovation has developed a robust mentorship framework to ensure the successful development of its incubated startups.

Our clinical mentors include experienced clinicians from GIMS, encompassing both academic and hospital settings. These mentors provide invaluable insights into the practical and clinical aspects of healthcare innovation.

GIMS has also collaborated with clinicians from other institutions, both public and private. This diverse pool includes clinical researchers who offer expertise in various medical fields, ensuring that startups receive well-rounded guidance on medical and clinical validation.

Industry mentors include venture capitalists who provide financial insights and support, helping startups navigate the complexities of fundraising and financial management.

We have experts in management and technology who mentor startups on business strategy, technological development, and market positioning, ensuring that they are well-prepared to succeed in the competitive healthcare market.

Our Incubation Heads and CEOs bring a wealth of experience in startup incubation and ecosystem development. They offer strategic advice and help startups integrate into the broader innovation ecosystem.

Global mentors from Stanford University Biodesign team provide world-class guidance, helping startups achieve international standards and preparing them for global markets.

A major advantage comes from the in-house medical fraternity at GIMS who offer readily accessible expertise, enabling continuous and immediate support for the startups. This close proximity ensures that startups can rapidly iterate on their ideas with direct input from practicing medical professionals.

GIMS serves as a validation and trial hub, leveraging its clinical mentors to facilitate rigorous testing and validation of medical devices and technologies. This capability is crucial for startups to prove the efficacy and safety of their innovations.

What is the long-term road map of GIMS incubation centre?

Adjacent to the Yamuna Expressway, UP government is establishing one of the largest medical device parks. GIMS will play a pivotal role in providing solutions for validation and trials to many companies located in this park, further enhancing the ecosystem for medical technology startups in Uttar Pradesh.

The main focus is to develop low-cost, high-quality healthcare technologies that can be adopted globally. Our goal is to create solutions that are affordable yet meet international standards, addressing both local and global healthcare needs.

Our initiative, "Make in UP for the World," underscores our commitment to regional development while contributing to global healthcare advancements. BS

Anusha Ashwin

"We anticipate starting sales of India's first invented antibiotic drug combination of Cefepime and Enmetazobactam by the next quarter"

Manish Dhanuka,
Managing Director,
Orchid Pharma

Orchid Pharma, based in Chennai, has recently received Drugs Controller General of India (DCGI) approval for the manufacturing and marketing of its invented New Chemical Entity Active Pharmaceutical Ingredient (API), Enmetazobactam, and to manufacture and market Finished Dosage Form (FDF) of Cefepime and Enmetazobactam as a dry powder injectable, to improve the treatment landscape for serious infections in India such as antimicrobial resistance (AMR). To discuss more about this development, and to find out about the company's growth plans this year and beyond, BioSpectrum spoke to Manish Dhanuka, Managing Director, Orchid Pharma in detail. ***Edited excerpts;***

What are the major plans in store for FY 24-25? How much growth is expected?

We have recently received DCGI approval for India's first invented Antibiotic Drug Combination of Cefepime and Enmetazobactam (NCE). We look forward to expanding access to advanced and affordable treatment options for patients. For the Indian market, Orchid will partner with a third party with comprehensive hospital coverage while also utilising our own Antimicrobial Solutions (AMS) division for product distribution.

Enmetazobactam has already received approval from both the US FDA and the European Medicines Agency. These approvals are a significant step forward for Orchid Pharma, opening doors to royalties from lucrative markets. In India, we have also been granted waiver for Phase III clinical trials and we will be conducting a Phase IV post-launch.

Our initial expectations for launching in mid-2025 have now been advanced, and we anticipate starting sales by the next quarter. This accelerated timeline will enhance our revenue streams substantially.

Besides this our new capacities coming online will lead to a healthy growth for the coming year in line with the past trend of 2-3 years.

How much revenue do you expect to add up through this product?

This will depend on the price elasticity, but we should be able to capture ~3 per cent of the market in the medium term.

How much revenue was generated by the company during FY 23-24?

For the full year FY2024, we achieved sales of Rs 819 crore, a significant jump from Rs 666 crore last year. Our full-year EBITDA stood at Rs 142 crore, up from Rs 103 crore in FY2023. This growth is reflected in our strong Compound Annual Growth Rate (CAGR) of 22 per cent in sales and 30 per cent in EBITDA over the past three years. These figures highlight our continuous progress and ability to adapt to market demands.

Are you exploring new partnerships with global pharma companies?

As an enterprise, we are always on a look-out for expansion and collaborations. We do see a massive need for our innovations globally. Several such deals are under discussions but due to confidentiality cannot be shared. One such outcome was the Orchid-GARDP-Shionogi partnership to tackle the growing menace of antimicrobial resistance. Orchid has received the license to make this product for 135 LMICs (Low and Middle Income Countries).

Are you planning new investments, or

facility expansions in India?

Orchid is committing close to Rs 800- Rs 1000 crore of capital investments in next 2-3 years.

How do you view the growing burden of AMR globally? What needs to be done?

Antimicrobial resistance (AMR) isn't just a scientific challenge; it's a growing threat to public health and has severe economic impact. The World Health Organization (WHO) considers AMR one of the top ten global health threats, highlighting its potential to send us back to a pre-antibiotic era. We may soon be returning to the pre-antibiotic era because antibiotics are losing their power. AMR is declared as the silent pandemic by the UN and WHO and it has contributed to almost 5 million deaths in 2019. In addition to death and disability, AMR has significant economic costs. The World Bank estimates that AMR could result in $1 trillion additional healthcare costs by 2050, and $1 trillion to $3.4 trillion gross domestic product (GDP) losses per year by 2030.

Combatting AMR requires more than just scientific advancements; it demands a shift in mindsets and behaviours. We see some steps that can support and build a future resilient to AMR:

Antimicrobial Stewardship Programmes that promote responsible antibiotic use in human and veterinary medicine is paramount. These programmes champion responsible prescribing practices, track resistance patterns, and advocate for rapid diagnostics.

Global Surveillance Networks: Establishing robust surveillance networks to monitor AMR trends across different regions is essential. This data will guide targeted interventions and inform research priorities.

Investing in Innovation: Increased investment in R&D for new antimicrobials, diagnostics, and alternative therapies is crucial. Public-private partnerships can accelerate innovation and ensure a steady stream of solutions.

Dedicated Funding for Innovation: Creating a dedicated "AMR and Innovation Fund" can incentivise continued research and development.

What are your views on pharma innovation in India? What are the gaps and challenges that need to be addressed?

Pharma innovation is progressing rapidly and is making strides in India, with significant advancements in drug discovery and development. However, there are still significant gaps and challenges to be addressed. Insufficient funding for research and development, limited collaboration between academia and industry, plus navigating regulations can feel like a maze. Additionally, we need to invest in better facilities and skilled workforce. By addressing these issues and challenges, India can truly become a global leader in innovative medicines.

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What are major expectations from the government to strengthen the pharma sector in India, in terms of R&D, innovation and quality?

Orchid Pharma is committed to developing life-saving medications, that's our passion and purpose. However, it is always better and efficient to have partnerships and support especially from government functionaries, it can accelerate this mission in India.

First, increased R&D funding will empower our scientists to develop cutting-edge treatments. Second, streamlining the process for approving new drugs that will get them to patients faster. Protecting intellectual property is also essential, inventors need to be rewarded for their hard work to encourage continuous innovation. Finally, fostering stronger ties between universities and drug companies, along with creating a conducive environment for startups, will get everyone working together to create the next big breakthrough and drive growth in the Indian pharma sector. BS

Dr Manbeena Chawla
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Integrating Research Data for Drug Efficiency in the Indian Pharma Landscape

« **Dr Mary Donlan,** Global lead- Product Marketing Team, Revvity Signals

The average cost to develop a new drug is approximately $2.6 billion, according to a study by the Tufts Center for the Study of Drug Development. This cost may be reduced by up to 30 per cent through the integration of AI/ML and data analytics, which would result in substantial savings for India's pharmaceutical industry and poised to strengthen its global competitiveness and contribute to a healthier world.

The Indian pharmaceutical industry has emerged as a global powerhouse, catering to over 60 per cent of the world's vaccine demand and ranking 3rd worldwide in drug production volume. However, to sustain this competitive edge, the sector must prioritise efficiency, innovation, and process optimisation across the drug development lifecycle. Driving this necessity is the transformative phase the Indian pharmaceutical industry is experiencing, fueled by technological advancements that enhance research capabilities and drug efficiency. Among these pivotal technologies are generative AI, AI/ML, and data analytics, which offer unprecedented opportunities to revolutionise drug development and boost efficiency. The integration of research data in the Indian pharma landscape, a critical step in leveraging these technological advancements will impact drug efficiency, cost reduction, regulatory harmonisation, and global competitiveness, while also addressing the associated challenges and strategic implications.

Enhancing Formulation Research through Data Integration

Formulation research, which determines the bioavailability, stability and efficacy of a medicinal product, plays a key role in the development of these products. Historically, data on product formulation have been fragmented across different systems, making it difficult to collaborate and slowing down the pace of market entry. Pharma companies can streamline the exchange of information, enabling researchers to make data driven decisions and accelerate the development of drugs, by integrating formulation data into a central electronic laboratory notebook (ELN).

The ELN solution acts as a unified repository, capturing structured and unstructured data from diverse sources, including lab instruments, electronic records, and manual entries. This comprehensive data integration fosters transparency, reduces errors, and empowers scientists to uncover insights that can optimise formulations for improved drug efficiency.

Transforming Generic Pharma R&D through Digitisation

India's generic pharmaceutical industry is booming and contributes significantly to affordable healthcare in the world. However, a shift to digital and data-centric approaches in research and development processes is necessary due to strong competition and strict regulatory requirements. Generic pharmaceutical companies can use solutions such as an ELN to streamline their research processes and ensure data integrity, traceability and compliance with regulatory requirements. In addition to improving efficiency, automated data capture, version control and audit trails are also facilitating the seamless transfer of information with a view to shortening time to market for generic drugs.

Moreover, the integration of data analysis capabilities into an ELN enables researchers to discover patterns, trends and correlations that can facilitate process innovation and optimise strategy for developing drugs in order to improve R&D effectiveness.

Generative AI and AI/ML in Drug Discovery

Generative AI and machine learning (AI/ML) are reshaping the drug discovery process by enabling the rapid identification of potential drug candidates. These techniques are used to predict molecular behaviour, optimise chemical structures and speed up the initial stages of drug development by analysing vast datasets. The integration of AI/ML can significantly improve the effectiveness of research, given that the pharma sector is an important part of the Indian economy.

The AI/ML algorithms are capable of processing millions of chemical compounds to determine which ones have the greatest potential for therapeutic success. The time and cost of traditional trial and error methods are greatly reduced by leveraging this capability. However, for AI/ML models to be truly effective, they require high-quality, structured data in an AI-ready format.

Data Analytics for Informed Decision Making

Data analytics provides pharmaceutical companies with a deeper understanding of various factors influencing drug development and commercialisation, enabling them to make informed decisions. By analysing market dynamics, and research findings, companies can identify trends, anticipate demand, and adjust their R&D strategies accordingly. The strategic use of data analytics is not only effective in maximising resource allocation but also in increasing market relevance and profitability. Data-driven insights empower pharmaceutical companies to decide which drug candidates to prioritise for development, optimising their pipelines and bringing the most promising and impactful therapies to market efficiently.

Leveraging Research Data for Drug Efficiency

By understanding how drugs relate to biological systems, the effective utilisation of research data can positively impact drug efficiency. Scientific data engineering solutions help structure and integrate diverse research data sources, enabling pharmaceutical companies to derive valuable insights. This data-driven approach minimises trial and error in drug development by facilitating the analysis of data from biological studies, clinical trials, and real-world evidence. Companies can optimise formulations, dosing schedules, and drug combinations based on these insights, leading to more effective treatments and better patient outcomes.

Moreover, by integrating and analysing genetic data, pharmaceutical companies can uncover opportunities for developing personalised medicines tailored to individual patients' genetic profiles. Solutions that empower researchers to leverage this genetic information increase the effectiveness of treatments through a deep understanding of each patient's unique characteristics.

Cost Reduction

The cost of discovering and developing drugs has been significantly reduced by the use of AI/ML and data analytics. These technologies reduce the financial costs associated with long and costly studies through the automation of routine tasks and improvements in prediction accuracy. Moreover, companies can avoid investing in less viable options and further reduce costs by identifying the most promising drug candidates early.

According to a study by the Tufts Center for the Study of Drug Development, the average cost to develop a new drug is approximately $2.6 billion. This cost may be reduced by up to 30 per cent through the integration of AI/ML and data analytics, which would result in substantial savings for India's pharmaceutical industry.

Improving Efficiency through Collaborative Research

Multidisciplinary teams working in different geographic areas are frequently involved in the study of pharmaceuticals, which requires coordination and data exchange. This gap could be bridged by connecting research data with solutions such as ELNs and data analytics solutions, and providing a platform on the web that allows collaboration and communication between researchers.

The sharing of experimental protocols, data and insights, the promotion of knowledge exchange and cooperation among synergistic working teams can be made possible by researchers. By exploiting a variety of perspectives and expertise, this collaborative approach is not only accelerating the time to develop new drugs but also promoting innovation.

Conclusion

Integrating research data is pivotal for enhancing drug efficiency in the Indian pharmaceutical landscape. By harnessing the power of generative AI, AI/ML, and data analytics, companies can drive innovation, reduce costs, and ensure regulatory compliance. As Indian pharma companies continue to evolve and adapt to these technological advancements, they are poised to strengthen their global competitiveness and contribute to a healthier world. BS

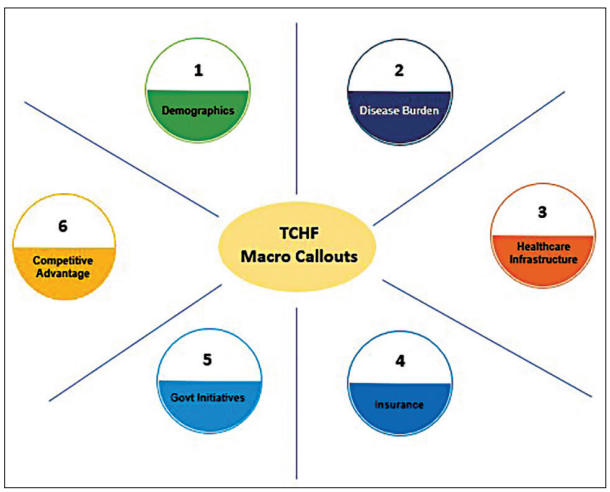
Macro Callouts for Healthcare Investing in India

« **Visalakshi Chandramouli,** Managing Partner, Tata Capital-Healthcare Fund

India will have ~1.2 billion people in the middle-income segment with over 42 per cent of the population in urban cities, by 2030. India's healthcare and lifesciences market is estimated to reach $285 billion by 2028 implying a growth that is twice our GDP growth. These developments will lead to an estimated $30-35 billion in private capital investment getting allocated to the sector over the next 5 years.

India's healthcare and life sciences sector is one of the fastest-growing healthcare and life sciences markets in the world. By 2030, India will have ~1.2 billion people in the middle-income segment with over 42 per cent of the population in urban cities. While on the one hand, the sector today stands at a threshold of significant supply-demand mismatch, on the other hand there are signs of improving affordability and availability of talent pool. This makes the sector a compelling investment opportunity for both private and public market players. As we see today, India's healthcare and lifesciences market is estimated to reach $285 billion by 2028 implying a growth that is twice our GDP growth.

This growth trajectory for the sector is underpinned by several favourable macro factors namely 1) Demographics - increasing affluence among the population; 2) Disease Burden - a dual disease burden; 3) Insurance Penetration - improving insurance penetration; 4) Infrastructure: gaps in healthcare infrastructure; 5) Government Initiatives - government's focus on healthcare and 6) India's competitive advantage – low cost and availability of talent.



Delving deeper into macro callouts

1) Demographics: By 2030, 140 million additional households will be classified as middle-class and more than 40 per cent of the population will live in urban areas. This shift in demographics will result in 3x-4x growth in healthcare expenditure. Urbanisation and modernisation lead to significant changes in lifestyle - sedentary jobs, lack of physical activity, and unhealthy dietary habits – contributing to increased prevalence of chronic diseases. Meanwhile, India will have more than 200 million elderly (60+) population by 2036; this combined with the rising life expectancy will create an unprecedented demand for healthcare services in the country. Significant investments towards increasing hospitals and other allied services capacity will be required to address the demand.

2) Disease Burden: An estimated 11.6 per cent of the population suffers from some form of NCD and ~ 6 million people die from chronic diseases every year. Cardiovascular disease is the leading cause of death in the country annually claiming over 3 million lives. It is estimated that the prevalence of Diabetes, Cardiovascular disease and Cancer will reach 226 million in 2030 from 169 million currently. In order to tackle the growing NCD burden, concerted efforts from both the government and private sectors are required. This has already been demonstrated in the remarkable reduction we

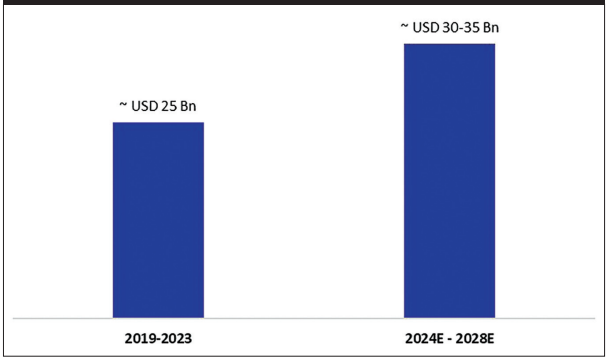
have achieved in communicable disease-related deaths. We believe that the country's chronic care management space has high scope for players to offer preventive/ therapeutic services.

3) Healthcare Infrastructure: India has made remarkable strides in medical infrastructure over the past decade with an estimated 1.2 million beds added, almost tripling the beds in 2013 (0.6 million beds). It is estimated that India with a current bed density of 1.3 per 1000 population needs 2.4 million additional beds to meet the WHO recommended ratio of 3 beds per 1000 population. Both the government and private enterprises are investing and increasing the bed density in Tier-II and beyond regions of the country. Given the significant demand for healthcare services and rising affordability, we expect the pace of investment in healthcare infrastructure to rise over the next five years.

4) Insurance Penetration: India's health insurance penetration has gone up from ~25 per cent in 2013 to 65 per cent in 2023 but is still low with 35 per cent of the population uninsured (~500 million people). This clearly constitutes the "Missing Middle" that needs urgent addressing. The country is also grappling with more than 50 per cent out of pocket expenditure (OOPE) in healthcare which significantly lags the global average of 18 per cent OOPE. The government has indeed taken marquee steps such as Pradhan Mantri Jan Arogya Yojana (PMJAY) to improve the insurance coverage to the underserved, meanwhile private health insurance companies have also played a pivotal role in reducing the OOPE and ease of claiming insurance through product innovation, distribution and technology.

5) Government Initiatives: Healthcare is a key focus area for the government, and public spending is estimated to reach 2.5 per cent of GDP by 2025. The government has launched its marquee four mission mode projects to improve healthcare accessibility and affordability namely PM-Ayushman Bharat Health Infrastructure Mission (PM-ABHIM), Ayushman Arogya Mandir (erstwhile AB-HWCs), PMJAY and Ayushman Bharat Digital Mission (ABDM). Recently, the government has also launched the Ayushman Bhav campaign which is a comprehensive nationwide healthcare initiative that aims to provide saturation coverage of healthcare services, reaching every village and town in the country. The government has also taken several steps such as offering Production

5 Yr Private Capital Investment in India Healthcare



Linked Incentive (PLI) Scheme in the Active Pharmaceutical Ingredients (API), intermediaries and Key Starting Material (KSM) production where import dependence is high. Medical Devices has also been a key area of focus for the government where several med-tech parks have been setup to boost indigenous manufacturing.

6) Competitive Advantage: India benefits from a vast skilled talent pool across physicians, nurses, science, and engineering graduates. India is renowned for its cost-effective healthcare solutions, offering medical treatments, surgeries, and pharmaceuticals at lower costs compared to many developed countries. Estimates indicate medical services in India at 80 per cent discount to the USA, this affordability factor attracts patients from around the world, approximately 2 million patients visit India each year from 78 countries for medical, wellness and IVF treatments, generating $6 billion for the industry. Additionally, India is the largest provider of generic medicines globally, occupying a 20 per cent share in global supply by volume. Indian companies have the largest share of the United States Food and Drug Administration (USFDA) Drug Master Files (DMFs) filings annually with ~ 35 per cent market share. With 670 USFDA approved plants, India has the highest number of USFDA compliant pharmaceutical plants outside of the USA. India is also one of the biggest global suppliers of low-cost vaccines with an estimated 60 per cent of global vaccines being produced in the country.

Conclusion

In summary, we estimate the outcome of the above positive macro environment will lead to an estimated $30-35 billion in private capital investment getting allocated to the sector over the next 5 years. BS

BioStartUps Webinar

Proper marketing strategy, IP management play critical role for startup's success: Experts

Highlighting that proper marketing strategy and Intellectual Property (IP) management play a critical role in the success of any new startup, experts from diverse background during a webinar, hosted by BioSpectrum in partnership with BioStartUps, focused on some of the key critical issues pertaining to the intellectual property rights, marketing strategies and role of digital marketing and shed light on how biotech startups can solidify their presence in the market by being there at the right time, and at the right place.

Panellists on the webinar including Dr Chandrashekaran Siddamadappa, Chairman & CEO, Vipragen; Dr Deepa Arora, CEO of Clinexcel Life Sciences; Rohan Agarwal, Founder of Vidcare Solutions and Abhinav Dhandia, CEO of Sphaera Pharma, shared their views, opinions and experiences with regard to intricacies of IP management and marketing strategies that are crucial for the growth and sustainability of emerging startup ventures. Dr Manbeena Chawla, Executive Editor, BioSpectrum India moderated the panel discussion.

Dr Chandrashekaran Siddamadappa, Chairman & CEO, Vipragen said that startups often commence operations with limited resources, necessitating strategic partnerships and innovative approaches to sustain growth. He also emphasised the critical need for startups to formulate revenue models early in their journey, highlighting it as a fundamental challenge faced by all startups universally. Underscoring the unique funding constraints experienced by Indian startups compared to their Western counterparts, he said, "We often lack large funding, forcing us to start small and immediately establish a revenue model. With limited resources, setting up marketing and distribution capabilities becomes crucial for sustainability."

He further outlined three guiding principles for startup sustainability: ensuring revenue generation through diverse avenues, fostering transformational innovations, and striving for leadership in their respective fields. This strategic approach, he emphasised, is crucial for navigating the competitive landscape and achieving market penetration.

Marketing Strategy

Dr Deepa Arora, CEO of Clinexcel Life Sciences stressed on the importance of a well-structured marketing strategy aligned with regulatory frameworks and target audience dynamics. She highlighted the necessity for startups to educate potential stakeholders early about novel products and technologies to ensure timely market recognition and acceptance. She emphasised that while digital platforms such as LinkedIn are essential for reaching broad audiences, personalised marketing strategies through forums and conferences remain crucial, especially when targeting specific professionals like doctors.

Stressing on the significance of crafting a brand identity that resonates with reliability and scientific credibility, Dr Deepa highlighted that effective communication through case studies and success stories on digital channels play a key role in promoting products and developing brands.

Giving his perspective on branding,

Rohan Agarwal, Founder of Vidcare Solutions, emphasised the importance of timing in marketing efforts. He suggested that while launching a product, focusing on building a strong employer brand and establishing thought leadership in the industry are crucial. Agarwal stressed on the need for founders to actively promote their innovations through both online and offline channels to gain recognition.

Shedding light on the marketing challenges,

Abhinav Dhandia, CEO of Sphaera Pharma differentiated between marketing and branding. He highlighted the founder's pivotal role in driving marketing efforts, emphasising the necessity for direct involvement

in understanding customer needs and adapting strategies accordingly.

Role of Digital Marketing

Stressing on the significance of digital marketing in biotech startup success, Dr Chandrashekaran echoed the panellists' sentiments on the interconnectedness of branding and promotion, particularly emphasising digital platforms' role in reaching initial clients and establishing market presence. He underscored the cost-effectiveness and broad reach of digital marketing, citing its effectiveness in attracting partnerships and investment.

Adding to it, Agarwal shed more insights on the pivotal role of digital marketing, particularly in engaging a broader audience. He acknowledged the effectiveness of email marketing and newsletters in maintaining connections with stakeholders. Emphasising LinkedIn as a cornerstone for business interactions, he cautioned against over-reliance on consumer-oriented platforms like Instagram and Facebook for business purposes. Instead, he advocated for leveraging digital tools strategically to foster community engagement and build credibility within the biotech industry.

Agarwal stressed on collaborative strategy focused on leveraging influencers across platforms such as YouTube and Instagram. He highlighted the efficacy of partnering with micro-influencers initially, scaling up as the company grows. He also emphasised the role of platforms like YouTube in creating awareness, complemented by offline methods like participating in industry expos for visibility.

Stressing on the strategic approach towards digital marketing, Dhandia, provided a contrarian view emphasising the need for a balanced approach to digital marketing. He advocated for dividing strategies into push (sustained campaigns on LinkedIn for B2B engagement) and pull (institutional brand building for B2C interactions) methods. He cautioned against investing heavily in digital platforms initially, urging startups to first understand their audience and refine their strategies before scaling investments.

IP Strategy

Underscoring the strategic significance of IP rights in biotech startup ventures, Dhandia emphasised that while IP may vary in importance depending on the business model, whether revenue-based or value-driven, it forms the cornerstone of innovation and differentiation. According to Dhandia, effective IP strategies not only safeguard technological advancements but also enhance a startup's market value and potential for global expansion. He advocated for tailored IP strategies that consider both domestic and international markets to maximise competitive advantage.

Dr Chandrashekaran, while echoing the viewpoints of Dhandia, focused on the broad spectrum of IP from trademarking to proprietary platform development. He highlighted the challenges associated with global patenting, citing the importance of a meticulous IP strategy that evaluates patent feasibility and value. He stressed the potential of IP to elevate a startup's valuation and attract strategic partnerships, albeit cautioning about the complexities and costs involved in IP management.

Agarwal shared insights on IP's critical role in fostering differentiation and competitiveness in global markets. He noted the evolving perception of IP in countries like India, highlighting a shifting landscape where robust IP protections are increasingly valued. Agarwal also pointed out recent governmental initiatives aimed at bolstering indigenous IP generation, predicting a rise in IP-related legal challenges that could spur innovation and strengthen India's biotech sector.

Dr Deepa, on the other hand, emphasised the importance of identifying points of differentiation beyond patents for biotech startups. She stressed incremental enhancements like formulation improvements and strategic use of IP avenues such as trademarks and copyrights to enhance product recognition and usability in diverse market segments.

Dhandia further brought attention to aligning IP creation with practical market demand, stressing the importance of developing assets that are not only monetizable for internal revenue but also attractive for potential licensing opportunities globally, particularly in regions like the US, Europe, and Japan.

Dr Deepa further emphasised the strategic importance of aligning operational bases with target markets. She highlighted that while Europe offers attractive grants, these are often tied to local operations, making partnerships with local entities essential for compliance & sustained business operations.

Conclusion

The webinar concluded with a consensus on the critical need for biotech startups to align IP strategies with operational realities and to adopt targeted digital marketing strategies tailored to specific product categories. The speakers underscored the importance of early market research and strategic partnerships in navigating the complexities of global markets effectively. BS

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JP Nadda takes charge of Health Ministry and Ministry of Chemicals and Fertilizers

The President of India, as advised by the Prime Minister, has directed the allocation of portfolios among the members of the Union Council of Ministers, for the Modi government's third term. Jagat Prakash Nadda (JP Nadda) has taken charge as Union Minister, Ministry of Health and Family Welfare, and Ministry of Chemicals and Fertilizers. He succeeded Dr Mansukh Mandaviya who got the charge of the Health Ministry and the Ministry of Chemicals and Fertilisers back in 2021. Nadda had served as the Union Health Minister from 2014 to 2019. He was appointed as a National Working President of Bharatiya Janata Party (BJP) in 2019, and was elected as a BJP National President in 2020. He has served as a Cabinet Minister in Himachal Pradesh.

Dr Jitendra Singh retains charge as Minister of Science & Technology

First from Jammu and Kashmir to secure a ministerial berth at the Centre for a third consecutive term, Dr Jitendra Singh retains charge of the Ministry of Science and Technology. He took over as the Minister back in 2014. Dr Jitendra Singh is currently serving as the Minister of State (Independent Charge) of the Ministry of Science and Technology; Minister of State (Independent Charge) of the Ministry of Earth Sciences; Minister of State in the Prime Minister's Office; Minister of State in the Ministry of Personnel, Public Grievances and Pensions; Minister of State in the Department of Atomic Energy; and Minister of State in the Department of Space. He is a physician known for his work on diabetes and endocrinology. Dr Singh has been a professor, a consultant, clinical practitioner, author of eight books, and a newspaper columnist and also the ex-chairman for the National Scientific Committee Diabetes and the Research Society for the Study of Diabetes in India.

Prataprao G Jadhav steps in as Union Minister of State in Ministry of Health & Family Welfare

Prataprao Ganpatrao Jadhav took over the charge as the Union Minister of State in the Ministry of Health & Family Welfare. He also holds the portfolio of the Union Minister of State (Independent Charge) of the Ministry of Ayush. Jadhav has represented the people of Maharashtra in various capacities, including as a Member of the Maharashtra Legislative Assembly for three terms and as a State Minister for Sports, Youth Welfare, and Irrigation. He was elected to the Lok Sabha from the constituency of Buldhana in 2009, 2014, 2019 and again in 2024. He was also the State Minister for Sports, Youth Welfare & Irrigation, Government of Maharashtra from 1997 to 1999.

Anupriya Patel takes charge as Union Minister of State in Ministry of Health & Family Welfare

Anupriya Patel has taken over the charge as the Minister of State (MoS) in the Ministry of Health & Family Welfare. Anupriya was elected to the Lok Sabha from the constituency of Mirzapur in 2014, 2019 and again in 2024. She was the Union Minister of State in the Ministry of Health and Family Welfare from July 2016 to May 2019 and Union MoS in the Ministry of Commerce & Industry from July 2021 to June 2024. She has served in various capacities, from being a Member of the Uttar Pradesh Legislative Assembly to her recent role as Union Minister of State in the Ministry of Commerce and Industry.

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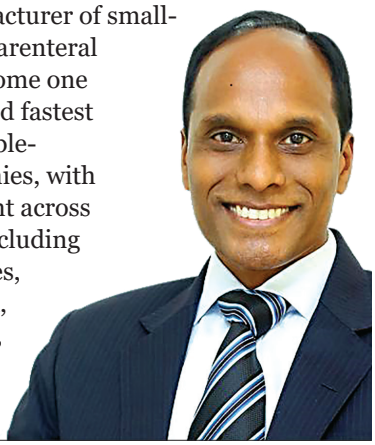
Mandeep Singh Kumar steps in as MD of India Medtronic

India Medtronic Private Limited, a wholly owned subsidiary of Medtronic plc has announced the appointment of Mandeep Singh Kumar as the new Vice President and Managing Director (MD) of India Medtronic. He succeeds Michael Blackwell who has moved back to the US to pursue new opportunities. Assuming this position, he will oversee sales, marketing, and commercial operations for Medtronic's business in India. Mandeep Singh Kumar has extensive experience spanning over 25 years and has demonstrated agile leadership in driving successful growth and business transformations across healthcare, pharmaceutical and med-tech sectors. His expertise includes strategy development, ensuring successful execution, driving commercial excellence, and building winning teams across the globe. Singh's previous role was as Country Leader with Intuitive India where he led the development and implementation of plans to broaden patient access, build a holistic ecosystem for robotic assisted surgery, and drive successful customer robotic programmes.

Srinivas Sadu steps in as Executive Chairman and CEO of Gland Pharma

Gland Pharma, a generic injectable-focused pharmaceutical company, has announced that Srinivas Sadu, the incumbent Managing Director (MD) and Chief Executive Officer (CEO), has been appointed as Executive Chairman and CEO of the company, effective June 10, 2024. Srinivas Sadu, a seasoned professional with over two decades of rich experience, has been a key part of Gland's journey. He assumed the role of MD and CEO on April 25, 2019, and has been instrumental in the company's growth and success. His career with the company began in 2000, and he steadily rose through the ranks to become chief operating officer in 2011. Gland Pharma was established in 1978 in Hyderabad and has grown over the years from a contract manufacturer of small-volume liquid parenteral products to become one of the largest and fastest growing injectable-focused companies, with a global footprint across 60 countries, including the United States, Europe, Canada, Australia, India, and other markets.



Organon India appoints Vivek Soares as new Country Lead for India and South Asia

Organon India has announced the appointment of Vivek Soares as its new Country Lead for India and South Asia. Soares will take the reins from Anjan Sen, who will retire after 35 years in the biopharmaceutical sector, which includes 11 years with MSD and Organon. Soares brings over 20 years of experience in the biopharmaceutical industry, having held numerous leadership roles at both country and regional levels. He has successfully led diverse teams across markets, developed and executed successful strategies, to increase sales and profitability, while building future capabilities. Prior to joining Organon India, Soares served as Strategic Partnerships & Business Development Lead for Organon Thailand. He has also held positions such as Director, Fertility Business Unit in Asia Pacific, Head of Tender & Key Account in Vietnam, and Senior Marketing Manager for Women's Health covering India, Sri Lanka, and Nepal.

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CSIR concludes Phenome India, first phase of longitudinal health monitoring project

The Council of Scientific and Industrial Research (CSIR) has announced the successful conclusion of the first phase of its groundbreaking longitudinal health monitoring project, the 'Phenome India-CSIR Health Cohort Knowledgebase' (PI-CheCK). To mark this significant milestone, CSIR recently organised a special event, 'Phenome India Unboxing 1.0', at the National Institute of Oceanography (NIO), Goa. The researchers explained that for the first time, a pan-India longitudinal study is being conducted with an aim to develop an enhanced prediction model for cardio-metabolic disease, especially diabetes, liver diseases and cardiac diseases. Such a study is vital as these diseases have both genetic and lifestyle factors that contribute to risk. Stating that study managed to cross their target of 10,000 samples, researchers called upon organisations to initiate similar sample collection drives. Launched on December 7, 2023, the PI-CHeCK project aims to assess risk factors in non-communicable (cardio-metabolic) diseases within the Indian populace. This unique initiative has already enrolled nearly 10,000 participants, who have volunteered to provide comprehensive health data.

Armed Forces Medical Services & IIT-H ink MoU for collaborative research and training

Armed Forces Medical Services (AFMS) has signed a Memorandum of Understanding (MoU) with the Indian Institute of Technology Hyderabad (IIT-H) to collaborate on research and training. The MoU was signed by Director General of Armed Forces Medical Services Lt Gen Daljit Singh, and Director of IIT Hyderabad Prof. B S Murty.

The MoU aims to foster innovation and research in developing novel medical devices and addressing health issues specific to soldiers serving in varied terrains. IIT Hyderabad, with its Departments of Biotechnology, Biomedical Engineering, and Bioinformatics, will provide the necessary technical expertise to tackle the diverse medical challenges faced by the Armed Forces. Key areas of collaboration discussed include drone-based patient transport, telemedicine innovations, the application of Artificial Intelligence in the medical field, and advancements in nanotechnology. Additionally, the MoU will facilitate student exchange programmes, short-term courses for undergraduates, and faculty exchange initiatives.

IIT-M & NASA lay focus on multidrug-resistant pathogens on international space station

Researchers at the Indian Institute of Technology Madras (IIT-M) and NASA's Jet Propulsion Laboratory (JPL) are studying multi-drug resistant pathogens on the International Space Station (ISS), which could have key applications for astronauts' health as well on earth.

The researchers conducted a comprehensive study to understand the genomic, functional, and metabolic enhancements observed in multidrug-resistant pathogens with a particular focus on Enterobacter bugandensis, a prevalent nosocomial pathogen found on surfaces within the ISS. Astronauts operating in altered immune conditions with limited access to traditional medical facilities face unique health challenges during space missions. Understanding the microbial landscape aboard the ISS is paramount for assessing the impact of these microorganisms on astronaut well-being.

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23rd AUGUST 2024

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Waters sets new standards with Xevo MRT Mass Spectrometer

US-based Waters Corporation has unveiled the Xevo MRT, its highest-performing benchtop mass spectrometer (MS), setting new standards for delivering high resolution and speed, critical for large population and epidemiology-type studies. It builds on the innovative technology pioneered by the Waters SELECT SERIES MRT MS. The new Xevo MRT MS combines the raw power and resolution speed of multi-reflecting time-of-flight (MRT) and hybrid quadrupole time-of-flight (QTof) technologies within a flexible benchtop platform. The Xevo MRT system delivers a class-leading 100,000 full width half maximum (FWHM) resolution at 100 Hz MS/MS scan speed and <500 parts per billion (ppb) mass accuracy. This enables deeper probing of biologically relevant concentrations with high levels of mass accuracy, independent of acquisition rate. The innovative multi-reflecting time-of-flight design of the Xevo MRT MS offers scientists the power to work at maximum resolution with high sensitivity and fast data acquisition rates.

Corning opens new digital & IT centre in Pune

Corning has announced the launch of its new Digital & IT Centre, a global capability centre (GCC), in Pune. The centre will foster new digital talent, helping Corning fill the technology roles of the future and support the company's growth both in the region and globally. The centre will create about 100 new jobs over the next two years and enhance the company's operations in information technology (IT), which require expertise in supply chain, data, cyber, and other digital areas. It is located near the company's existing research, development, and engineering facility, Corning Research Centre India. Over the past two years, the company opened its Wireless India Development Centre to help global and Indian enterprises adopt 5G technology and established a joint venture with SGD Pharma for a new glass-tubing facility.

Qiagen introduces new library preparation kit, facilitating multi omic studies

Qiagen has announced the launch of its QIAseq Multimodal DNA/RNA Library Kit. The new kit enables seamless preparation of DNA and RNA libraries for next-generation sequencing (NGS), such as whole genome sequencing (WGS) and whole transcriptome sequencing (WTS), as well as downstream target enrichment based on hybrid-capture from a single sample. The QIAseq Multimodal DNA/RNA Library Kit facilitates multiomics, the studies of several omic fields like genomics, transcriptomics and proteomics, aiming to gain a deeper understanding of biological processes and systems – something crucial for studying diseases like cancer. The kit offers a streamlined and rapid workflow to generate WGS and WTS libraries from a single sample by combining chemistry optimised for DNA and RNA simultaneously. Using traditional methods, separate workflows for DNA and RNA sequencing require a large amount of sample material, labour-intensive library preparation procedures, and long turn-around times. Researchers can also use the QIAseq Multimodal DNA/RNA Library Kit for generating DNA-only or RNA-only libraries.

Agilent offers cutting-edge advances in GC/MS and LC/Q-TOF technology

US-based Agilent Technologies Inc. has introduced two new products- The Agilent 7010D Triple Quadrupole GC/MS System which targets the food and environmental markets, offers precision and sensitivity in gas chromatography-mass spectrometry; and the Agilent ExD Cell for use with the 6545XT AdvanceBio LC/Q-TOF system, serves the biopharma market and life science research. The Agilent 7010D Triple Quadrupole GC/MS System (7010D GC/TQ) features the new HES 2.0 ion source, providing attogram-level sensitivity, unmatched robustness, and industry-leading uptime. Built-in intelligence, including SWARM autotune and Early Maintenance Feedback (EMF), streamlines analytical workflows and reduces unplanned instrument downtime, making it a reliable partner in navigating evolving regulatory requirements. The Agilent ExD Cell available for the 6545XT AdvanceBio LC/Q-TOF enhances peptide and protein characterisation capabilities by adding electron capture dissociation (ECD). With the trend towards increasingly complex biotherapeutics this meets the need for more thorough structural characterisation.

Thermo Fisher launches 'Make in India' air quality monitoring system analysers

US-based Thermo Fisher Scientific has announced the commencement of manufacturing of Air Quality Monitoring System (AQMS) analysers in India. The analysers will be engineered, manufactured and validated at Thermo Fisher's facility at Nasik, Maharashtra. Thermo Fisher has been supporting leading players in cement, metals, mining, oil and gas, power, chemicals and other industries in India with these analysers, manufactured at its facilities in the USA and China. The analysers are then assembled into Make in India Class 1 Continuous Ambient Air Quality Monitoring Station (CAAQMS) at its Pune facility. By now manufacturing these analysers in India, Thermo Fisher has further fortified its commitment to India's localisation and environmental stewardship efforts. Designed to provide accurate data on air pollutants and gases, the AQMS analysers play a crucial role in monitoring and regulating industrial emissions, contributing to the government's efforts in curbing air pollution.

Sciex unveils newest mass spectrometer in quantitative portfolio

US-based leader in life science analytical technologies, Sciex has announced the launch of the Sciex 7500+ system, the newest mass spectrometer in the quantitative portfolio, building upon a legacy of reliable, sensitive quantitation. While sensitivity is critical to solve the most impactful analytical challenges, scientists are under pressure to meet deadlines faster and to quantify from increasir various and complex sample types. The Scie 7500+ system delivers both sensitivity and resilience when scientis need it most. The 7500 system offers increased resilience across a large suite of sample types and workflows, and improved user-serviceability. At 800 MRM per second, the Sciex 7500+ system is the fastest Sciex Triple Quad to date. This increases the scope for large quantitation panels that need to incorporate new compounds of interest, improving the overall productivity of the lab. It is supported by new functionality in Sciex OS that allows users to track instrument performance and automate decision making, reducing the potential for failed batches and repeat measurements.

Leveraging Space Lab for Novel R&D

Microbes continue to puzzle us by growing in the most challenging conditions. One such challenging condition is the space environment. The harsh environment of space proves to be ideal for the acquisition of adaptive mutations, particularly in microbial organisms. Adaptive evolution plays a major role in the appearance of new phenotypes in nature and is of key importance in biomedical research, including the onset of carcinogenesis and in the emergence of drug-resistant microorganisms.

A recent study by researchers at the Indian Institute of Technology Madras and NASA's Jet Propulsion Laboratory (JPL) is focused on exploring the presence of multi-drug resistant pathogens on the International Space Station (ISS), which could have key applications for astronauts' health as well on earth. The knowledge gained from this study could shed light on microbial behaviour, adaptation, and evolution in extreme, isolated environments that allow in designing novel countermeasure strategies to eradicate opportunistic pathogens, thus protecting the health of astronauts.

The ISS has previously been used to detect the presence of many bacteria and even fungi in order for scientists to understand the impact that residing and traveling through outer space can have on microorganisms and humans.

This is just one of the many research studies being done within the space environment. For instance, space is also helping scientists find new treatments through stem cell research. Scientists are taking advantage of the space station's microgravity environment to study the properties of non-embryonic stem cells.

The University of California San Diego Sanford Stem Cell Institute has recently launched several new nano-bioreactor experiments onto the ISS via the second Axiom Space Private Astronaut Mission, to expand research on human stem cell ageing, inflammation and cancer in low Earth orbit.

Increasing evidence shows that microgravity conditions can accelerate ageing, inflammation and immune dysfunction in human stem cells. Understanding this process is not only helpful for keeping astronauts healthy, but it could also teach us how to better treat cancer on Earth.

Another research project in the US is examining the effect of gravity on a type of stem cells derived from bone marrow known as mesenchymal stem cells, or adult stem cells with growth factors and healing potential. They play a key role in tissue repair and regeneration. The experiment could have implications for future space flights that include taking humans to Mars.

Further, to unlock insights into protecting our brains from cognitive decline, a team of researchers in the US are probing the effects of space conditions on the human brain to inform potential applications for treating and preventing late-onset diseases like Alzheimer's and dementia. The research team is leveraging the unique space environment to study how microgravity, radiation, and other factors influence the brain's ageing process at the molecular level.

Not to forget, 3D printing stands at the forefront of transforming space exploration, offering unprecedented on-demand and rapid manufacturing capabilities. To date, 3D printing has revealed promising opportunities across diverse space applications, including the production of space devices and food, advancements in space biomedicine, repairs of electronics and sensors, and the recovery and utilisation of space resources. While global space leaders have recently explored 3D printing technologies in space, the field is currently in the early stages of technology validation, requiring extensive foundational research and key technological advancements.

But since space exploration began decades ago, it has over the years led to new technology and medical advancements. As a result, scientists across the globe are focusing on multiple projects such as studying bone and muscle loss in microgravity, which impacts care of patients with back pain, osteoporosis or limited mobility; developing new terrestrial and spaceflight applications for ultrasound-based bone health diagnostic tools; conducting first-of-its-kind genomics work on the International Space Station, with many more to come. BS

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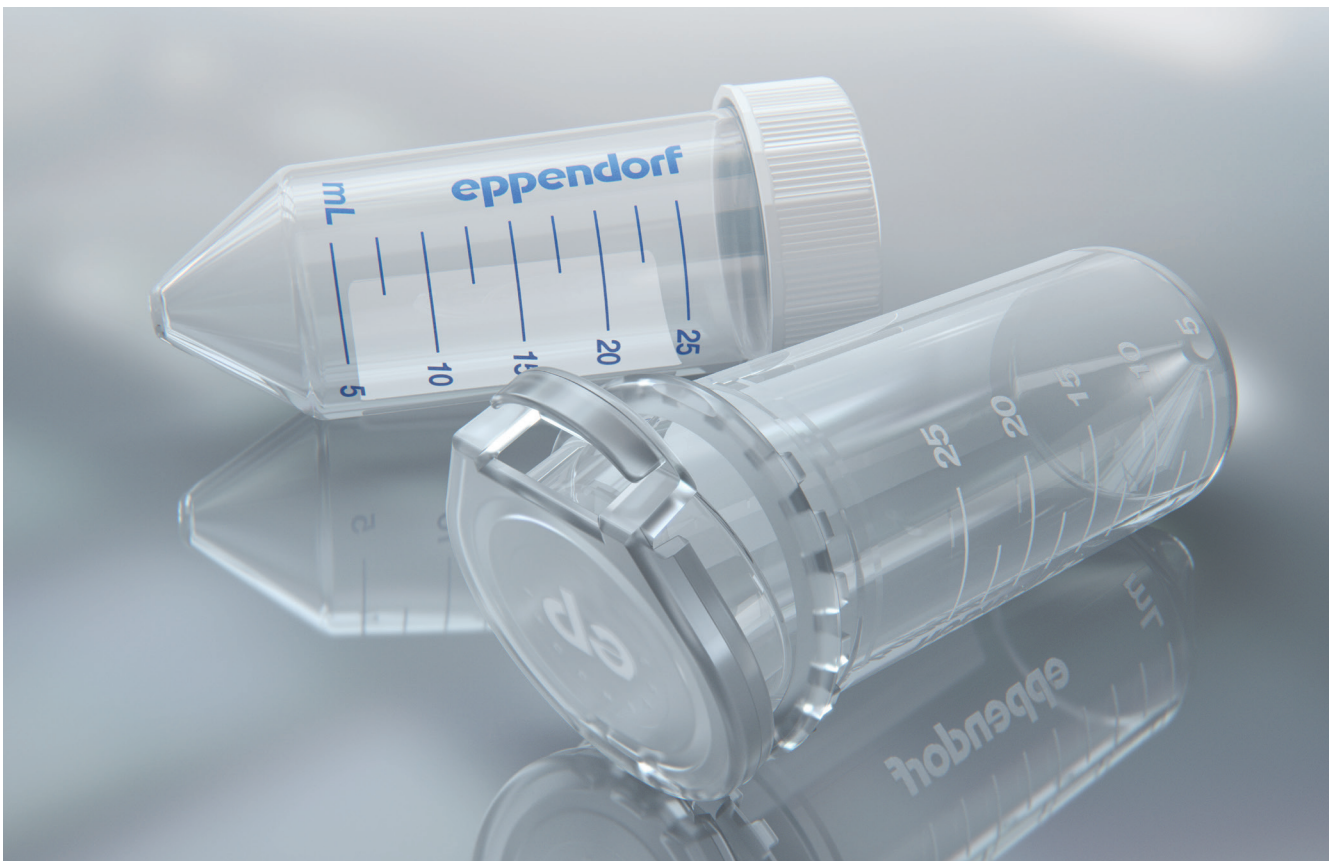

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