An MM ACTIV Sci-Tech Communications Publication

the business of Bio & Health Sciences

BioSpectrum

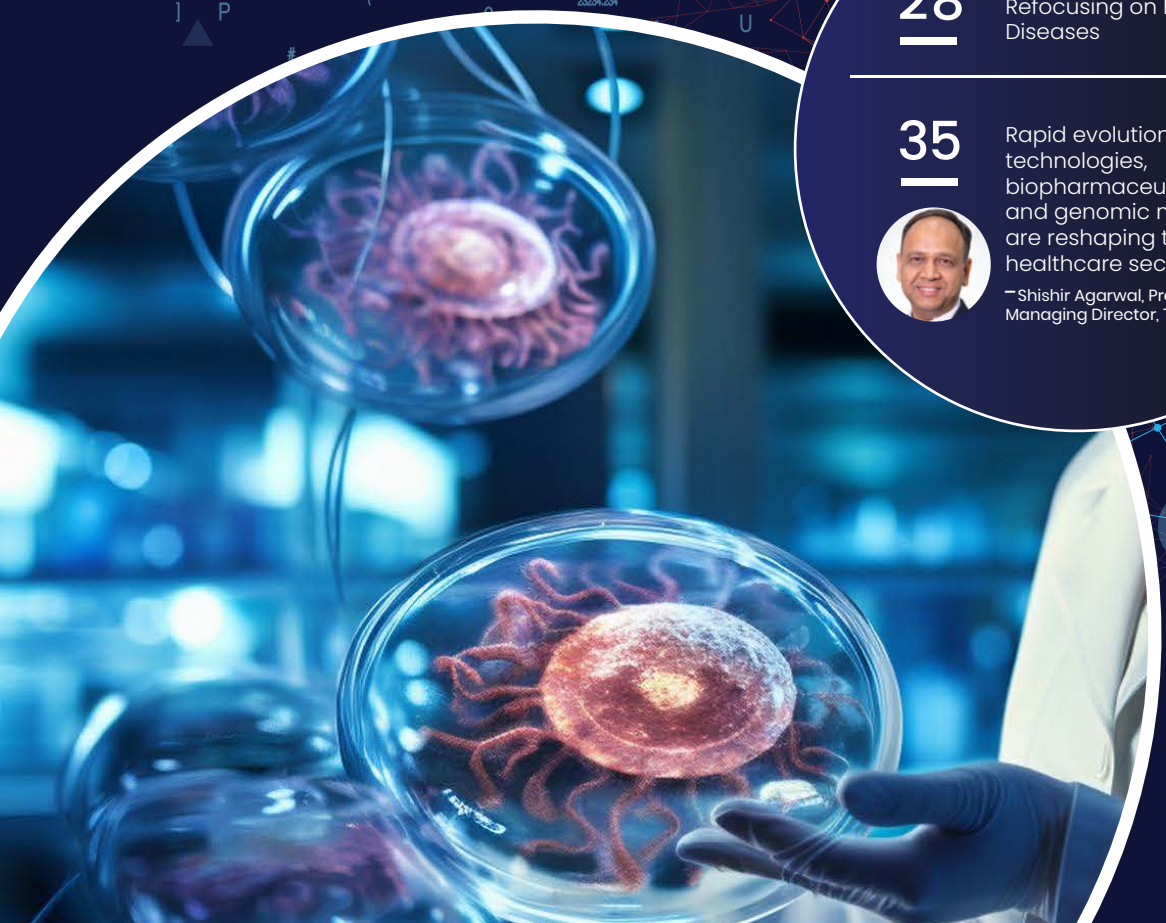
PUNE ▪ Volume 22 ▪ Issue 02 ▪ February 2024

www.biospectrumindia.com

₹150

Total pages including cover 52

Can ORGANOIDS Usher In Cheap & Effective Cancer Therapeutics?



BioStartUps

Leading Platform for Emerging StartUps

- INDUSTRY PARTNERS -

- INVESTMENT PARTNERS -

CEO and Founder Conclave'24

Fueling Innovation and Growth in Biotechnology

12th April, 2024

CIDCO Convention Hall, Mumbai

Early Bird Offer

~~25,000 INR~~

10,000 INR

Seize the thrill with our exclusive early bird deal and embark on a journey of growth and success

- ECOSYSTEM PARTNERS -

Contact for more information:

apoorva.mahajan@mmactiv.com | vrushti.kothari@mmactiv.com

Visit our website for more details

www.thebiostartups.com/ceo-and-founder-conclave-2024

HealthtechNext: From the Swiss Horizon

swissnex

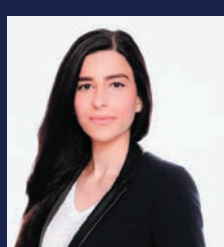
Swissnex in India, Consulate General of Switzerland, as part of its Swiss startup internationalisation program to connect Indian and Swiss entrepreneurial communities, introduces four cutting-edge life sciences and medtech solutions from Switzerland for potential collaborations and Make-in-India co-development opportunities. These technologies, developed by spinoffs from Switzerland's top universities, cover a broad spectrum of fields, including pharmaceuticals, medical devices and diagnostics, offering universal applicability.

Enantios:
Tabletop system for structural analysis of complex chiral molecules and biologics

Enantios is a Swiss, ETH Zurich-spinoff that uses advanced measurement technology to enable users to determine the structure of complex chiral molecules and biologics, a key step in understanding how a molecule will interact with the body. Their instrument is a compact, tabletop system that can be used without calibration on virtually any molecule and without a second analytical technique. Leveraging Raman Optical Activity, Enantios' technology can determine the structure of complex chiral molecules and biologics, can measure almost all molecule types, and can measure in a variety of solvents, including aqueous (biologically relevant) buffer solutions. This is in stark contrast to current, more time-consuming technologies. ***Enantios's Dr. Carin Lightner seeks to collaborate with Indian pharmas/CROs/drug discovery R&D organisations.***

Breathe Medical: Advanced, portable ventilator technology

Breathe Medical is an ETH-Zurich medtech spinoff that has designed a battery-operated portable ventilator, combining Swiss engineering precision with adaptability to meet local operational realities. ***This ventilator is robust, user-friendly, and features a long-lasting battery, making it suitable for both urban hospitals and remote rural clinics.*** This ensures reliability in emergency situations. Breathe also provides an integrated digital training platform to ensure effective onboarding and instrument utilisation by medical and paramedical personnel. ***Breathe Medical's Dr. Thomas Lumpe is exploring India for potential Make-in-India manufacturing options and deployment synergies.***



Beyond Genomix: Telomerase analysis for longevity

Beyond Genomix is a Neuchatel-based Swiss medtech startup that uses machine learning-empowered non-coding DNA analysis technology to measure telomere length, including associated variables at single-cell resolution. The patented technology combined with proprietary software and databases is applicable to the longevity field, allowing accurate assessment of the individual's biological age and ageing rate, thus helping doctors to personalise health intervention. It is also applicable for idiopathic infertility diagnosis. This test has a sensitivity 10x higher than its main competitor, and is 3x faster and cheaper. ***Beyond Genomix's Dr. Myriam Merarchi is in India to explore synergies with genetic testing providers and hospitals.***

NXI Therapeutics:
Novel topical medication for dermatological autoimmune-inflammatory conditions

NXI Therapeutics AG is a University of Basel spinoff developing a novel, ***highly-selective class of immunosuppressive drugs for dermatological autoimmune-inflammatory diseases.*** NXI has developed a unique molecule for topical formulation that displays quick-onset therapeutic efficacy while avoiding problems seen with topical steroids, JAK inhibitors and calcineurin inhibitors. NXI Therapeutics' founder, ***Dr. Rajesh Jeyachandran MD, is exploring potential licensing or co-development partnerships via Make-in-India schemes to enable further development, manufacturing and commercialisation of their topical product*** for major inflammatory dermatological diseases like psoriasis, atopic dermatitis, vitiligo and prurigo nodularis.

For more details please reach out to: aparna.kumaraswamy@swissnex.org

Meet us at BioAsia 2024

BioSpectrum

Scan QR code to access BioSpectrum India Digizine

Vol 22; Issue 1; January 2024

Acknowledgement/ Feedback

Thank you BioSpectrum for the story on bacteriophages and AMR. With the scarcity of effective antibiotics, bacteriophages offer a viable alternative.

- Dr Rachna Dave, Chennai

Great to kick off 2024 with a phage feature in BioSpectrum India's January edition, titled 'Combating AMR with Bacteriophages', with insights from key phage researchers and proponents of phage therapy in India.

- Pranav Johri, New Delhi

India is aspiring to grow its bioeconomy to more than $150 billion by 2025, and biopharmaceuticals is a major part of it. But affordability and accessibility of biopharmaceutical products is a bit of a challenge. Continuous integrated bioprocessing has elicited considerable interest from the biopharma industry for the many purported benefits it promises.

- Prof. Anurag S Rathore, New Delhi

Vol 22; Issue 2; February 2024

MM Activ Sci-Tech Communications
Media | Events | Partnering | Advisory

Publisher & Managing Editor:
Ravindra Boratkar
CEO
Manasee Kurlekar
manasee.kurlekar@mmactiv.com
Editorial:
Chief Editor: Dr Milind Kokje
milind.kokje@mmactiv.com
Advisor - Content: Vijay Thombre
Editor:
Narayan Kulkarni
narayan.kulkarni@mmactiv.com
Executive Editor:
Dr Manbeena Chawla
manbeena.chawla@mmactiv.com
Assistant Editor: Nitesh Pillai
nitesh.pillai@mmactiv.com
Content Team:
Singapore: Hithaishi C. Bhaskar
hithaishi.cb@mmactiv.com
General Manager (Strategy and Marketing)
Ankit Kankar
ankit.kankar@mmactiv.com
Social Media Communications:
Poonam Bhosale
poonam.bhosale@mmactiv.com
Operations and HR: Asmita Thakar
asmita.thakar@mmactiv.com
Production & Design:
MM Activ Sci-Tech Communications
Anil Walunj
Subscription:
Asmita Thakar
asmita.thakar@mmactiv.com
Circulation and Media Enquiry:
Sudam Walekar
sudam.walekar@mmactiv.com

South Region
Vrushti Kothari
Business Development Executive
"NITON", No. 11/3,
Block "C", Second Floor,
Palace Road, Bangalore,
Karnataka- 560052
Mobile: +91-7798935660
vrushti.kothari@mmactiv.com

Mumbai
Mandar More
Regional Business Manager
1st Floor, CIDCO Convention Center, Sector 30A, Vashi, Navi Mumbai, Maharashtra-400703.
Mobile: +91-9870009281
mandar.more@mmactiv.com

Nagpur
Manisha Boratkar
402, Govind Apartments, Shankar Nagar Square,
Nagpur - 440 010. Tel. +91-712-2555 249

New Delhi
Dr Manbeena Chawla
Executive Editor
103-104, Rohit House 3,
Tolstoy Marg, Connaught Place,
New Delhi - 110 001
Mobile: +91-8861043732
manbeena.chawla@mmactiv.com

Pune
Apoorva Mahajan
Marketing and Communication Specialist
Ashirwad, 36/A/2,
S.No. 270, Pallod Farms,
Baner Road, Pune-411045
Mobile: +91-7724025888
apoorva.mahajan@mmactiv.com

INTERNATIONAL

Singapore
MM Activ Singapore Pte. Ltd.
Saradha Mani
General Manager
#08-08, High Street Centre,
1 North Bridge Road,
Singapore - 179094
Tel: +65-63369142
Fax:+65-63369145
saradha.mani@mmactiv.com

Asia Pacific and South East Asia-
Ankit Kankar
General Manager (Strategy & Marketing)
#08-08, High Street Centre,
1 North Bridge Road,
Singapore - 179094
Mobile: +65 90150305
ankit.kankar@mmactiv.com

North America and Europe
BioSpectrum Bureau
MM Activ
Sci-Tech Communications
Mobile: +65 90150305
E-mail: digital@mmactiv.com

'BioSpectrum' monthly publication is owned by MM Activ Sci-Tech Communications Pvt. Ltd., **Published and Printed by** Ravindra Boratkar, **Printed at** Spectrum Offset, D2/4, Satyam Industrial Estate, Behind CDSS, Erandawana, Pune - 411 038. and **Published at** 'Ashirwad', 36/A/s, S. No. 270, Pallod Farms, Baner Road, Near Bank of Baroda, Pune - 411 045. **Editor:** Narayan Kulkarni.
Website: www.biospectrumindia.com Reprinted for private Circulation

Letter from Publisher

Ravindra Boratkar
Publisher &
Managing Editor,
MD, MM Activ Sci-Tech
Communications Pvt. Ltd.

Dear Readers,

Drug discovery is a key factor in the current pharmaceutical scenario. The emergence of biotechnology opened up new vistas in drug development. It is still progressing with immense possibilities. However, its potential and possibilities are yet to be exploited fully and may take years to achieve. Another promising area of drug development appears to be drug development from organoids.

Organoids are three-dimensional (3D) miniaturised versions of organs or tissues that are derived from cells with stem potential. They can self-organise and differentiate into 3D cell masses, recapitulating the morphology and functions of their in vivo counterparts. They can mimic the occurrence and progression of original tissues and have been widely used in disease models in recent years. In one path breaking experiment, organoids were sent to the space station to study the stress levels they undergo in space.

Over 30 payloads, sponsored by the ISS National Laboratory, many of which were life science investigations, were returned to earth from the international space station. One of them was from University of California, San Diego (UCSD), which studied microgravity's effects on stem-cell derived brain organoids. These organoids are paving the way for personalised medicines. The knowledge derived from this study, wherein organoids were sent to space and returned, appears to be helping in understanding the effect of disease like cancer on cells and that could transform the face of drug discovery research.

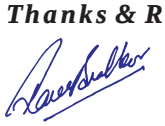
Our content team has covered the role of organoids in the development of cheap and effective cancer therapeutics. I am sure this futuristic drug discovery path will be informative and interesting to the core.

A senior scientist from DBT has laid out the impact of AI that is already visible in the biotech sector and there is a startup boom using AI for various applications. However, there is a need to develop a holistic regulatory system to make the technology more responsible. India has over 1900 AI startups including biotechnology. The pharma industry will be a major beneficiary of AI's applications and might spend around $3 billion on AI in drug discovery by 2025.

Another expert article, takes a deep dive into antibiotic resistance which is intrinsically linked to animal and human consumption patterns, partly driven by inappropriate use of antibiotics. It discusses how the emergence of antibiotic resistance fuels changes in consumption patterns, as more costly broad-spectrum antibiotics become required to manage even common conditions.

Overall, this edition delves into the latest concerns of the industry and the futuristic tech trends.

Thanks & Regards,

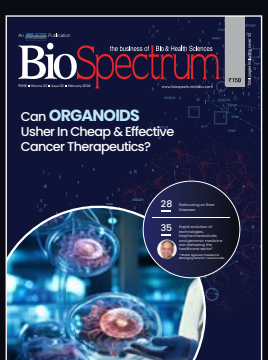


Ravindra Boratkar,
Publisher & Managing Editor

COVER 21

Can organoids usher in cheap & effective cancer therapeutics?

Dozens of science and technology development payloads returned to Earth from the International Space Station (ISS) as SpaceX's 29th Commercial Resupply Services (CRS) mission, contracted by NASA, successfully concluded on December 22, 2023. More than 30 payloads sponsored by the ISS National Laboratory returned on this mission, many of which were life science investigations aimed at benefiting humanity by improving care for patients on Earth. One among the payloads was an investigation from the University of California, San Diego (UCSD), which studied microgravity's effects on stem-cell derived brain organoids (lab grown replicas of human organs). While this might seem like science fiction, the story of organoids dates back to 1907. Fast forward to today, these tiny replicas of human organs are experiencing a dramatic surge in popularity, transforming the face of drug discovery research. Dubbed as powerful 'human modelling systems', organoids are paving the way for personalised medicines and shaking up the global drug development scene. India, too, is joining the bandwagon. Let's explore the world of organoids and how it is pushing the boundaries of personalised medicine research and precision oncology.



COVER DESIGN BY:
DOMINIX STRATEGIC DESIGN PVT. LTD.

Rare Diseases

28
Refocusing on Rare Diseases

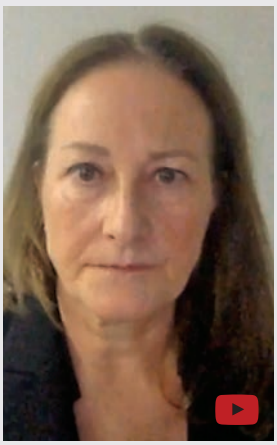
31
Breakthroughs in Rare Diseases Therapeutics

Speaking With

AI & Biotech

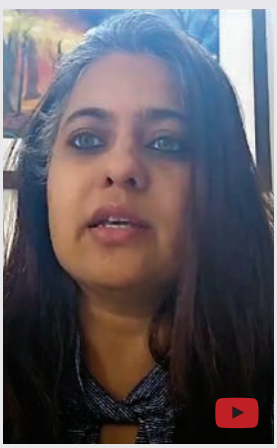
AMR

Top Video



Dr Anna Cabanes, Chief of Public Health, Vara talks about how artificial intelligence (AI) as an intervention can help alleviate breast cancer burden of India.

Scan the QR Code »



Runam Mehta, Chief Executive Officer, HealthCube points out the latest trends of the health tech startup sector in 2024.

Scan the QR Code »

Regulars

A Restorative Move

At last, the government seems to be taking steps to improve standards of manufacturing practices to ensure quality control in the pharmaceutical sector. Last month, the government revised Schedule M of the Pharmaceuticals and Cosmetics Rules 1945 which deals with good manufacturing practices (GMPs).

The Union Health Ministry's move could be attributed to some pharma companies bringing disrepute to the Indian pharma sector by their slipping manufacturing standards. About a year and a half back, Indian medicines, particularly cough syrups, were linked to children's deaths in some countries. That tarnished the image of the $50 billion Indian pharma sector.

The revised rules in the schedule have introduced a pharmaceutical quality system, quality risk management, product quality review, change control management, self-inspection and quality audit team and guidelines for qualification and validation of equipment and supplier audit. One important aspect in this category is the introduction of computerised storage systems for all drugs. All these measures are vital in ensuring quality products.

Another important factor in the revised schedule is that defective or adulterated drugs can be recalled even if they reach the market. But, at the same time manufacturers will have to assume responsibility for the quality of the pharma products on three counts – fit to their intended use, comply with license requirements and not put patients at risk by inadequate safety, quality and efficacy. The companies will be able to market the finished products only after getting satisfactory results of tests of ingredients and retaining a sufficient quantity of the samples of intermediate and final products for repeated testing or verification of a batch. Overall, the new schedule complies with GMP guidelines.

It also introduces five new categories of drugs including pharma products containing hazardous substances like sex hormones or steroids, biological products, radiopharmaceuticals, phytochemicals and investigational pharma products for clinical trials. The inclusion of biological products as a category is significant since that is the future of the pharma industry. The overall thrust of the revised schedule is to bring the GMPs on par with international quality standards. Such a move is important for an industry which exports $27 billion worth of drugs and aspires to reach $130 billion by 2030 and $450 by 2047.

These initiatives become all the more significant in light of the fact that inspection of 162 pharma factories since December 2022 revealed an "absence of testing of incoming raw materials". In the inspection of 254 manufacturing facilities and 112 public testing labs, major issues included poor documentation, lack of processes and analytical validations, absence of self-assessment, absence of quality failure investigation, absence of internal quality review and infrastructural deficiencies.

Notwithstanding the government's intentions to improve manufacturing prowess matching international standards, one problem in implementation is that nearly 8,500 drug factories are in the small-scale sector, rendering them difficult to monitor. Only less than a quarter of them meet WHO's international drug manufacturing standards. The government has given these factories in the small and medium sectors, with an annual turnover of less than Rs 250 crore, one year to comply with the new guidelines. Companies with more than Rs 250 crore turnover have six months to implement the changes.

Changes in schedule M containing GMP mandatory standards were overdue for improvements. They were incorporated in Schedule M in 1988 and were last amended in 2005. Hence, the new revised schedule matches the current situation and demands.

While the efforts to ensure the quality of Indian drugs are on, the Indian pharma industry has entered the last quarter of the fiscal year with good news. ICRA's latest projection shows that revenues of 25 leading domestic pharmaceutical companies are expected to rise by 9 to 11 per cent in the current financial year (2023-24). This is possible due to 11 to 13 per cent expansion of the US market and 7 to 9 per cent domestic growth among others.

With stringent implementation of the new Schedule M guidelines, the revenues may show a major surge, and may also translate to a surge in drug exports. BS

Dr Milind Kokje
Chief Editor
milind.kokje@mmactiv.com

HIMEDIA Celebrating 50 Golden Years 1974 - 2024

CELLBIO™

- Filtration Membranes
- Syringe Driven Filters
- Glass Fibre Pre-Filters & Filter Papers
- Blotting Membranes
- Vacuum Driven Filters

FILTRATION SOLUTIONS

Secure what Matters to You !!!

We have the right solution for your application, whether you need to separate and concentrate proteins and other biomolecules or collect and remove contaminants from air or liquid samples prior to downstream analysis.

- Filter Holders
- Stainless Steel Sterility Test Manifold Systems
- Vent Filters

HIMEDIA®
For Life is Precious

ISO 9001-2015 CERTIFIED ISO 13485-2016 CERTIFIED WHO GMP CERTIFIED CE
• • • expect only quality from us™

www.himedialabs.com +91-22-6147 1919
atc@himedialabs.com, info@himedialabs.com

Ayush Ministry invests Rs 53 Cr to increase R&D of ayurveda and folk medicine in Arunachal

Sarbananda Sonowal, Union Minister of Ports, Shipping & Waterways and Ayush, and Pema Khandu, Chief Minister of Arunachal Pradesh recently laid the foundation stones for capacity expansion at the North Eastern Institute of Ayurveda and Folk Medicine Research (NEIAFMR) at Pasighat, Arunachal Pradesh. With a total investment of Rs 53 crore, additional infrastructure will be developed at the institute. The institute has also been working towards scientifically document, record, research as well as validate the folk

medicine of the Northeast. The capacity expansion at the institute includes an academic building, hostels for boys and girls students, staff quarters as well as director's bungalow. The hostels will accommodate 70 boys and 70 girls students from the institute. The investment will cater to development of additional infrastructure for opening of Ayurveda college for imparting quality undergraduate courses in Ayurveda, Bachelor of Ayurveda Medicine and Surgery (BAMS) as well as Post Graduate courses in due course of time. The new Ayurveda college at NEIAFMR, Pasighat will promote and develop Ayurveda through Education, Research and Extension Services. The Engineering Projects (India) Limited, a Government of India enterprise, is the executing agency for the project.

Centre unveils MedTech Mitra platform to empower innovators and advance healthcare solutions

MedTech Mitra is a platform that will help the young talents of the country by holding their hands and giving them final shape to their research, knowledge, logic etc. and help them in getting regulatory approval, stated Dr Mansukh Mandaviya, Union Minister of Health and Family Welfare and Chemicals & Fertilizers as he virtually launched 'MedTech Mitra', a strategic initiative to empower MedTech innovators and advance healthcare solutions, in the presence of Prof. SP Singh Bhagel, Union Minister of State for Health and Family Welfare who virtually joined and Dr VK Paul, Member Health, Niti Aayog recently. The role of MedTech Mitra would be in handholding the innovators for clinical evaluations and regulatory compliance. It will empower emerging startups and ensure ease of innovation, ease of doing research and development, ease of rendering service in building an Atmanirbhar Bharat, further harbouring collaboration amongst all stakeholders, and effectively break silos, catalysing growth and independence in this sector.

MedTech mitra | Handholding MedTech innovators for clinical evaluation, regulatory facilitation and uptake of new products
A NITI Aayog-ICMR-CDSCO initiative

Health Ministry to open new state branches of National Centre for Disease Control and BSL-3 labs

Union Minister of Health and Family Welfare Dr Mansukh Mandaviya recently laid the foundation stone for National Centre for Disease Control (NCDC) Regional Branch in Assam, State branches in 6 states (Haryana, Tamil Nadu, Karnataka, Odisha, West Bengal and Mizoram) and biosafety level or BSL-3 labs in 2 States (Himachal Pradesh and Jharkhand) virtually. He also inaugurated a temporary NCDC Regional branch in Bhopal, Madhya Pradesh. These new NCDC branches and BSL-3 labs will strengthen the country's capacity for pandemic preparedness and disease surveillance with One Health approach. State branches of NCDC and BSL-3 laboratory once functional will augment the capacity of region/state for preparedness and response especially for outbreak prone diseases by high-risk pathogens. The government is planning to establish 30 NCDC state branches, 5 NCDC regional branches and 10 BSL-3 laboratories in a phase-wise manner for decentralising the presence of NCDC.

Govt lays focus on emerging startup trends in North India with Startup Expo in Jammu

The Vice President of India, Jagdeep Dhankhar inaugurated a Mega StartUp Expo under the theme 'Emerging Startup Trends in North India' on January 4, 2024, at Kathua, the border town sharing its boundaries with Jammu & Kashmir (J&K), Himachal Pradesh & Punjab, in the presence of Dr Jitendra Singh, Union Minister of State (Independent Charge) Science & Technology. The Expo witnessed more than 200 delegates participating & 25 Biotech Startups that showcased their innovations in different areas of biotechnology. The participating startups were engaged in solving local problems leveraging local resources such as medicinal plants, aromatic & essential oil-bearing plants for developing therapeutics. Out of the 25 biotech startups, 11 were from J&K, 3 from Chandigarh/Mohali, 6 from Noida & Gurgaon, 3 from Kanpur, 1 from Dehradun & 1 from Roorkee. With respect to the different domain areas, 12 startups were from industrial biotechnology/ secondary agriculture sector; 2 from Devices & Diagnostics; 4 from Agriculture; 2 from Environment & waste-to-value; 1 from Space; 2 from artificial intelligence; 1 from veterinary; & 1 from food/nutraceuticals.

Centre reconstitutes National Startup Advisory Council

Upon completion of two year term of the 'National Startup Advisory Council' (NSAC), the Central Government has nominated the non-official members on NSAC representing various stakeholders such as founders of successful startups, veterans who have grown and scaled companies in India, persons capable of representing interest of investors into startups, persons capable of representing interests of incubators and accelerators, representatives of associations of stakeholders of startups and representatives of industry associations. The two-year journey of NSAC has become a key example for stakeholder-driven public policy regime and has played a pivotal role in devising programmes and measures to cater to the evolving requirements of the Indian startup ecosystem. Majority of members of the council have owned and mentored various programmes which have been pivotal to the expansion of Startup India initiative, including NavIC Grand Challenge, Startup India Investor Connect Portal, MAARG Portal, National Incubator Capacity Building Programme, Doordarshan's Startup Champions, amongst others.

Gujarat becomes first Indian state to launch FDCA-mDMLA app for online medicine licensing

In a pioneering move towards efficient governance, Gujarat has achieved a remarkable milestone by becoming the first state in the country to introduce online licenses for allopathic medicines through the newly launched FDCA-mDMLA mobile app. Unveiled on Good Governance Day, December 25, 2023, by Bhupendra Patel, Chief Minister of Gujarat, this mobile application promises to streamline and expedite the licensing process for pharmaceuticals. The FDCA-mDMLA app, a leap in m-governance, consolidates various online platforms into a single interface, providing stakeholders with real-time access to the status of their applications. This initiative extends its benefits to Ayurvedic medicine and cosmetic manufacturers and sellers, aligning with the state's commitment to e-governance. This groundbreaking mobile app assures transparency and accountability in the licensing process. It allows users to obtain digitally signed licenses, certificates, and approvals through their mobile devices, providing real-time updates on the status of their applications. Furthermore, the app encompasses all services under the Right of Citizens to Public Service (RCPS) Act.

Sanjivani Paranteral raises funds worth Rs 30.88 Cr

Sanjivani Paranteral, a Mumbai-based pharmaceutical company specialising in the manufacturing and distribution of high-quality parenteral and oral solid products, has approved issuance of 600,000 convertible warrants to promoter Ashwani Khemka priced at Rs 135.10 per warrant, amounting to Rs 8.1 crore. The company has also approved preferential allotment of 16,86,000 equity shares at Rs 135.10 per share, amounting to Rs 22.77 crore to non-promoter investors. Some of the marquee investors who participated in this issue include India Bridge Fund (India Equity Fund1), Ashish Kacholia, Monika Garware, Anurag Jain, Ashika Global Securities. This issuance marks a defining moment for the company, setting the stage for continued expansion and steadfast dedication to advancing its position as a leading force in the development of a cutting-edge manufacturing facility in collaboration with Hindustan Antibiotics Limited for the production of IV formulations and IV sets. A part of the funding will be allocated towards modernising the existing facilities, reinforcing infrastructure to meet the demands of progressive technology and industry standards.

Gujarat witnesses Rs 6000 Cr worth investment for bulk drug units & formulations biz

The Gujarat Food and Drug Control Administration (FDCA) boasts of Rs 6000 crore plus worth Memorandums of Understanding (MoUs) signed recently related to bulk drugs and formulations production in Gujarat by the hands of the Gujarat Chief Minister Bhupendra Patel. The MoUs will translate into setting up of new bulk drug units in Vadodara and expansion of pharma formulations businesses in Ahmedabad. This will add heft to the growing power of Gujarat pharma production which contributes to 28 per cent of pharmaceutical exports in the country. This comes close on the heels of fifteen major and small pharmaceutical companies having entered into MoUs worth Rs 3,555 crore with the Gujarat government earlier in December 2023. These companies would be manufacturing bulk drugs, formulations and medical devices offering a wide range of product categories. Zydus Life Sciences is investing Rs 5006 crore for expansion of business in bulk drugs and formulations in Ahmedabad; Mumbai headquartered BDR Pharmaceuticals International is investing Rs 500 crore in anti-cancer APIs and formulations; and ALS Pharma has proposed to invest Rs 515 crore in a bulk drug manufacturing unit in Vadodara.

Indian Immunologicals invests Rs 700 Cr in new vaccine manufacturing plant at Genome Valley

Indian Immunologicals Limited (IIL) has started construction of its new greenfield veterinary vaccine facility to manufacture the Foot and Mouth Disease Vaccine (FMD-Vac) as well as Foot and Mouth Disease + Haemorrhagic Septicaemia Vaccine (FMD+HS-Vac) in Hyderabad's Genome valley. This brand-new unit will have a BSL3 facility for the manufacture of drug substances and a fill-finish capability for the production of both drug products FMD vaccine and the FMD+HS vaccine. Telangana State Industrial Infrastructure Corporation Ltd (TSIIC), a Government of Telangana undertaking, had allotted the land to IIL at Biotech Park, Phase III, Karkapatla, Siddipet district in Telangana. The proposed facility has a capacity of 150 million doses/annum of FMD vaccine or FMD+HS vaccine each. With an investment of approximately Rs 700 crore, the proposed facility is expected to create more than 750 direct and indirect jobs.

InvAscent injects Rs 110 Cr in Hyderabad-based API player Fleming Laboratories

India Life Sciences Fund IV (ILSF), a fund managed by InvAscent, a healthcare-focused private equity firm in India, has invested Rs 110 crore in Hyderabad-based active pharmaceutical ingredient (API) player Fleming Laboratories.

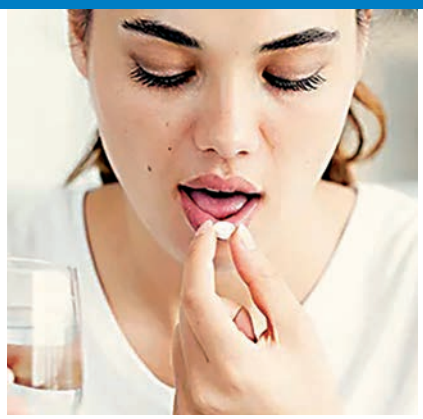
Fleming is engaged in the business of manufacture and marketing of bulk drugs and intermediates. Fleming is planning to use the funds to expand its capacity by building its third manufacturing unit as well as for its foray into fermentation-based API manufacturing. Lakshmikumaran and Sridharan Attorneys (LKS) advised Fleming and its promoters with deal structuring, drafting, and negotiations of the transaction documents & assisted in closure of the deal end to end. On the other hand, Quillon Partners advised InvAscent on this investment deal.

Tynor announces Rs 800 Cr investment into orthopaedic manufacturing facility in Punjab

Tynor Orthotics, a leading brand in orthotic appliances, has inaugurated a groundbreaking manufacturing facility in Mohali, Punjab. Equipped with state-of-the-art technology, processes, and infrastructure, this newly established facility is poised to revolutionise the orthopaedic and healthcare landscape in India and beyond. The new state-of-the-art manufacturing facility at the proposed location, boasts a built-up area of approximately 240,000 square feet. This marks a strategic expansion, set to diversify product range by manufacturing an array of healthcare solutions, including Mobility aids, Hot & Cold Therapy, Traction Kits, Advanced Knee Braces, Finger Splints, Silicone & Foot Care, Cervical Aids, allied products such as cushioned seats, backrests, pillows and many more. Tynor Orthotics further solidifies its position with a strategic investment of Rs 800 crore in Punjab & anticipating full operational capacity, the facility is poised to generating 3000 jobs, particularly empowering underprivileged women, bolstering its commitment to fostering job creation.

Lupin expands global presence with acquisition of Sanofi's brands for Rs 91 Cr

Mumbai-based pharmaceutical company Lupin has announced its strategic move to acquire two established brands from the French firm Sanofi Pharmaceuticals. The acquisition is a part of Lupin's plans to broaden its market footprint, particularly in Europe and Canada. The completion of the acquisition is anticipated in the first quarter of 2024. The purchase consideration for the brand portfolios is set at Rs 910 million or Rs 91 crore (EUR 10 million), with an additional contingent amount of up to Rs 72.8 crore based on future sales milestones. Lupin Atlantis Holdings SA Switzerland (LAHSA), wholly-owned subsidiary of Lupin, has entered into an asset purchase agreement to acquire a portfolio of accretive established products. The identified brands are AARANE in Germany and NALCROM in Canada and the Netherlands. The revenue generated from the target products in relevant markets in FY23 is $6.494 million (Rs 53.7 crore).



Akums introduces Doxylamine + Pyridoxine extended-release tablets for severe morning sickness

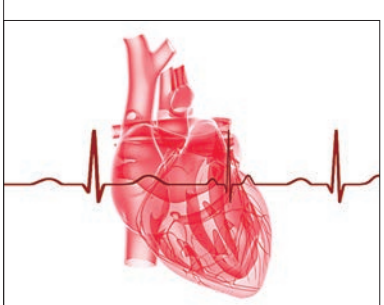
Akums Drugs and Pharmaceuticals, a Contract Development and Manufacturing Organisation (CDMO), has announced the launch of Doxylamine + Pyridoxine extended-release tablets, a therapy approved by the CSDCO (Central Drugs Standard Control Organisation), India and the United States Food and Drug Administration (USFDA). Pregnancy-related nausea and vomiting impact 70–80 per cent of women, and for some, the symptoms persist beyond the first trimester, potentially leading to hyperemesis gravidarum (HG) if left untreated. Doxylamine, a competitive histamine H1 receptor inhibitor with sedative and anticholinergic effects, is paired with Pyridoxine Hydrochloride (Vitamin B6), known for its anti-emetic properties and its role in haemoglobin production and neurotransmitter metabolism. This combination aims to offer an effective tool to manage symptoms of nausea and vomiting during pregnancy, ensuring better outcomes for both mothers and infants.

Menarini India strengthens dermatology portfolio, partners with French pharma firm

A. Menarini India, a leading Italian pharmaceutical company, strengthens its presence in dermatology, and has solidified its strategic position by entering into an exclusive partnership with French pharmaceutical giant - Pierre Fabre Laboratories. Under this strategic collaboration, Menarini India has obtained exclusive rights to market and distribute the dermo-cosmetic brands, EAU THERMALE AVÈNE and DUCRAY in India. The partnership forms a perfect synergy between the two pharma giants to deliver innovative solutions for the Indian market, promising a better future in the dermatology and cosmetics landscape in the country. EAU THERMALE AVÈNE, a Pierre Fabre dermo-cosmetic brand, is a sanctuary for sensitive, intolerant, and allergic skin. On the other hand, DUCRAY, another brainchild of the Pierre Fabre Laboratories, offers safe, effective, high-quality solutions for diverse hair and skin concerns. The product range tackles hair loss, dandruff, oily scalp, acne, eczema, and more.

Medtronic and Cardiac Design Labs bring advanced heart rhythm monitoring technology in India

India Medtronic, a wholly owned subsidiary of Ireland-headquartered Medtronic plc, has announced a strategic collaboration with Cardiac Design Labs (CDL) to launch, scale up, and expand access to CDL's novel diagnostic technology, Padma Rhythms, an external loop recorder (ELR) patch designed for comprehensive, long-term heart monitoring and diagnosis. As part of the collaboration, Medtronic will become the exclusive distributor of Padma Rhythms in India, while both Medtronic and CDL will jointly develop training and education programmes to expand reach of the ELR technology across the country. The ELR device combines the convenience of an external patch with the advanced capabilities of a Holter, ensuring accurate and insightful data for the monitoring period. It has been designed and manufactured in India by CDL and is powered by a first-of-its-kind connected platform for managing tests, data, algorithms, analysis, review, and reporting. CDL's innovation includes wearables designed for use in sweat inducing conditions with dependable workflows and minimal interventions for use of devices.



Piramal Pharma Solutions announces opening of expanded ADC manufacturing facility in Scotland

Piramal Pharma Solutions (PPS), a Contract Development and Manufacturing Organisation (CDMO) and part of Mumbai-based Piramal Group, recently celebrated the opening of its expanded antibody-drug conjugate (ADC) manufacturing facility in Grangemouth, Scotland, UK. This expansion further enhances the site's capacity by approximately 70-80 per cent, enabling scale-up of commercial ADC manufacturing batches. The capacity expansion, which has been completed for commercialisation, features two new ADC manufacturing suites specifically designed to complement the existing three. The commissioning of the facility represents the culmination of a £45 million investment to address rapidly growing demand for ADC manufacturing, supported by a £2.4 million Scottish Enterprise grant.

Glenmark first to launch biosimilar of anti-diabetic drug Liraglutide in India

Mumbai-based Glenmark Pharmaceuticals has launched a biosimilar of the popular anti-diabetic drug, Liraglutide, for the first time in India. The drug is being marketed under the brand name Lirafit following the approval from the Drug Controller General of India (DCGI). Priced at around Rs 100 for a standard dose of 1.2 mg (per day), this will lower the cost of therapy by approximately 70 per cent, and will be available only under prescription. Liraglutide belongs to the class of glucagon-like peptide receptor agonist (GLP-1 RA) drugs, which increase glucose-dependent insulin secretion and decrease in appropriate glucagon secretion. It has been approved globally for the management of type 2 diabetes mellitus in adult patients in the United States and the European Union. Liraglutide has a proven efficacy in improving glycemic control in patients with type 2 diabetes mellitus. Clinical trials on Indian adult patients with type 2 diabetes mellitus over a 24-week period have demonstrated Lirafit to be effective, safe and well-tolerated.

Emcure Pharmaceuticals expands manufacturing footprint in Gujarat

Emcure Pharmaceuticals has inaugurated its recently commissioned facility at Mehsana in Gujarat. The inauguration was done by Rushikeshbhai Patel, Minister of Health and Family Welfare, Gujarat. The new plant manufactures injectables for sale in India as well as for export to global markets. Emcure's manufacturing operations have been established for decades, and are spread across 13 sites in India. The company currently has an oral formulations manufacturing line at Mehsana and the new unit commissioned in August, 2023 is now ready for commercial supplies to domestic and international markets.
With dedicated manufacturing facilities for different platforms and packaging formats, Emcure's manufacturing facilities across the country are capable of producing pharmaceutical and biopharmaceutical products across a wide range of dosage forms, including oral solids, oral liquids, injectables, including liposomal and lyophilised injectables, biotherapeutics and complex APIs. The new manufacturing plant will aim at creating additional job opportunities in the local market.

SCIINV Biosciences inks MoU with WTC-Shamshabad to digitally combat AMR

Hyderabad-based startup SCIINV Biosciences and World Trade Centre (WTC)-Shamshabad, India, have announced a Memorandum of Understanding (MoU) that will leverage the strengths in digital diagnostics to combat antimicrobial resistance (AMR). SCIINV BioSciences, a startup founded by women entrepreneurs from Hyderabad, has developed an artificial intelligence/ machine learning (AI/ML) led clinically validated digital diagnostic tool AMRx for combating antimicrobial resistance. The clinically validated digital diagnostic tool is developed in collaboration with Sri Satya Sai Institute of Higher Learning (SSIHL). This collaboration is expected to help launch multiple digital diagnostic products for various bacterial infections in humans, animals and plants - an approach known as 'One Health'.

Mestastop Solutions and Vipragen Biosciences sign MoU to improve extensive oncology services

Mestastop Solutions, a Bengaluru-based cancer drug discovery startup, has signed a Memorandum of Understanding (MoU) with Vipragen Biosciences, a contract research organisation (CRO) based in Mysuru, specialising in preclinical drug discovery and development services. Under this agreement, Vipragen and Mestastop will collaborate to improve the extensive oncology services of Vipragen, being delivered to their global customers, by using proprietary Mestastop platforms. The MoU establishes the terms and conditions under which the two parties will collaborate for novel drug discovery, drug repurposing, and profiling current anti-cancer leads or candidates for their anti-metastatic effects. The primary mission of this collaboration would be to represent each other's services for comprehensive solutions around cancer and metastasis. Each party would retain ownership of the respective intellectual property it brings into the collaboration.

FlexifyMe raises funds to enhance technology

FlexifyMe, a Pune-based health-tech platform focused on helping people manage chronic pain, has raised funds from ah! Ventures Angel Platform. The company is already backed by Flipkart Ventures GSF, iHub Anubhuti, Chandigarh Angels (CAN), Venture Catalyst, OneCapital, and several other prominent individual investors. This funding round will help the company speed up its growth trajectory. The company said in a statement that it has grown almost 5X in the last 12 months and the recent capital infusion will help it with fast growth. The funds from this round will be additionally used to further enhance the artificial intelligence (AI) motion coach, making it available in local languages and expanding the platform's reach in the Middle East, North Africa (MENA) and North American regions.

Qure.ai receives national recognition as Best AI Solution for Global Health

Mumbai-based startup Qure.ai, a leading artificial intelligence (AI) solutions provider for imaging technology, secured the first prize at the AI Gamechanger Awards held during the 2023 Global Partnership for Artificial Intelligence (GPAI) Summit, from December 12-14, 2023 in Delhi, inaugurated by Prime Minister Narendra Modi. The AI Gamechanger Awards aimed to recognise innovation in the implementation of Artificial Intelligence across diverse sectors. Qure.ai, as the winner in the Global Health category, shared the prize with Neodocs Healthcare, a provider of instant lab tests on smartphones. Qure's winning solution, qXR software for Chest X-rays, offers AI-based chest X-ray interpretation instantaneously and can spot up to 30 lung abnormalities, including signs of pulmonary TB, lung nodules, and other ailments. By integrating qXR within the existing healthcare framework, the healthcare providers were able to amplify the accuracy and reach of TB screening using everyday chest X-rays.

Peptris raises $1M in pre seed funding led by Speciale Invest

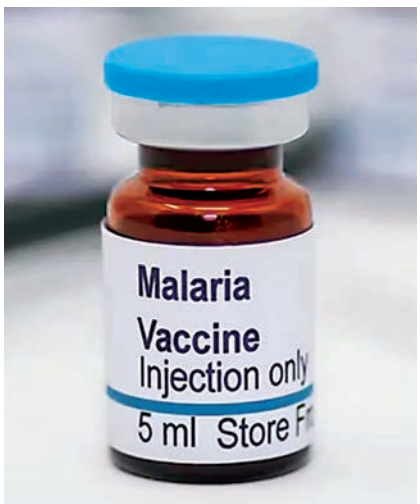
Peptris Technologies, a Bengaluru-based artificial intelligence (AI) drug discovery company, has announced $1 million in pre seed round investment led by Speciale Invest. This strategic funding marks a pivotal step in boosting Peptris' efforts in advancing AI-driven solutions in the drug development/discovery sector, with a special focus on developing novel therapies for undruggable targets, particularly in oncology, inflammation, and rare diseases. Peptris is revolutionising drug discovery through the implementation of its state-of-the-art AI platform. It is transforming the traditionally lengthy and costly drug discovery process, which often spans over a decade and incurs substantial costs, making essential medications financially out of reach for many. The company intends to leverage and capitalise on the recent maturation of AI technology in developing its proprietary drug discovery platform. The startup is broadening its research scope to include rare diseases, in addition to its ongoing work in oncology and inflammation.

Clirnet partners with American Association of Physicians of Indian Origin

Clirnet, a digital healthcare startup based in Mumbai, has entered into a groundbreaking collaboration with the American Association of Physicians of Indian Origin (AAPI) to run a Mentorship & Observership programme jointly. The Mentorship & Observership Model aims to provide valuable inputs and expertise from AAPI medical experts in the USA to young and emerging healthcare professionals in India. Mentorship, a crucial component of medical training,

is an important component in enhancing career development, professional satisfaction, and overall well-being of trainees. The programme will also offer doctors in India the opportunity to apply for observerships with AAPI physicians in the USA across various medical specialties. Experienced AAPI physicians will facilitate interactive sessions, webinars, and forums, encouraging collaborative learning and the exchange of clinical knowledge. The intent of the initiative is to involve 60 per cent of AAPI practitioners in training programmes to contribute their expertise to shape the next generation of healthcare professionals.

WHO prequalifies R21/Matrix-M malaria vaccine for disease prevention



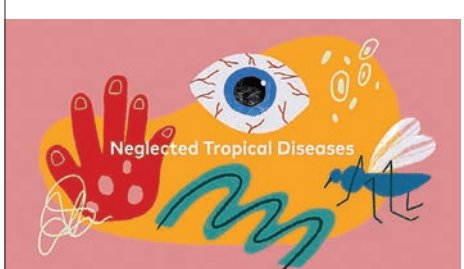
The World Health Organization (WHO) has added the R21/Matrix-M malaria vaccine to its list of prequalified vaccines. In October 2023, WHO recommended its use for the prevention of malaria in children following the advice of the WHO Strategic Advisory Group of Experts (SAGE) on Immunisation and the Malaria Policy Advisory Group. The prequalification means larger access to vaccines as a key tool to prevent malaria in children with it being a prerequisite for vaccine procurement by UNICEF and funding support for deployment by Gavi, the Vaccine Alliance. The prequalification of the world's second malaria vaccine, developed by Oxford University and manufactured by Serum Institute of India, is poised to expand access to malaria prevention through vaccination. The R21 vaccine is the second malaria vaccine prequalified by WHO, following the RTS,S/AS01 vaccine which obtained prequalification status in July 2022.

WHO and UNICEF publish new psychological intervention to support adolescents

The World Health Organization (WHO) and United Nations International Children's Emergency Fund (UNICEF) have published a new psychological intervention, Early Adolescent Skills for Emotions (EASE), to support adolescents affected by distress and their caregivers. 1 in 7 adolescents globally experience mental health conditions, which mostly go unseen and untreated. EASE is the first WHO-UNICEF psychological intervention to address the critical shortage of mental health care for adolescents experiencing distress. The EASE skills are adapted from aspects of Cognitive Behavioural Therapy and include psychoeducation, stress management, behavioural activation, and problem solving. It was culturally and contextually adapted and field-tested in four countries: Jordan, Lebanon, Pakistan and Tanzania, which included two large randomised controlled trials in Jordan and Pakistan.

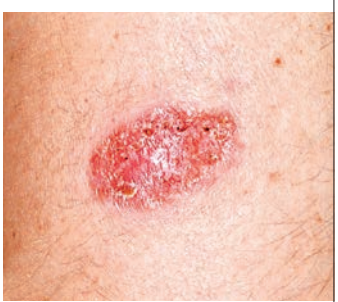
WHO officially recognises noma as neglected tropical disease

In a pivotal move towards addressing one of the world's most under-recognised health challenges, the World Health Organization (WHO) has announced the inclusion of noma (cancrum oris or gangrenous stomatitis) in its official list of neglected tropical diseases (NTDs). Noma, a severe gangrenous disease of the mouth and face, primarily affects malnourished young children (between the ages of 2 and 6 years) in regions of extreme poverty. Accurate estimation of the number of noma cases is challenging due to the rapid progression of the disease and the associated stigma, which contributes to leaving many cases undiagnosed. Cases of noma are mostly found in sub-Saharan Africa, although cases have also been reported in the Americas and Asia. The recognition of noma as an NTD aims to amplify global awareness, catalyse research, stimulate funding, and boost efforts to control the disease through multisectoral and multi-pronged approaches. Interventions addressing the burden of this devastating disease will contribute to achieving universal health coverage, as they will specifically target pockets of underserved populations.



Latin American countries use thermotherapy to treat cutaneous leishmaniasis

With the support of the Pan American Health Organization (PAHO), Ecuador, Honduras, Nicaragua, and Venezuela have begun to implement new therapies to treat cutaneous leishmaniasis, a disease that affects around 42,000 people each year in Latin America and which can leave disfiguring scars. Thermotherapy generates high-frequency waves that are applied locally over the lesion at a temperature of 50 degree celsius for a period of 30 seconds. The treatment consists of a single session and generates savings for the health system as well as for the affected persons and their families. The earlier the care is sought, the greater the possibility of opting for this treatment alternative. Since the update in guidance, PAHO has donated thermotherapy equipment to Ecuador, Honduras, Nicaragua and Venezuela and provided training to health personnel on its use. This equipment is also available for purchase for countries in the region through PAHO's Regional Revolving Funds.



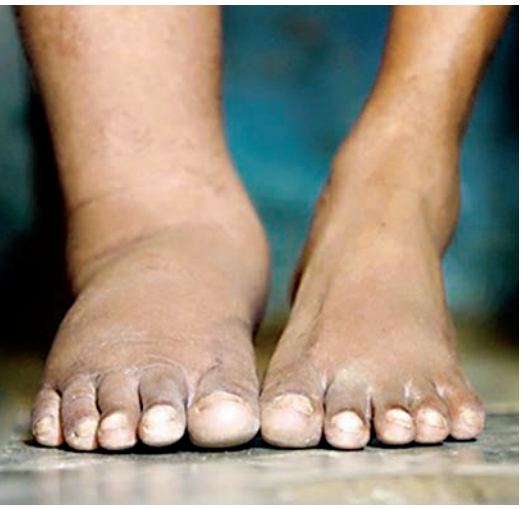
3-way partnership aims to advance vaccine against MERS coronavirus

A partnership between Norway-based Coalition for Epidemic Preparedness Innovations (CEPI), UK-based Barinthus Biotherapeutics and the University of Oxford, aims to fast-track the development of a potential vaccine known as VTP-500 for the prevention of Middle East Respiratory Syndrome (MERS), the often fatal disease caused by the MERS coronavirus. The three-way partnership, which awards up to $34.8 million to Barinthus Bio in addition to funds previously committed to the University of Oxford, builds on the early-stage development of VTP-500, which is based on the same viral vector platform technology as the licensed Oxford-AstraZeneca COVID-19 vaccine, Vaxzevria. VTP-500 has already completed Phase I clinical trials in Britain and Saudi Arabia, and the University of Oxford is now conducting a CEPI-funded extension to the Phase I trial in the UK to assess vaccination of older adults, the age group most in need of this vaccine. The VTP-500 programme was awarded PRIME designation earlier in December by the European Medicines Agency (EMA). MERS is a severe respiratory infection caused by MERS-CoV, a coronavirus that was first identified in 2012 in Saudi Arabia.

US FDA creates new advisory committee for genetic metabolic disease treatment

The US Food and Drug Administration (FDA) has announced that it is creating a new advisory committee related to potential treatments for genetic metabolic diseases. When called upon, the Genetic Metabolic Diseases Advisory Committee will provide the FDA independent, knowledgeable advice and recommendations on technical, scientific and policy issues around medical products for genetic metabolic diseases. Committee members will evaluate evidence on key issues about the applications brought before the advisory committee and offer their recommendations for FDA consideration. The group will be comprised of experts in the areas of metabolic genetics, management of inborn errors of metabolism, small population trial design, translational science, paediatrics, epidemiology or statistics and related specialties.

Maldives strengthens screening of Lymphatic Filariasis



The Ministry of Health (MoH) & Health Protection Agency (HPA) in Maldives are working with the World Health Organization (WHO) in formulating a screening strategy to better understand the extent of the spread of Lymphatic Filariasis, caused by a chronic mosquito-borne parasitic infection. The ministry is currently working with the assumption that all positive cases identified thus far are imported from regions where the Lymphatic Filariasis are endemic, with no local cases identified. The MoH and HPA have requested support from the Maldivian Red Crescent (MRC) scaling up health screening efforts to establish the scale of diseases across the country. The MoH confirms that the immediate approach is to carry out mass drug administration (MDA) for the at-risk population. Based on the initial findings, the MOH and HPA are scaling up health screening for Lymphatic Filariasis in wider cities across the Maldives with a particular focus on migrant communities.

Sri Lanka lays focus on controlling dengue

The National Dengue Control Unit in Sri Lanka organised a week-long island-wide control programme in January 2024. The initiative aims to tackle the breeding grounds of the mosquito-borne disease at every single premise across the country. This decisive action comes in response to a significant spike in dengue cases fuelled by the ongoing rainy season. Over 87,000 cases were reported in 2023 alone, highlighting the severity of the situation. Dengue Prevention Week prioritised thorough inspections in 70 high-risk dengue medical officer divisions across 15 districts. The National Dengue Control Unit is the focal point for the National Dengue Control Programme in the Ministry of Health, Sri Lanka. It was established in 2005 as a decision taken by the Ministry of Health following the major dengue outbreak in 2004. It is responsible for the coordination of dengue control or preventive activities with different stakeholders.

Nepal launches global health security programme

The United States Agency for International Development (USAID) and Nepal's Ministry of Health and Population have jointly launched USAID's Global Health Security programme, a strategic partnership to strengthen the Government of Nepal's capacity to prevent, detect, and rapidly respond to emerging infectious diseases. This partnership will advance US efforts to strengthen technical capacities in 50 countries by 2025 as part of the Administration's goal to strengthen health security and pandemic preparedness globally. Through this programme in Nepal, USAID will fund the Ministry of Health and Population to strengthen the One Health platform and surveillance systems. This programme will be implemented through "One Health," a collaborative, transdisciplinary approach that recognises the interdependence among the health of ecosystems, wildlife and domestic animals, and humans. USAID will also work through the World Health Organization (WHO) and the Food and Agriculture Organization (FAO). Through FAO, USAID will support strengthening antimicrobial resistance (AMR) surveillance in animal health; strengthening of zoonotic disease surveillance; and improving biosafety and biosecurity in Nepal.

Can organoids usher in cheap & effective cancer therapeutics?

Dozens of science and technology development payloads returned to Earth from the International Space Station (ISS) as SpaceX's 29th Commercial Resupply Services (CRS) mission, contracted by NASA, successfully concluded on December 22, 2023. More than 30 payloads sponsored by the ISS National Laboratory returned on this mission, many of which were life science investigations aimed at benefiting humanity by improving care for patients on Earth. One among the payloads was an investigation from the University of California, San Diego (UCSD), which studied microgravity's effects on stem-cell derived brain organoids (lab grown replicas of human organs). While this might seem like science fiction, the story of organoids dates back to 1907. Fast forward to today, these tiny replicas of human organs are experiencing a dramatic surge in popularity, transforming the face of drug discovery research. Dubbed as powerful 'human modelling systems', organoids are paving the way for personalised medicines and shaking up the global drug development scene. India, too, is joining the bandwagon. Let's explore the world of organoids and how it is pushing the boundaries of personalised medicine research and precision oncology.

The ISS payload project, mentioned above, that analysed brain organoids was undertaken to study the mechanisms of cognitive decline in humans by investigating the effects of accelerated ageing in space. The brain organoids were employed as surrogates, where the lab-grown brain models derived from human stem cells served as windows into the human brain's response to space-related stressors. The researchers believe that the results from this study could possibly lead to new ways to treat dementia, Alzheimer's, and other neurodegenerative conditions.

By definition, organoids are three-dimensional (3D) miniaturised versions of organs or tissues that are derived from stem cells and have the potential to self-organise and differentiate into 3D cell masses, recapitulating the morphology and functions of their in vivo counterparts. Organoid culture is an emerging 3D culture technology, and organoids derived from various organs and tissues, such as the eyes, brain, lung, heart, liver, and kidney, have been developed across the world by researchers for various medical purposes.

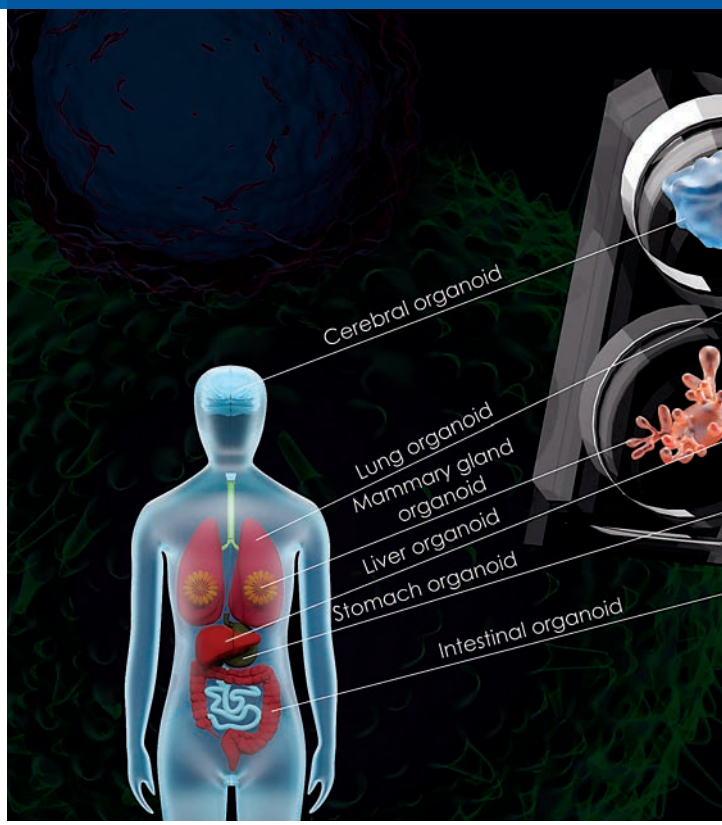
When compared with traditional bidimensional (2D) culture, organoid culture systems have the unique advantage of conserving parental gene expression and mutation characteristics, as well as long-term maintenance of the function and biological characteristics of the parental cells in vitro. All these features of organoids open up new opportunities for drug discovery, large-scale drug screening, and precision medicine.

Further, organoid technology has emerged as a rapidly growing field that has the potential to revolutionize the way diseases are studied and treated. This emerging technology has improved the chance of translatability of drugs for preclinical therapies and mimicking of the complexity of organs, proposing numerous approaches for human disease modelling, tissue engineering, drug development, diagnosis, and regenerative medicine.

Organoid technology stands out as having a major market, with a lot of scientific and business advancements in the fields of stem cells and tissue regeneration. A report by Future Market Insights predicts a 13 per cent CAGR for the global organoids industry between 2023 and 2033, driven by their increasing role in drug discovery, personalised medicine, and disease modelling. By 2033, the market is expected to reach $205.3 million, significantly expanding from its 2023 value of $60.4 million.

Why India is Bullish on Organoid Tech

Organoid technology in India may be at a nascent stage, but some significant developments are undeniably taking place. Several research institutions in the country are actively exploring organoids for various applications like drug discovery, disease modelling, and personalised medicine. Initiatives like the Department of Biotechnology's 'Mission Innovation for Drug Discovery' is further fuelling this research landscape.



Before we go ahead onto knowing some of those details on organoid-based research activities taking place in India, we need to know where organoid technology scores better than other drug testing technologies. Firstly, organoid technology provides researchers with a platform for conducting laboratory studies on living diseased tissue, which is impossible to accomplish in patients. It can create human modelling systems in a petri dish, which can be used to develop and test medications before they go through costly clinical trials.

Secondly, the ban on animal testing in various regions and the growing ethical concerns over animal source usage is contributing to the rise in organoid tech. The low translational efficiency of animal models to humans is drawing a lot of attention towards organoids and organ-on-chip. Few years back, a road-map was drawn by Indian Council for Medical Research (ICMR) regarding alternatives to animals in research in India and it also held a special session in January 2018 to discuss latest developments in new human-relevant model systems.

Sharing a few pertinent points about the

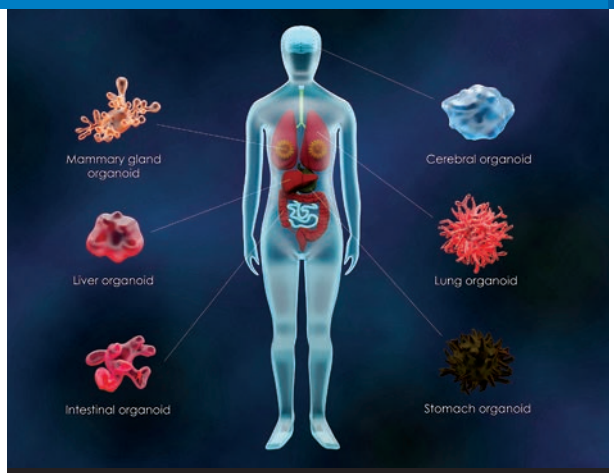
advantages of organoid technology, ***Dr Dwijit GuhaSarkar, Lead Scientist, Organoid Laboratory, Tata Translational Cancer Research Centre (TTCRC), Tata Medical Center, Kolkata,*** says, "Animal models, though more physiologically and clinically relevant and being an in vivo (inside body) system, suffers from several limitations. The test (e.g., drug response) can be influenced by the animal system, which is often different from the human system. It is usually highly expensive, time consuming and definitely not scalable for high throughput screens. Whereas, Patient Derived Organoids (PDOs) are developed from human primary cells. While this is an ex vivo (outside body) system, it still recapitulates the 3D context of tissue microenvironment. PDOs also capture the individual differences (thus personalised model). Moreover, unlike animal models, organoids are scalable for high throughput drug screens within a turnaround time that is clinically relevant for personalised medicine. So, in short, this model system retains most of the advantages of both the conventional models."

According to Dr GuhaSarkar, the pre-clinical testing of potential drug molecules will be much faster with organoid tech. He adds, "It will also be cost-effective as animal studies for large numbers of molecules is prohibitively expensive. Moreover, finding an alternative to animal use in research is ethically a better approach. Personalised medicine is a feasible idea with PDOs because of the clinically relevant turnaround time unlike animal studies."

Another point to consider is that India's diverse and large population provides a readily available source of biomaterial for organoid generation. This facilitates personalised medicine research and allows for studying various disease models relevant to the Indian context. ***Anushka Banerjee, Scientific Development and Communication Officer at the National Institute of Mental Health and Neuro Sciences (NIMHANS), Bengaluru,*** says, "I believe, organoids provide a more physiologically-relevant environment in which we can study diseases and more importantly, accurate drug responses at the pre-clinical research stage, minimising late-stage development failures. This is complemented by genomic data analytics in relevant human – like models, that provides insights into underlying genetic causes and therefore, helps identify potential molecular drug targets and companion diagnostic biomarkers."

Several laboratories across the country are now increasingly leaning towards organoids. One of the notable pioneers is IIT Madras, which joined hands with the prestigious Massachusetts Institute of Technology (MIT) on some exciting organoid-based research, specifically focusing on growing human brain tissue. The researchers have developed a 3D printed bioreactor that enables the growth of human brain tissues to study the tissue in its growth and developmental stage. The study will facilitate in accelerating the medical and therapeutic discoveries for diseases such as cancer and neurological disorders like Alzheimer's and Parkinson's.

Also, researchers at the National Centre for Cell Science (NCCS) in Pune, India, have developed patient-derived brain organoids from paediatric glioblastoma, a highly aggressive and often fatal childhood brain cancer. These organoids capture the unique genetic and biological features of each



A few domestic companies deploying organoids (list is not exhaustive)

1. **Stempeutics Research Private Limited:** Based in Bengaluru, it is a pioneer in personalised medicine, especially focusing on disease modelling and drug discovery using patient-derived organoids. They have developed organoids for various diseases, including liver fibrosis, neurodegenerative diseases, and cancer.
2. **Asteria Cells Private Limited:** Situated in Kerala, Asteria Cells specialises in generating organoids for various applications, including drug screening, toxicity testing, and personalised medicine. They offer a wide range of organoid models, including brain, gut, liver, and pancreas organoids.
3. **CellSight Technologies Private Limited:** Located in Chennai, CellSight Technologies focuses on developing and applying microfluidic technologies for organoid culture and analysis. Their novel platforms enable automated and high-throughput organoid experiments, accelerating research and development.
4. **Zyta Life Sciences Private Limited:** From Hyderabad, Zyta Life Sciences utilises its expertise in stem cell biology and bioengineering to develop organoids for drug discovery and regenerative medicine applications. They are actively involved in collaborative research projects with various academic institutions.
5. **ReMedi Therapeutics Private Limited:** Based in Pune, ReMedi Therapeutics leverages its deep understanding of cancer biology to develop patient-derived organoid models for personalised cancer treatment. They offer comprehensive services for tumour organoid generation, drug testing, and patient-specific treatment recommendations.

patient's tumour, offering a more personalised approach to understanding and treating the disease.

Not only are research studies happening at different institutions, but a few companies are also showing potential interest. In April 2023, InSphero AG announced that the company is making their patented Akura 96 and 384 Spheroid Microplates available to researchers in the Indian market by signing a distribution agreement with Bionova Supplies in biotechnology and scientific instruments.

Organoids, Genomics and Cancer Therapeutics

While cancer remains a leading cause of death globally, hurdles remain in bringing new cancer therapies to patients, with up to 97 percent of drug candidates claimed to be failing in clinical trials. Hence, in this scenario, the synergy between organoid technology and genomics is revolutionising cancer therapy by offering a more precise and personalised approach. Researchers collectively opine that unlike traditional cell cultures, organoids have the ability to retain the intricate architecture and cell-cell interactions of their original tumours, mimicking their diverse genetic makeup and drug sensitivities. This allows researchers to study how different populations within a single tumour behave and respond to treatment, providing valuable insights into tumour evolution and resistance.

Organoids are giving a new lease of life to many rare cancers and its therapies that have no defined treatment pathways so far. Breakthroughs in understanding the cancer pathology and drug discovery using organoid in such cases go a long way. For example, in April 2023, scientists from the Princess Máxima Centre for Paediatric Oncology and the Hubrecht Institute in the Netherlands reported that organoids and CRISPR-Cas9 permitted them to acquire more knowledge into the tumours biology and biological ramifications of various changes to DNA in fibrolamellar carcinoma (FLC), a rare form of child's liver cancer.

Dr Dwijit GuhaSarkar, being a scientist in the translational cancer research field, opines that in cancer, the most challenging issue is heterogeneity – the same type of cancer in different patients behave differently with respect to drug treatment. "Even within the same patient, tumour is not homogeneous and that is why, while some cancer cells are killed by a certain drug, other cancer cells can be resistant. These resistant cancer cells eventually cause recurrence, which often results in the patient's demise. PDOs are models that can recapitulate these genetic, epigenetic heterogeneity at a personalised level in the tissue culture system. Therefore, it is possible to find out what alternative drugs (already

approved or new drugs) or new combinations of existing drugs can be effective for a particular patient's tumour which is otherwise resistant to the standard of care treatment", adds Dr GuhaSarkar.

"Currently available alternative treatment approaches, such as monoclonal therapies or engineered cell (CAR-T) therapies are effective but extremely expensive and beyond the reach of most patients in India. PDO-based testing approaches can help identify alternative chemotherapeutic drugs that are indigenous developed or already approved for other treatments which can be repurposed without causing a significant financial burden to the patients."

While organoid technology might already be futuristic, the projected trend is pointing towards the convergence of organoids, genomics, and AI-based high-throughput screening (HTS). It is anticipated that the synergy of organoids, genomics, and AI-driven HTS holds immense promise for accelerating drug discovery and improving patient outcomes in fascinating ways. Progress in the field of AI/ML-based programmes has remarkably broadened the applications of 3D culture-based technologies, like many other fields, enabling handling of high throughput complex data analysis and drug response predicting model development.

Scientist Anushka Banerjee cannot agree more on this development. She says, "The organoid-genomics duo technologies have immense potential, especially in drug development for cancer research and treatment. Personalised medicine is the cornerstone of the future of drug development. The combination of genomics and organoid research allows us to analyse patient-specific, tumour microenvironment, which enables accurate testing of potential drug response, while providing insights into genetic changes that drive the disease in each individual and therefore, personalised targets – personalised therapy. This overall systems biology-led synergy can enhance the efficacy and specificity of cancer treatments."

Sharing some valuable knowledge on the synergy, ***Dr Vishnu Akhil Raj Kumar Yerra, Founder, Innovation Without Limits Garage, Raipur,*** says, "Organoid patterns can be analysed from various perspectives. For instance, examining the physical response of organoids to drug exposure – including changes in temperature, density, and other physical parameters – is crucial. Additionally, the analysis extends to biochemical parameters, ranging from ions to biomolecules, and encompasses various imaging techniques like ultrasound, elastography, thermal scanning, X-rays, and MRI. Histopathology remains a fundamental, gold-standard technique, utilising various staining methods to highlight changes pre- and post-drug exposure. Compiling these diverse parameters into a comprehensive dataset, which varies with different drug concentrations, is a complex task. Developing an intricate mathematical framework that can effectively correlate these parameters with drug efficacy in disease treatment is crucial for advancing our understanding".

Adds Dr Yerra, in the realm of biomolecules and organoid patterns associated with disease states, similarly complex architectures are required. These systems must be capable of processing varied variables and yielding meaningful insights into the organoid responses under different disease conditions. Thus, the integration of neural networks and artificial intelligence is vital for decoding and understanding the intricate patterns exhibited by organoids in response to drug treatments, patterns which are otherwise challenging to interpret."

Leveraging Versatility of Organoids

Ever since scientists have found ways of culturing organ-specific tissue from stem cells it has ushered in numerous abilities to change the way diseases are studied and treated. These mini lab organs are proposing big dreams, revealing cancer's and many other diseases' hidden codes, eventually rewriting the future of personalised medicine. Organoid technology is certainly bringing a paradigm shift in biomedical research and drug development and its versatility and precision is opening new avenues for understanding complex diseases and discovering potential therapeutic interventions.

While organoid technology comes with a huge set of advantages, it has its own limitations. Challenging culture requirements and a lack of commercially available cultivation media systems are limiting the experimental abilities. However, companies like Thermo Fisher are working towards addressing the limitations. In mid 2023, the company launched OncoPro Tumoroid Culture Medium Kit, which is their new off-the-shelf, modular tumoroid culture medium kit that is designed to make complex cancer models more accessible to researchers.

Therefore, to imagine a world where rare diseases have cures, complex health conditions are better understood, and cancer treatment is specifically tailored to each individual, the power of organoids needs to be leveraged. By fostering open collaboration and integrating expertise in these cutting-edge technologies, the potential to supercharge disease-centric research and transform biomedicine is absolutely possible. BS

Anusha Ashwin

BioStartUps
Leading Platform for Emerging StartUps

Unleashing Bio-Tech Excellence: Dive into the Future at **BioStartUps Conclave 2024!**

Are you ready to witness the sparks of innovation, the pulse of collaboration, and the birth of groundbreaking biotechnological advancements? Look no further than the **BioStartUps Conclave 2024** – a premier event designed to ignite innovation, fuel futures, and pave the way to Bio-Tech brilliance!

Ignite innovation. Fuel futures. Build brilliance. The BioStartUps Conclave 2024 – Your Gateway to Bio-Tech Excellence!

Don't miss the opportunity to be part of a transformative event that can propel your biotech startup to new heights. Join us at the BioStartUps Conclave 2024 – where CEOs and Founders forge the path to Bio-Tech Brilliance!

MORE DETAILS CAN BE FOUND HERE
www.thebiostartups.com

DATE
12th April 2024

LOCATION
CIDCO Convention Hall,
Vashi, Navi Mumbai, India

WEBSITE
BioStartUps Conclave 2024

Visit BioStartUps Conclave 2024 to secure your spot and be part of the Bio-Tech revolution!

Fueling the Bio-Tech Revolution: What to Expect

The BioStartUps CEO & Founder Conclave 2024 is not just an event; it's a convergence of minds, a nexus of ideas, and a catalyst for the future of biotechnology. Here's why you cannot afford to miss this exclusive one-day affair:

Unparalleled Networking Opportunities: Connect with the trailblazers, influencers, and game-changers in the biotech startup ecosystem. Forge collaborations that transcend boundaries and lay the foundation for future success.
Knowledge Sharing Sessions: Gain insights from the best in the business! The conclave features thought-provoking sessions where CEOs and Founders share their experiences, challenges, and strategies for navigating the dynamic landscape of bio-tech entrepreneurship.
Collaborative Environment: Experience a vibrant atmosphere where ideas flourish. The BioStartUps Conclave encourages open dialogue, fostering an environment where collaboration is not just encouraged but celebrated.

Emerging Trends and Innovations:
Stay ahead of the curve with discussions on the latest trends, emerging technologies, and innovations that are reshaping the future of biotechnology. Gain a competitive edge by being at the forefront of industry insights.
Interactive Workshops and Panels: Participate in hands-on workshops and engaging panel discussions led by industry experts. Deep dive into topics that matter, ask questions, and engage in discussions that can shape the trajectory of your startup journey.
Secure Your Spot Today: Be Part of the Bio-Tech Movement!

Send an Email at : apoorva.mahajan@mmactiv.com I vrushti.kothari@mmactiv.com

Refocusing on Rare Diseases

The US Food and Drug Administration (FDA) approval in December 2023, of two milestone treatments, Casgevy and Lyfgenia, representing the first cell-based gene therapies for the treatment of a rare disease called sickle cell disease (SCD) in patients 12 years and older, is a huge development. With rare diseases posing significant challenges due to the scarcity of information, limited research, and insufficient awareness among healthcare professionals and the public, introduction and approval of specific treatments can provide a much needed boost to tackle the growing burden of rare diseases globally. However, an integrated approach with enhanced coordination and cooperation across the ecosystem is the need of the hour.

The scientific community has a critical role to play in accelerating rare disease research and contributing to improving diagnosis and treatment. Although innovations in sequencing technology and machine learning approaches are positively affecting diagnostic success, more coordinated efforts are needed to move towards effective therapies for this important, and underestimated, class of diseases, which is not so rare any longer.

In November 2023, the Union Health Ministry authorised the sale of four generic medications for the treatment of rare diseases. This approval is a significant milestone in the fight against rare diseases in India. These approved indigenous products, along with other products yet to be approved, will aid patients suffering from rare diseases by improving quality of life as well as overall healthcare outcomes. However, a major obstacle to effectively combating rare diseases in India is the lack of awareness and inadequate diagnosis in the country, says GlobalData, a leading data and analytics company.

The four approved medications are used to treat Wilson's disease, Gaucher's disease, Tyrosinemia Type I and Dravet-Lennox Gastaut syndrome. Earlier, these therapies were imported to India and would cost Rs 1.8- 3.6 crore for annual treatment. With this approval, patients with rare diseases can now access these therapies at a significantly reduced cost of Rs 3- 6 lakh, which is 100 times less than the imported therapies. Over the next few months, the ministry is expected to release medications for additional rare illnesses, such as hyperammonaemia and phenylketonuria.

Furthermore, in December 2023, the US Food and Drug Administration (FDA) announced the approval of first gene therapies to treat patients with Sickle Cell Disease, a rare, debilitating and life-threatening blood disorder with significant unmet need.

The new technical advances in rare disease genetics research that apply the latest technologies to improve diagnosis ensures an exciting time ahead but a lot more needs to be done. The rare disease research is currently very siloed and often organised around single disorders. A more integrated structure with appropriate support for researchers to coordinate across rare diseases is required to minimise redundant efforts, increase efficiency, potentially accelerate development and the implementation of successful therapies in India and around the world.

Challenges Surrounding Research & Innovation for Genetic Diseases

The estimated burden of rare genetic diseases is 72- 96 million in India and the average time for diagnosis is 7 years. No effective treatment is available for many of the disorders and less than 5 per cent have therapies. Thus, the right diagnosis and treatment are crucial for improving the quality of the life of patients.

Quoting an example, ***Dr Jogin Desai, Chief Executive Officer, Eyestem Research*** says, "Retinitis pigmentosa is a rare congenital retinal disease which is significantly underdiagnosed due to lack of awareness leading to insufficient data and thus societal inaction. We need to integrate genetic insights into societal knowledge, and lay the

groundwork for a comprehensive understanding of these often-overlooked conditions."

From the diagnostic perspective, the optical genome mapping test is garnering attention as a highly advanced diagnostic tool that uses cutting-edge technology to provide a comprehensive and accurate assessment of genetic changes in patients. Optical genome mapping can be used for accurate diagnosis where more common or traditional techniques fail.

Explaining the clinical utility of optical genome mapping, ***Dr Karthik Bharadwaj, Scientist, Genetic disorders- Diagnostics, CSIR-Centre for Cellular & Molecular Biology (CCMB)*** says, "Optical Genome Mapping is automated and performs with more than 95 per cent sensitivity. In a case of Hemophilia A where whole exome sequencing was not able to report a common mutation, optical genome mapping has helped in identifying inversion in intron 22. In another case with developmental delay, dysmorphism, a balanced translocation was identified in chromosome 12 showing ~16mb, fusion depicting copy number gain. Other examples include fragile X and disruption of AUTS2 gene. However, the limitations with optical genome mapping include lack of adequate reference data, inability to detect structural variants across acrocentric regions and poorly labelled regions."

On the other hand, big pharma companies, by virtue of their resources and influence, are making efforts in developing new drugs and therapies for rare diseases in India, but there are multiple challenges that lie ahead of them.

Because of the low number of affected populations with rare genetic diseases, they have been recognised in the Orphan Drug Act 1983 which is formulated for drugs with a limited market. With the narrow market, drug manufacturers need some incentives to invest in this cause. Therefore, the government needs to formulate certain laws to boost the production of these drugs indigenously.

Another possible challenge that can come across in developing therapies is in the form of market challenges or small population sizes. Even after developing therapies, the challenge of the market comes with high costs and with the idea of developing drugs for a small population, thus the industry interference is limited. This can be tackled by introducing smart acceleratory pathways from government funding and certain waivers for clinical trials. There is a need to look through a global perspective, and the stringent rules that hinder pharmaceutical companies from looking into rare diseases.

According to ***Dr Rita Sarin, Advisor, Intellectual Property,*** "We cannot overlook the financial hurdles hindering drug development for rare diseases. The lengthy, expensive process of creating a drug molecule is a major deterrent for pharmaceutical companies due to low returns. Further, there are intricacies of licensing and patenting. To ensure success in indigenous medication development, collaborative research should be fostered by integrating research pipelines, paving the way for industry-academia to drive innovations."

Adding his perspective, ***Dr Ashwin Dalal, Head, Diagnostics Division, Centre for DNA Fingerprinting and Diagnostics,*** highlights "India's substantial contribution to the rare genetic disease burden is due to its vast population and diversity. There is absence of a specific rare disease definition due to inadequate epidemiological data. Traditional diagnostics have shifted from cytogenetics to next generation sequencing (NGS), yet treatment cost remains a challenge. For determining disease prevalence and carrier frequency, technologies like exome sequencing can be used. Also, there are various country-level initiatives like India's Rare Disease Policy under which 12 centres of excellence (CoEs) have been established across the country . The National Policy for Rare Diseases categorises rare genetic diseases into three groups, granting eligible patients financial aid and offering up to Rs 50 lakh for select patients but that remains a temporary solution."

Laying focus on the CoEs, these are tertiary care multi-speciality centres which come with their own set of challenges. The first challenge is to sensitise the medical staff for the rare diseases, who otherwise receive patients with multiple medical manifestations. Due to heterogeneity of the conditions of the rare disease patients, it is difficult to tell the exact number of rare disease patients visiting the centres. Also in such conditions, the patients need to visit multiple wards and it is thus time consuming and difficult for the patients as well as the clinicians. The procurement of the medicines, the associated paperwork, delays in receiving the drugs and the changes in the required dosage of the medicines that are weight dependent, are other associated challenges.

India's substantial contribution to the rare genetic disease burden is due to its vast population and diversity. There is absence of a specific rare disease definition due to inadequate epidemiological data. Traditional diagnostics have shifted from cytogenetics to next generation sequencing (NGS), yet treatment cost remains a challenge. For determining disease prevalence and carrier frequency, technologies like exome sequencing can be used. Also, there are various country-level initiatives like India's Rare Disease Policy under which 12 centres of excellence (CoEs) have been established across the country.

What's the Right Approach?

With the democratisation of knowledge after COVID-19, it is easier to create awareness of therapeutics and discovery of potential drugs for rare disease. If more companies in India are established to tackle drug discovery, there will be an increase in treatment, i.e. the treatment would not be rare and hence the costs will be brought down gradually. But how do we translate this in the form of a permanent solution?

"A few success stories are all that are needed for a model to go forward. We need to make prenatal and newborn screening mandatory for treatable disorders. Exploring repurposed and low-cost drugs is required, establishing infrastructure for drug testing, and fostering collaboration partnerships between government, administrative and private stakeholders - both in R&D and policy is required. Building strong partnerships between researchers, clinicians, and industry stakeholders; utilising cutting edge technologies such as CRISPR and mRNA technologies to bring down costs and ensure quality manufacturing; exploring philanthropic funding, CSR initiatives, and the National Research Foundation; and creating a federation of databases and leveraging digital tools for virtual consultations are some of the key strategies to be implemented", says ***Dr Rakesh Mishra, Director, Tata Institute for Genetics and Society (TIGS) India.***

A crucial observation underscores the potential of government laboratories to motivate private companies to engage in the development of therapeutics for rare genetic diseases. The need to address awareness of these diseases among people can be a milestone in dealing with respite care and disease management apart from therapeutics and diagnostics.

"Early diagnosis; epidemiological data collection; therapeutics availability and affordability; awareness and expertise development; and dedicated research initiative are some of the various ways in which the government is supporting rare genetic disease research. To address the critical challenges of therapeutic availability and affordability, there should be an increase in the number of grants, more collaboration, and networking efforts", says ***Dr Nabendu Chatterjee, Biochemist, ICMR-National Institute of Cholera and Enteric diseases.***

He further advocates for existing government initiatives such as genomics projects, networking between patient advocacy groups and other stakeholders, therapeutics development for inherited rare diseases, and the National Apex Committee: National Consortium for Research and Development on Therapeutics in Rare Diseases (NCRDTRD).

The need for policy reforms, ensuring easier access to healthcare and research opportunities for patients, is resonating across the ecosystem. It all requires integration in order to set in motion the pathways to accelerate solutions in the rare genetic diseases field. BS

Dr Manbeena Chawla
manbeena.chawla@mmactiv.com

(Key takeaways of this article are based on the inputs provided by various experts at the Rare Genetic Diseases Research Summit (REDRESS) 2023 hosted by the Tata Institute for Genetics and Society (TIGS) and the Organization for Rare Diseases India (ORDI), along with the Indian Council for Medical Research (ICMR) as the knowledge partner, with BioSpectrum as the media partner)

Breakthroughs in Rare Diseases Therapeutics

2024 rings positive for those suffering from some kind of rare disease. On January 16, 2024, Vertex Pharmaceuticals and CRISPR Therapeutics announced that the US Food and Drug Administration has approved the use of Casgevy, a therapy that uses CRISPR gene-editing to treat the serious blood disorder, transfusion-dependent beta-thalassemia, marking the second major US regulatory approval for the emerging gene-editing technology. This approval is a testament to the breakthroughs in therapeutics for rare medical conditions.

The previous year witnessed many promising developments in the fight against rare diseases. The recent Casgevy's FDA approval for beta-thalassemia comes just one month after the US drug regulator approved the use of Casgevy in treating sickle cell disease — which is notably the first time the CRISPR-based treatment received a regulatory green light in the United States.

Casgevy uses the novel CRISPR gene-editing technology to modify patients' blood cells and transplant the modified cells back into the bone marrow, triggering an increase in the production of haemoglobin, according to the FDA.

Rare diseases are considered as a significant health challenge. Between 5,000 and 8,000 rare diseases have been identified and these diseases, though not prevalent like other diseases, as a group, affect 6 to 8 per cent of the global population. Rare diseases present unique problems for not only the individuals living with the rare medical condition but for caregivers, researchers, policymakers, and industries as well.

More than 80 per cent of rare diseases are caused by genetic or congenital aberrations, and 75 per cent present with a wide range of neurological symptoms and physical and intellectual disabilities. Sadly, rare diseases mostly affect children or young adults, and even worse, several siblings can be affected in the same family. As such, these diseases come with substantial hardship for both parents and patients. Hence, advancing therapies to cater to their well-being is of utmost critical.

Urgency for R&D

The APAC region is teeming with exciting new frontiers in rare disease treatment, offering hope for patients previously facing limited options. Ever since the 'Action Plan for Rare Diseases' was launched in 2018 by the APEC Life Sciences Innovation Forum (LSIF) – to improve access to diagnosis, treatment, and care for people with rare diseases – several countries in the Asia Pacific region have become members. As of October 2023, 21 APEC member economies are participating in the plan that is dominated by APAC-based countries.

Several drugs have either been approved by the respective country's regulatory authorities or have been approved for clinical trial initiation. In 2023, for Acute Graft-versus-Host Disease (GVHD), a cell therapy developed by the Australian company Genetic Technologies received approval in Japan for treating steroid-refractory acute GVHD. This offers a new option for patients facing this life-threatening complication of bone marrow transplants.

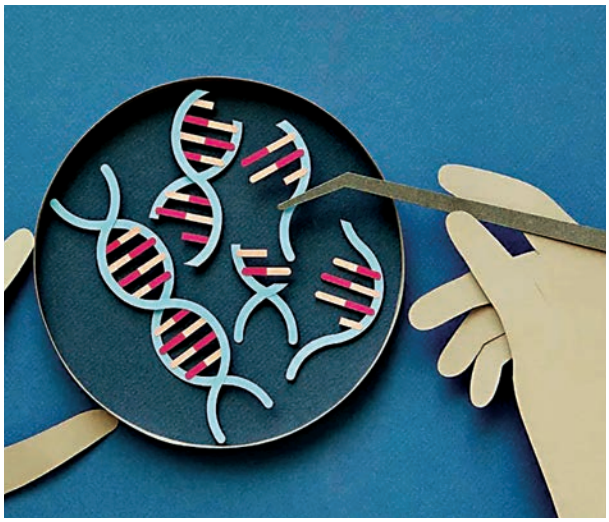
Zolgensma, a gene therapy for Spinal Muscular Atrophy (SMA) types 1 and 2, was approved in China in 2023. This groundbreaking therapy offers a single-dose solution for infants and young children with SMA, addressing a critical need in the region.

Funding for this unmet area has also been recorded. The Australian government has announced 27 grant recipients under the 2021 Rare Cancers, Rare Diseases and Unmet Need (RCRDUN) grant opportunity. The grants have been awarded to 27 projects, which aim to increase clinical trial activity in Australia for rare cancers and rare diseases by supporting new, high-quality research.

Significant strides in the rare diseases in the APAC region include:

1. Precision Medicine: Traditional one-size-fits-all approaches are giving way to targeted therapies based on individual genetic profiles. This personalised approach holds immense potential for rare diseases with diverse genetic causes, allowing for more effective and specific treatments.

Early last year, the National Health Research Institutes (NHRI) inked an MoU for precision medicine collaboration with Singapore's KK Women's



and Children's Hospital. The two parties will collaborate in three areas: whole-genome sequencing (WGS) clinical services and translational research for rare diseases, with a particular focus on Chinese genetic characteristics.

2. Gene Editing Tech: Techniques like CRISPR-Cas9 and TALENs offer the potential to permanently correct genetic defects at the source, leading to potential cures for various rare diseases. While still in the early stages, preclinical and clinical trials are ongoing for conditions like Leber's congenital amaurosis, Duchenne muscular dystrophy, and beta-thalassemia.

South Korea's Celltrion is developing a gene therapy for Duchenne Muscular Dystrophy (DMD) using CRISPR-Cas9 technology, with plans for clinical trials in 2024. This potentially curative approach targets specific genetic mutations causing DMD.

3. Gene and Cell Therapy: Stem cell transplants and gene therapy vectors are being explored to introduce healthy genes or repair defective ones. This approach holds promise for diseases like haemophilia, sickle cell disease, and lysosomal storage disorders. For instance, China's GenScript Biotech is developing gene therapies for Hunter syndrome and Leber's congenital amaurosis. GenScript is also developing gene therapies for both types of haemophilia, aiming to provide a permanent cure by introducing functional copies of the missing clotting factor genes. In late 2023, Japan approved Cerezyme, a recombinant enzyme replacement therapy, for Gaucher disease type 1. This approval expands treatment options and access for patients in the region.

4. AI and Big Data: Advanced computational tools are aiding in drug discovery, patient diagnosis, and clinical trial design. By analysing vast amounts of genetic and clinical data, AI can help identify disease patterns, predict treatment responses, and accelerate the development of new therapies.

Researchers at China's Peking University are developing AI models to analyse medical images like CT scans and MRI scans for early detection of rare lung diseases like idiopathic pulmonary fibrosis. Australian researchers, on the other hand, are working on AI-assisted diagnosis of genetic diseases. Researchers at the Garvan Institute of Medical Research are developing AI models to analyse facial features and genomic data for rapid diagnosis of rare genetic syndromes, particularly in newborns.

Building virtual patient cohorts has also been trending for the past few years and is showing a higher trend for future research and deployment. AI is being used to create virtual patient cohorts based on clinical data and electronic health records. This allows researchers to study rare diseases more effectively even with limited patient numbers.

Several startups have also forayed into this space. For example, Ubie Inc., a Japan-based startup, has signed a comprehensive collaboration agreement with Takeda Pharmaceutical Co. to promote digital transformation, which aims to guide people to appropriate medical care for rare diseases.

Regional Collaboration

This story throws some light on the progress taking place in APAC's rare disease drug discovery and its market. However, the landscape of rare disease medicine in the Asia Pacific is much more dynamic and is constantly evolving. Examples cited here are just a glimpse into the promising efforts underway in the regions, offering hope for a brighter future for patients and their families.

But, it's important to note that access to these innovative therapies remains a big challenge in many parts of APAC. Affordability, healthcare infrastructure, and awareness of early detection all play a role in ensuring equitable access for patients across the region.

Though the Orphan Drug Act of many APAC countries incentivises drugmakers to prioritise rare diseases in their pipelines and gives companies marketing exclusivity for additional years before generics enter the market, there is a long road ahead. The APAC region needs to solidify more collaboration between governments, academic institutions, and biopharma companies. Efforts like the APEC Rare Disease Action Plan and the Asia Pacific Rare Disease Network (APRDN) need to increase their knowledge sharing, resource allocation, and clinical trial opportunities. BS

Anusha Ashwin

"Genomics holds immense potential in future outbreaks by identifying the genetic basis of infectious agents"

Tuberculosis (TB) has been a long-standing problem in India. To effectively treat TB, it is imperative to find newer targets, which are important for in-vivo bacterial survival and persistence. The Centre for Cellular & Molecular Biology (CCMB), from Hyderabad lead by its director Dr Vinay Kumar Nandicoori is working on finding new TB targets. In an interaction with BioSpectrum, he shed light on key focus areas of CCMB's research in molecular biology and particularly genetic research in addressing personal and targeted medicines for patients suffering with TB & breast cancer. ***Edited excerpts;***

« **Dr Vinay Kumar Nandicoori,** Director, Centre for Cellular & Molecular Biology (CCMB), Hyderabad

Can you tell us about the challenges and goals of CCMB's research in TB?

TB is a global concern, and India bears a significant burden. We face challenges in the continuous spread of the disease and the emergence of drug resistance in 15 per cent of patients. Our collaborative research involves sequencing clinical genomes of TB strains to identify novel mutations and understand prevalent strains in India, especially those contributing to drug resistance. In our labs, we aim to understand the basic mechanisms of Mycobacterium TB. Studying specific proteins helps us grasp their functions within the pathogen and the host. This fundamental research contributes to identifying potential therapeutic targets for drugs and enhances our understanding of how Mycobacterium TB operates.

How do you see genomics contributing to the field of breast cancer research and TB?

In breast cancer research, genetic sequencing helps ascertain the cause at specific stages. Identifying new mutations and changes in expression patterns correlated with cancer progression is vital. Through statistical analysis and validation in larger populations, we aim to develop biomarkers aiding in diagnosing and understanding the disease. Similar approaches are taken in tuberculosis research, emphasizing the potential of genomics in unravelling the complexities of these health conditions.

Can you tell us the key focus areas in genomics and genetic research at CCMB, specifically in the development of targeted and personalised medicine?

Our focus areas in genomics cover a wide spectrum, ranging from understanding genes' structure, function, & regulation to their impact on health, diseases, & evolution. Key areas include Personalised Medicine, Genomic Medicine, Population Genomics, Functional Genomics, Epigenetics, Human Evolution & Migration, Microbiome Research, Cancer Genomics, Infectious Disease Genomics, & addressing Ethical, Legal, & Social Implications (ELSI). These areas collectively contribute to advancing medical applications and insights into human biology. However, the challenge lies in the affordability of genomic sequencing for the entire population, especially for developing personalised medicines.

Speaking of personalised medicine, how is genomics used in the study of rare genetic diseases, and what role does Exome sequencing play in this context?

In case of rare genetic diseases, it becomes crucial to explore the genetic basis for accurate diagnosis. Utilising technologies like Exome sequencing, a cost-effective alternative to whole-genome sequencing, helps identify mutations in coding regions of proteins. This aids in understanding the genetic foundations of these diseases, providing valuable information for addressing complex medical conditions more effectively.

How do you envision the future use of genomics in addressing major disease outbreaks, and what role does it play in gene therapy for cancer?

Genomics holds immense potential in future disease outbreaks by identifying the genetic basis of infectious agents and chronic diseases. Take for instance the gene therapy for cancer; specific cohorts undergo sequencing to identify genetic markers associated with particular cancers, serving as biomarkers for faster and more accurate diagnoses. BS

Amguth Raju

"Early diagnosis through advanced screening tech, coupled with heightened awareness is crucial"

« **Alok Malik,** President & Business Head - India Formulations, Glenmark Pharmaceuticals Ltd

The oncology market in India is steadily growing, driven by an increasing cancer incidence and a strong demand for advanced treatments. However, there remains substantial untapped potential, primarily in improving access to cutting-edge therapies and expanding reach to underserved regions. Glenmark Pharma, with its patient-centric approach and innovative solutions, has been steadily increasing its market share by introducing high-quality and affordable cancer drugs. Alok Malik, President & Business Head - India Formulations, Glenmark Pharmaceuticals Ltd, in an exclusive interview with BioSpectrum, spoke at length about the company's mission to enhance access to high-quality cancer care in India and the untapped market potential, new launches and the plans ahead. ***Edited excerpts:***

What are Glenmark's latest launches in oncology?

Chemotherapy, a widely used cancer treatment, often results in distressing side effects such as nausea and vomiting. In an exclusive collaboration with Helsinn, a Swiss biopharma Group Company, we are pioneering the introduction of the innovative I.V. injection formulation, AKYNZEO IV, in India. This ground-breaking treatment is designed to alleviate chemotherapy-induced nausea and vomiting (CINV) and is the first of its kind in the country. Additionally, we have introduced Candipoz GR 300 for prophylaxis against invasive fungal infections in the region, further underlining our commitment to advancing treatment standards. In continuation of our supportive care portfolio expansion strategy, we have introduced the Eltrog brand (Eltrombopag tablets) used for thrombocytopenia and severe aplastic anaemia. Globally, we are developing and working towards commercialising our innovative oncology products.

With cancer cases rising in India, how do you see the drug market growing?

With the increasing incidence of cancer cases in India, the industry is witnessing growth driven by several factors. Early diagnosis through advanced screening and diagnostic technologies, coupled with heightened awareness, is crucial in ensuring effective treatment. The government has launched several initiatives such as the National Cancer Control Programme and the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases, and Stroke. These programmes are primarily aimed at creating awareness and strengthening the existing infrastructure of cancer treatment. The industry continually advances with personalised medicine, immunotherapies, and innovative drugs. Collaborative efforts are key in making these treatments more accessible and affordable to a broader segment of the population. Additionally, holistic cancer care, including supportive measures and preventive strategies, plays a vital role in addressing the growing cancer burden. Glenmark, as a key player, remains committed to pioneering innovative oncology solutions and contributing to the evolving landscape of cancer care in India.

The drugs and treatment costs for cancer take a toll. How does your patient support programme help such patients?

Our Oncology Patient Support Programme is designed to address the multifaceted challenges patients encounter when seeking cancer treatment. This initiative, operating through a unified platform, replicates the patient's journey and empowers them to overcome access barriers, including issues related to accessibility, awareness, and treatment adherence. Each year, over 3,000 patients derive substantial benefits from our Programme called Enable.

What are the company's plans for oncology? Are any M&As or launches planned this year?

With ongoing efforts to introduce new treatments for Prostate, Breast, and Renal Cancers, our focus on oncology remains strong. Additionally, we are committed to addressing CINV through innovative therapies, with an emphasis on first-in-market releases. BS

Bhagwati Prasad

"Rapid evolution of technologies, biopharmaceuticals, and genomic medicine are reshaping the healthcare sector"

Terumo India, the Indian arm of Japan-based medtech firm Terumo Corporation, has recently announced the launch of new medical tools, intended for use in the management of liver cancer. With World Cancer Day, on February 4, 2024, calling to improve prevention, detection and treatment of cancer, new products are being launched in the Indian market to shape a way forward. BioSpectrum India spoke to Shishir Agarwal, President and Managing Director, Terumo India about the current scenario of the oncology medical devices market in the country. ***Edited excerpts-***

« **Shishir Agarwal,** President and Managing Director, Terumo India

For the first time in India, Terumo has introduced an advanced therapy for the management of liver cancer. What challenges are being addressed with this introduction? What are the objectives to be achieved?

Cancer continues to be a major contributor to the global disease burden. Hepatocellular carcinoma (HCC) is the most common type of primary liver cancer, emphasising the importance of its awareness and intervention. Recognising this pressing need, the introduction of Balloon-TACE (B-TACE) in India is a pivotal step in addressing critical challenges associated with liver cancer management. With Occlusafe, Terumo's B-TACE device, patients benefit from more precise and targeted delivery of chemotherapy drugs to the tumour. Additionally, damage to surrounding healthy tissues is minimised. This is associated with improved response rates with significantly fewer repeat treatments required versus TACE alone. This offers the potential to preserve liver function.

Is Terumo planning to launch more products in the Indian oncology market? Please share details.

With more than 100 years of experience, Terumo's extensive medical device portfolio ranges from vascular intervention, cardio-surgical solutions, blood transfusion, and cell therapy technology to medical products essential for daily clinical practice.

Yes, Terumo India aims to expand interventional oncology portfolio with novel therapeutic solutions, and to provide a more comprehensive toolkit for managing cancer care. Our commitment to advancing healthcare in India is built on the foundation of research and cutting-edge technology through a profound understanding of the healthcare system. Terumo Corporation (Japan) has a wide range of portfolios. Our plan is to gradually bring in all relevant latest technologies to India after carefully assessing the healthcare needs.

What are the current challenges facing the oncology medical devices market in India?

Cancer's global impact drives an escalating demand for chemotherapy, acting as a key catalyst propelling the growth of the oncology devices market, according to FICCI. However, challenges persist, particularly in developing countries like India, where healthcare spending is lower as compared with their developed counterparts. Despite government efforts to streamline regulations and bureaucracy, the landscape remains intricate. Accelerating growth demands creation of an efficient ecosystem, skill development, and unwavering support for ease of doing business.

How is Terumo leveraging the concept of genomics in the medical technology space for cancer detection and treatment, or for other diseases?

The healthcare landscape is undergoing a profound global paradigm shift, influenced by the ageing population and the increasing prevalence of chronic illnesses. Concurrently, the rapid evolution of technologies, encompassing digitalisation, biopharmaceuticals, and genomic medicine, is reshaping the healthcare sector. As we conclude the second term of our 5-Year Growth Strategy, GS26, we remain focused on the innovation strategy vision of "From Devices to Solutions." The strategic pillars, encapsulated by the 3Ds (Delivery, Digital, Deviceuticals), will guide our solutions towards innovation and synergy. BS

Dr Manbeena Chawla
manbeena.chawla@mmactiv.com

How Biotech Sector Can Capitalise on AI

« **Dr Rajneesh K Gaur,** Scientist F, Department of Biotechnology, Ministry of Science and Technology, Government of India

Artificial Intelligence (AI) is now ramified in every sector including biotechnology. The impact of AI is already visible in the biotech sector and there is a boom of startups using AI for various applications. However, there is a need to develop a holistic regulatory system to make the technology more responsible. Let's explore further.

India has over 1900 AI startups including biotechnology (Zinnov-NASSCOM India Tech Start-up Landscape Report 2022). The pharma industry will be a major beneficiary of AI's applications and might spend around $3 billion on AI in drug discovery by 2025.

In the biotech sector, AI has a big role to play in the analysis, learning, prediction and better decision-making of innovative solutions in areas of agriculture. It includes crop harvesting, monitoring crop and soil, gene editing, forecasting plausible yield), health (such as medical data analysis for finding novel drug targets, forecasting drug efficacy and toxicity, speed up the drug development process, creating personalised medicine, medication management, detecting abnormalities like cancerous tumours, to build new wearable devices that can detect and monitor certain disorders), to modify the genes and traits of animals and create mixed or cross-breed versions, to provide efficient production and better product quality, to identify the locations of genes, classification of protein along with protein's catalytic role and biological function, analysis of gene expression and predictive modelling.

In the last few years, several AI-enabled biotech startups have come up. The application of AI has resulted in the development of a few notable algorithms such as new AI models e.g. 'ProtGPT2' and 'ProGen'. ProtGPT2 and ProGen have been trained on 45 million and 280 million protein sequences respectively. These model software have been used to design new proteins. Application of machine learning resulted in enhancing the accuracy of structure prediction from 70 to >80 per cent. By forecasting the 3D protein structure, AI helps in determining the effect of a substance on the target as well as safety considerations before its synthesis or production e.g. AlphaFold (2023), a Google subsidiary DeepMind algorithm, significantly improved the modelling of 3D protein systems from amino acid sequences. The other biotech startups in the last few years added to the growth of generative AI, including 'Jasper' and 'Stability AI', which has its text-to-image generation tool called 'Stable Diffusion (2022)'. Open-source AI programmes such as 'CRISPR libraries' and 'H2O.ai' are convenient for executing repetitive tasks like data entries and analysis.

AI applications are now slowly culminating in product development and their commercialisation. In the USA, the FDA recently approved a few Software as a Medical Device (SaMD) e.g. IDx-DR (2018) for screening of diabetic retinopathy and 'DiA Imaging Analysis's AI program' (2023) to assist clinicians in performing cardiac ultrasound exams. In 2021, Abbott launched its new artificial intelligence-powered coronary imaging system in Europe. AI is also changing the field of Radiology and Radiotherapy processes and helps in making 'Nanorobots' as novel drug delivery systems to enhance drug efficacy and reduce adverse effects. In India, the development of AI-based products, especially, Medical aids is supported by the Biotechnology Industry Research Assistance Council (BIRAC).

Regulatory Framework

AI provides easier, cheaper, and faster production capabilities with the danger of misusing the technology. In the biotech sector, it may lead to solutions which might compromise social security and the life of human beings such as the design and development of new bioweapons or toxins which are hard to detect. Under these circumstances, AI needs tougher measures to control its misadventure. All the

major governments in the world are formulating a regulatory framework to control the AI field. The USA has multiple Acts for regulating the AI's activities. The various Acts are 'National Artificial Intelligence (AI) Initiative Act (2020)', Algorithmic Justice and Online Transparency Act, Artificial Intelligence (AI) Training Act, AI in Government Act and recently Artificial Intelligence Research, Innovation and Accountability Act (AIRIA), 2023. In line with these acts, the US Food and Drug Administration (FDA) issued the "Artificial Intelligence/Machine Learning (AI/ML)-based Software as a Medical Device (SaMD) Action Plan".

The EU proposed the Artificial Intelligence Act (AIA), which contemplates regulation of AI based on its potential risks, and the General Data Protection Regulation (GDPR), Digital Services Act, Digital Markets Act to protect users privacy and to curb the anticompetitive practices of the tech giants. Australia's 'Artificial Intelligence (AI) Ethics Framework' examines the probability of risk, together with the consequence via suggestive frameworks. Countries like Singapore, China, UAE and Brazil have issued 'National AI Strategies'. In China, no company can produce AI services without proper approvals. India does not have specific laws for data protection but personal information is safeguarded under section 43A and Section 72A of the 'Information Technology Act', 2000. The provisions of the IT Act, combined with the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 (SPDI Rules) establish a technology-agnostic regime for protecting sensitive personal information for all corporate bodies. Recently, the Ministry of Electronics and Information Technology (MeitY), India proposed the 'Digital India Act (DIA)' and stated that the proposed law would regulate "high-risk AI systems" through legal, quality testing framework to examine regulatory models, algorithmic accountability, zero-day threat and vulnerability assessment, examining AI based ad-targeting, content moderation, etc. The Act will be implemented alongside the 'Digital Personal Data Protection Act (2023)'.

Indian Initiatives

The Government of India is also well aware of the potential implications of AI in the country's industrial landscape and has taken several initiatives to enable the AI ecosystem. In 2018, NITI Aayog published its discussion paper titled 'National Strategy for Artificial Intelligence' for identifying some of the sectors like Healthcare, Education, Agriculture, Smart Cities and Mobility for deployment of AI. The Indian Government launched the National Artificial Intelligence Portal called https://indiaai.gov.in/ in May 2020. The portal is a one-stop digital platform for AI-related developments in India, sharing resources such as articles, startups, investment funds in AI, resources, companies and educational institutions related to AI in India. The Data Empowerment and Protection Architecture (DEPA) by NITI Aayog presents a technical framework for people to retain control of their personal data and the means to leverage it to avail services and benefits.

In 2021, the Department of Science and Technology (DST), New Delhi through the Indo-US Science and Technology Forum (IUSSTF) launched a joint collaborative US-India Artificial Intelligence (USIAI) initiative. Under this initiative, Research and Technology Development in AI is being promoted and implemented in the country through a network of 25 technology innovation hubs set up under the National Mission on Interdisciplinary Cyber-Physical Systems (NM-ICPS). The Ministry of Electronics

Artificial Intelligence (AI) based product development supported by Biotechnology Industry Research Assistance Council (BIRAC)

S. No.	Product	Application
1.	Agropeeper App	Quality Assessment and Shelf life evaluation of fruits
2.	CervASTRA	Point of care cervical cancer detection system
3.	COGNIABLE	Early detection and intervention in children with developmental disorders
4.	Dozee	Contact-free monitoring of the vital parameters of the patients on a normal bed
5.	FetalLite	Foetal ECG signal extraction for mothers in labour or post 37 weeks of gestation
6.	GAITSENSE	Gait Analysis Technology
7.	Neukelp	Smart Posture Trainer
8.	Robot X 100	Multipurpose Robot for Agriculture
9.	SAVEMOM	IoT based Maternal Healthcare solutions
10.	Seed Vision	Seed classifier and Quality Analyser
11.	SWAASA	Platform for Respiratory Assessment
12.	Thermalytix	Algorithms to interpret thermal images for breast health

Indian companies and their AI-based applications

S. No.	Company	Headquarter	AI-based Application
India			
1	Acuradyne	Mumbai	Preventive healthcare
2	Aganitha Cognitive Solutions	Hyderabad	Accelerate drug discovery and development through Insilco solutions
3	Artelus	Bengaluru	Technologies to support clinicians in diagnosis, prognosis and treatment of diseases
4	Cellix	Balanagar, Hyderabad	Synergix AI a platform aims to create a diversified portfolio of drug candidates for multiple indications
5	DocPlexus	Pune	Knowledge upgradation of Clinicians
6	Dozee	Bengaluru	AI based patient monitoring system for healthcare providers
7	HCL technologies	Noida	AI based medical Science solutions
8	HealthKart	Gurugram	Medical and Nutrition products
9	HealthPlix	Bengaluru	AI and cloud based electronic medical record management solution
10	Infosys	Bengaluru	AI based Medical Solutions
11	Kellton Tech solutions	Gurugram	AI powered platform to provide personalised care to patients
12	Lybrate	Gurugram	Healthcare communication
13	Mfine	Bengaluru	AI-powered telemedicine mobile app
14	Mindtree	Bengaluru	AI based medical Science solutions
15	Muse Diagnostics	Bengaluru	eTaal digital stethoscope and Surr app for listening to, recording, sharing and analysing body sounds
16	Neurosynaptic communication	Bengaluru	High-quality ReMeDi Remote Healthcare Delivery Solutions
17	Nirmai Health Analytix	Bengaluru	Identification of Breast Cancer
18	Oncostem	Bengaluru	Application in oncology
19	Persistent Systems Ltd	Pune	AI based solutions in Healthcare
20	PharmEasy	Mumbai	To provide medicines at affordable rate
21	Predible Health	Bengaluru	Flagship Product 'LungQ' for lung disease diagnosis
22	Qure.ai	Mumbai	AI based decision support tool for diagnostic images
23	Semantic Web India	Bengaluru	Data analysis software for Genomics Diagnostics and Research
24	Sigtuple	Bengaluru	AI platform to perform 'screening & advanced diagnosis of urine, blood, semen samples, along with retinal scans & X-rays'
25	Skyware automation	New Delhi	AI enabled scientific storage solutions for agri-warehouses
26	TCS	Mumbai	AI based medical science solutions
27	Tech Mahindra	Pune	AI based medical science solutions
28	The Gene Box	Mumbai	predictive genetic analysis to identify innate variations
29	Wipro	Bengaluru	AI based medical science solutions
30	Molecule AI	New Delhi	AI based drug discovery
31	Immunito AI	Bengaluru	AI based drug discovery
32	Prescience Insilico	Bengaluru	AI based drug discovery
Multinational			
1	AIRA Matrix	Mumbai	Drug discovery and Development
2	Autonomize	Bengaluru	Human-centred AI company that is democratising access to data to power human health outcomes
3	Bloodsure	Indore	Connecting the blood donors and making blood available
4	ChironX	Gurugram	Computer aided diagnostics
5	Cyient	Hyderabad	Healthcare Software and Life Science Solutions
6	Fitcircle	Mumbai	AI powered fitness training and diet coaching app
7	Orbuculum	Chennai	AI to screen for chronic disease through genomic data
8	Swagene	Chennai	Genetics & molecular diagnostics laboratory, Personalised for precision medicine by providing targeted genetic insights

and Information Technology (MeitY), India has also operationalised a clutch of Centers of Excellence (CoEs) to assist in knowledge management and creating capabilities to capture new and emerging areas of technology.

BIRAC, either alone or in association with MeitY and the National Association of Software and Services Companies (NASSCOM), supports Indian industries in the AI area. Further MietY and NASSCOM jointly initiated a programme 'Futureskills PRIME' – a certification programme for reskilling/upskilling IT professionals in 10 emerging areas including Cloud computing and Artificial Intelligence for making India a Digital Talent Nation. The Department of Biotechnology also implemented a programme on Artificial intelligence under the Niti-Aayog's 'Responsible AI #AIforAll' guidelines to ensure the safe and responsible use of AI (R-AI).

The department is also in the process of initiating a Programme on 'Bio-manufacturing'. This initiative will have an in-built component on establishing Bio-artificial Intelligence (Bio-AI) Hubs. These hubs will support AI-powered platforms for the microbial engineering of small molecules at an industrial scale. The initiative will bring together scientific and technological advancement towards achieving a major goal of the Department's vision of BioE3 (i.e. Biotechnology for Economy, Environment and Employment) for green, clean and prosperous India.

Conclusion

Biotechnology has immense scope and applications of AI in streamlining the bio-manufacturing processing, data generation and analysis, executing detailed repetitive tasks, decision making, etc. Industries have already embraced and started delivering AI-based products. To capitalise on AI, a nurturing ecosystem, with the support of open and responsible inter-state regulatory systems is demanded. BS

Bracing for 10 million AMR deaths per year by 2050

« **Vivek Padgaonkar,** Former Director, The Organisation of Pharmaceutical Producers of India (OPPI)

« **Dr Hari Natarajan,** Founder & Managing Partner, Pronto Consult

Antibiotic resistance is intrinsically linked to animal and human consumption patterns, partly driven by inappropriate use of antibiotics. In turn, the emergence of antibiotic resistance fuels changes in consumption patterns, as more costly broad-spectrum antibiotics become required to manage even common conditions. India is the largest consumer of antibiotics globally in terms of absolute volume. Various research studies from India have reported poor prescription quality, including unindicated prescription of broad-spectrum antibiotics without evidence of bacterial infection. These findings are of particular public health relevance considering that India reports high antibiotic resistance in bacteria that cause certain common infections.

Variations exist between Indian states in terms of their population age structure, health-seeking behaviour, infectious disease burden, health systems organisation and the relative contribution of the public and private sectors in healthcare.

The rapid emergence of resistant bacteria is occurring worldwide, endangering the efficacy of antibiotics, which have transformed medicine and saved millions of lives. Many decades after the first patients were treated with antibiotics, bacterial infections have again become a threat. The antibiotic resistance crisis has been attributed to the abuse, overuse and misuse of these medications, as well as a lack of new drug development by the pharmaceutical industry due to reduced economic incentives and challenging regulatory requirements.

In Asia, infectious diseases make up a substantial 40 per cent of the total disease burden. This includes formidable illnesses like Malaria, Tuberculosis (TB), and Human Immunodeficiency Virus (HIV), which necessitate treatment with antibiotics. Unfortunately, in India, there is a lack of a robust surveillance system. When it comes to Malaria, the conventional treatment with Chloroquine has proven ineffective, thereby requiring the use of more costly artemisinin derivatives. Shockingly, 28 per cent of TB cases in the region are classified as Multi-Drug Resistant (MDR) TB. Moreover, second-line therapy for managing HIV is six times more expensive. This not only makes the fight against these diseases more challenging, but it also significantly escalates the associated costs.

In a recent study conducted by the Indian Council of Medical Research (ICMR), alarming revelations about Antibiotic resistance have emerged, painting a grim picture of healthcare in India. The abuse and overuse of antimicrobials, including antibiotics, antivirals, and antifungals, have led to widespread resistance to these drugs within the community.

The battle against antibiotic resistance is a critical one, demanding a collective effort from healthcare professionals, researchers, and policymakers alike.

Antibiotic Development

Antibiotic development is no longer considered to be an economically wise investment for the pharmaceutical industry. Because antibiotics are used for relatively short periods and are often curative, antibiotics are not as profitable as drugs that treat chronic conditions, such as cardiac, diabetes, psychiatric disorders, asthma, or gastroesophageal

reflux. A cost–benefit analysis by the Office of Health Economics in London calculated that the net present value (NPV) of a new antibiotic is only about $50 million, compared to approximately $1 billion for a drug used to treat neuromuscular disease. Because medicines for chronic conditions are more profitable, pharmaceutical companies prefer to invest in them. Over 80 years, a total of 150 antibiotics have been developed. However, it is not anticipated that any new antibiotics will be introduced for a minimum of 10 years.

Because of these factors, many large pharmaceutical companies fear a potential lack of return on the investment that would be required to develop a new antibiotic. The Infectious Diseases Society of America (IDSA) reported that as of 2013, very few antibacterial compounds were in phase 2 or 3 development.

Co-trimoxazole Clinical Effectiveness

Clinical Effectiveness comparison of Co-trimoxazole versus leading antibiotic molecules and against leading diseases conclusively proves that this most economical molecule ie Co-trimoxazole is considered the antimicrobial agent of choice in the treatment of many diseases, minimising the risk of vital organ involvement and relapses and is superior or equal to many molecules that are prescribed in the country.

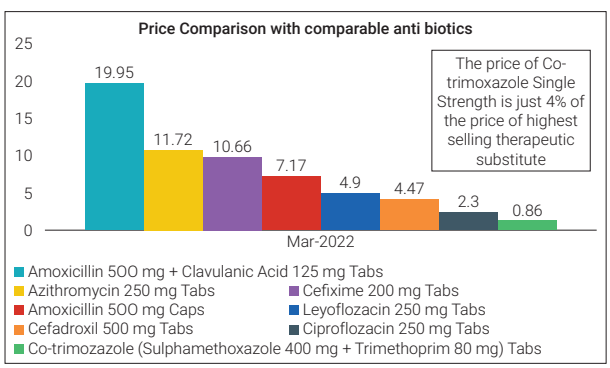
Therapeutic Substitutes in Antibiotics

In India, out-of-pocket expenditure constitutes ~60 per cent of total health expenditure with a substantial 40 per cent being incurred on medicines (Report of Standing National Committee on Medicine SNCM 2022). With this background, it is of paramount importance that the accessibility and availability of essential medicines be enhanced to reduce the financial burden.

The National List of Essential Medicines (NLEM) of the Ministry of Health & Family Welfare (MOHFW) is incorporated in the Schedule-I of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). The formulations under Schedule-I of DPCO, 2013 are mentioned according to their therapeutic category. There is no separate classification of antibiotics based on the generations i.e., 3rd or 4th generation Antibiotics. However, Section 6.2 of Schedule-I of DPCO, 2013 deals with the class, "Antibacterials", which includes 95 formulations of 27 medicines. Out of these, ceiling prices for 74 formulations have been fixed under NLEM 2022 and 11 formulations under NLEM 2015 as of July 31, 2023, by the National Pharmaceutical Pricing Authority (NPPA).

Prices of other molecules which are used as therapeutic substitutes for bacterial infections in case of non-availability of Co-trimoxazole. (Trimethoprim 80 mg) + Sulfamethoxazole 400 mg) tabs

Molecule	Price per tab excluding GST (March 2022)	Source
Amoxicillin 500 mg + Clavulanic Acid 125 mg Tabs	19.95	NPPA S.O. 1499 (E) March 30, 2022
Azithromycin 250 mg Tabs	11.72	
Cefixime 200 mg Tabs	10.66	
Amoxicillin 500 mg Caps	7.17	
Levofloxacin 250 mg Tabs	4.90	
Cefadroxil 500 mg Tabs	4.47	
Ciprofloxacin 250 mg Tabs	2.30	
Co-trimoxazole (Trimethoprim 80 mg) + Sulfamethoxazole 400 mg) tabs Tabs	0.86	NPPA S.O. 1499 (E) March 30, 2022



"A considerable price difference was observed between brands of a particular generic formulation marketed by different firms. To illustrate, one of the top-selling formulations in the antibiotic category, namely, amoxicillin + clavulanic acid (Tablet, 125/500 mg), is currently sold by 217 companies under 292 brands. Substantial price variation was observed between companies selling different brands, ranging from Rs 40 to Rs 336 for a pack of six tablets."

"The price difference for antibiotics was in the range of 82–193 per cent "

Source: CCI Report market-study-on-the-pharmaceutical-sector-in-India

As evidenced by the data, despite the seemingly strong generic competition, gauged in terms of the number of players present in each of the therapeutic areas and at the level of formulations/molecules, consumers in India ostensibly pay a premium for brands.

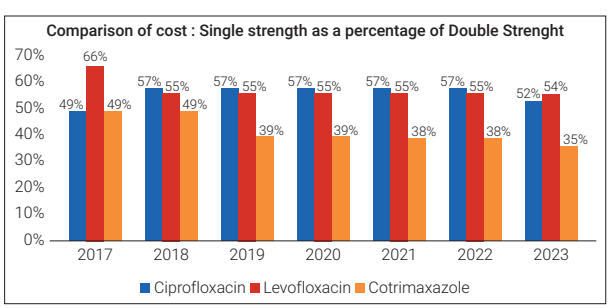
The substantially large price variations amongst various brands cater for the same therapeutic areas. (CCI Nov 18, 2021, mentions about the same formulations)

Anti-infective therapy Penetration			
Therapy Area	**No. of Formulations**	**No. of Brands**	**No. of Brands Per Formulation**
Anti-Infective	290	5349	18

The average number of brands per formulation across therapy areas hides the stark variation observed within each formulation. The number of brands varies considerably even between different strengths and doses.

Price Comparison: Single Strength vs Double Strength formulations in Antibiotics

Molecule (Tablets)	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Ciprofloxacin 500 mg		4.01	3.9	3.23	3.42	3.57	3.64	3.66	4.05	4.24
Ciprofloxacin 250 mg		2.1	2.27	1.58	1.95	2.03	2.07	2.08	2.3	2.19
Ratio		52%	58%	49%	57%	57%	57%	57%	57%	52%
Levofloxacin 500 mg				6.09	7.57	7.89	8.04	8.08	8.95	8.80
Levofloxacin 250 mg				4.00	4.14	4.32	4.40	4.42	4.9	4.76
Ratio				66%	55%	55%	55%	55%	55%	54%
Cotrimaxazole 800/160	1.28	1.37	1.33	0.96	0.99	1.32	2.02	2.03	2.25	2.52
Cotrimaxazole 400/80	0.58	0.6	0.62	0.47	0.49	0.51	0.78	0.78	0.86	0.89
Ratio		45%	47%	49%	49%	39%	39%	38%	38%	35%



The difference in costing of the single strength and double strength is usually attributed to the quantum of API, whereas the rest of the cost components such as excipients and packaging costs are similar, therefore in terms of costing, the cost of single strength is usually more than 50 per cent of double strength. A similar difference can be observed in the prices in the above table which exemplifies that the ratio of the price of single strength as a percentage of double strength is over 50 per cent for antibiotics like levofloxacin and Ciprofloxacin, whereas for cotrimoxazole it is as low as 35 per cent.

The relatively larger number of brands are typically present in markets with a larger number of formulations. In some therapy areas, the number of brands created is disproportionately larger than the number of formulations.

The market failure (non-availability of medicines in the market) with respect to pharmaceuticals in the context of India can be attributed to several factors, but the main reason is that the demand for medicines is largely prescription driven and the patient has very little choice in this regard. The sales promotion drives doctors' prescriptions. The sales promotion budget is a function of the revenue generated by the brand.

Co-trimoxazole (Trimethoprim 80 mg+Sulfamethoxazole 400 mg) tabs proved to be significantly lower in price to the patients, with fewer options than any of the above-mentioned therapeutic substitutes for patients suffering from bacterial infections. Unfortunately, if the financial unviability continues, companies marketing Co-trimoxazole may be left with no option but to exit from this category leaving ailing patients with many costly exploitative options.

AMR & Health Care Professionals (HCPs)

In the latest study which was conducted amongst 763 HCPs across India including Metros and Class I, II towns and beyond. All of the HCPs opined that AMR is something that they are aware of in their clinical practice. Medical practitioners recognise that AMR is a global health threat and poses a significant challenge to their ability to treat infections effectively, which can lead to higher mortality rates and longer hospital stays.

In the 1436 bills from the chemist's shops across the country analysed in another research study, it was observed that patients buy some antibiotic or the other, in 63 per cent there was one or more antibiotics present.

One of the medical practitioners mentioned, "Antibiotics are less effective when used repeatedly and without any control. We have seen more than 50 per cent of cases wherein repeated usage of Antibiotics has resulted in AMR in our patients and we are very concerned with the same in India."

Answering the Query whether they feel pressured to prescribe antibiotics even when they suspect they may not be necessary, HCPs mentioned that patients pressurise them to prescribe an antibiotic as they feel that the antibiotic will provide quick relief and they can get back to work faster. The medical practitioners said that they believe in the importance of educating patients about antibiotics and they spend time

AMR discussed in Lok Sabha

Union Health Ministry has taken several initiatives to spread awareness about the appropriate use of antibiotics and control AMR which include:

a. Red line campaign was launched to curb over-the-counter sale of antibiotics.
b. The Antibiotics Stewardship Programme (AMSP) has been implemented in 20 tertiary care hospitals to control the misuse and overuse of antibiotics in hospital wards and ICUs.
c. The National Action Plan on AMR was launched in 2017 with the objective of intersectoral coordination, improving awareness, strengthening knowledge and evidence through surveillance of AMR, reducing the incidence of infection through effective infection prevention and control and promoting optimal usage of antibiotics.
d. Issued guidelines for Antimicrobial use in common syndrome in 2019.
e. Developed guidelines on Infection Prevention and Control in 2020.
f. Guidelines for the management of carbapenem resistance have been developed in 2022.
g. To regulate the sale of antibiotics, it has been included in Schedule H and H1 of the Drugs Rules, 1945 and are required to be sold by retail only under the prescription of a Registered Medical Practitioner.
h. State Licensing Authorities are empowered to take action against any violation. The State Drugs Controllers/other stakeholders have been sensitised in this regard.
i. Various Notices/Advisories /Letters have been issued to all State drug controllers, and other stakeholders for strict compliance with the requirements of the Drugs and Cosmetics Act and Rules.

Source : Lok Sabha Unstarred Question No. 4894; Dr M P Abdussamad Samadani

explaining to their patients when antibiotics are necessary and when they are not.

When Pronto Consult conducted a study amongst 456 chemist shops on the key question of "How often do you encounter patients requesting antibiotics for conditions that do not typically require them?", almost 73 per cent of the chemists revealed that patients directly ask them for an antibiotic and want to buy. Most of them don't have a doctor's prescription and want to buy an antibiotic, maybe a formulation of Amoxy-Clav, Azithromycin or Cefixime.

Pronto Consult also spoke with 874 consumers on their awareness of Antimicrobial Resistance. 71 per cent were not aware of AMR while 29 per cent said they have heard or read in the news. This is a serious concern which needs to be addressed by proper education and needs to be taken up by all stakeholders.

A reply to a question posed to consumers, "Do you pop an antibiotic every time you are ill?", 81 per cent mentioned they have taken antibiotics most of the time they have fallen ill and 71 per cent stop the medicine as soon as they feel fine without completing the full prescribed course of the antibiotic.

Dr Karishma Shah, Founder, Pronto Consult said, "Doctors generally view AMR as a complex and critical issue that requires a multifaceted approach, including responsible antibiotic prescribing, patient education, research, and collaboration among healthcare professionals and policymakers to combat this growing threat to public health."

Karishma adds "Antimicrobial Resistance reminds us that in the battle between man and microbe, adaptability is the true measure of strength. It's a call to action for responsible stewardship of antibiotics and the pursuit of innovative solutions, as our survival depends on the wisdom to evolve with the ever-changing microbial world."

Government's Initiatives on AMR

The Government has taken cognisance of the increasing issue of Antimicrobial Resistance (AMR) which can be one of the public health crises in coming years and has taken the following initiatives planned to prevent the increasing risk of AMR;

The Government is planning to expand and diversify the AMR National Action Plans (NAPs) with the robust surveillance systems that will be followed in the hospitals to facilitate early detection of AMR. The centre is aware of the challenges posed by AMR in India. It is a multifaceted problem with significant consequences for individuals as well as Health Care Systems. To capture the trends and patterns of AMR in India, ICMR has established an AMR surveillance and research network (AMRSN) to monitor data on the trends and patterns of antimicrobial resistance of clinically important bacteria and fungi limited to human health from 30 tertiary hospitals.

The MoH&FW has taken several steps to address the issue of AMR including:

i. AMR surveillance network has been strengthened by establishing labs in State Medical Colleges. 38 sites in 30 States/UTs have been included in this network so far.

ii. A national action plan for containment of Antimicrobial Resistance (NAP-AMR) focusing on

the One Health approach was launched in April 2017 to involve various stakeholder ministries/ departments. Delhi Declaration on AMR– an interministerial consensus was signed by the ministers of the concerned ministries pledging their support in AMR containment.

iii. AMR Surveillance Network: ICMR has established an AMR surveillance and research network (AMRSN) comprising 30 tertiary care hospitals, both private and government, to generate evidence and capture trends and patterns of drug-resistant infections in the country.

iv. AMR Research & International Collaboration: ICMR has taken initiatives to develop new drugs/ medicines through international collaborations to strengthen medical research in AMR. Further, to create awareness IEC materials including audio, videos, social media messages and Outdoor Media have been developed and are also shared with states for further dissemination. MoHFW released the National Guidelines for Infection Prevention and Control in Healthcare Facilities in January 2020.

The National Centre for Disease Control under MoHFW is conducting several stakeholder consultations to monitor the implementation of the existing National action plan on AMR by various departments and ministries. The consultations are also to guide the development of a more practical and implementable National action plan on AMR 2.0.

Under the National Programme on AMR Containment, 38 state medical colleges/large Government hospitals in 30 states/UTs have been strengthened to do AMR surveillance on 7 priority pathogens. These sites have robust surveillance systems to facilitate early detection of AMR. AMR emerging alerts are also confirmed at the National Reference Laboratory.

Threat to Humanity

The impact of loss of antibiotic efficacy due to the emergence of drug resistance in various bacterial pathogens is creating a ´silent pandemic'.

AMR poses a substantial threat to humanity, with the potential to render some of our most innovative medicines ineffective against common infections that for decades, and in some cases over a century, have been easily managed with antibiotics.

With the potential for AMR to push 28 million people into poverty and 10 million deaths/year by 2050 (especially in countries), the time to invest in solutions is now. As per the latest estimates for 2021, AMR-related deaths were already more than 4 million. The global response does not match the scale of the problem. The market for new antibiotics is nearly non-existent and, as a result, more than 82

per cent of all antibiotic approvals occurred before the year 2000.

The Supreme Court of India vide Order dated 12.11.2002 in SLP no. 3668/2003 (Union of India vs K.S. Gopinath & others) has directed the Government to ensure that essential and life-saving drugs should be available & affordable to the common public.

The market failure alone may not constitute sufficient grounds for government intervention, but when such failure is considered in the context of the essential role pharmaceuticals play in the area of public health, which is a social right, such intervention becomes necessary, especially when exploitative pricing for the therapeutic substitutes makes medicines unaffordable and beyond the reach of most and also puts huge financial burden in terms of out-of-pocket expenditure on healthcare.

The continuous price control has led to financial unviability therefore causing an erosion in the value of Co-trimoxazole (Trimethoprim 80 mg+ Sulfamethoxazole 400 mg) from 2013 to 2023 ~ 84 per cent erosion of value.

A Collective Responsibility

The government should make the availability of drugs at affordable prices while ensuring affordability, accessibility cannot be jeopardised and the lifesaving essential medicines must remain available to the general public at all times. Therefore, the government needs to take the considered view that the financial unviability of these formulations -Co-trimoxazole (Trimethoprim 80 mg+ Sulfamethoxazole 400 mg)tabs should not lead to a situation, where these drugs become unavailable in the market and the ailing patients are forced unfortunately to switch to very costly alternatives and therapeutic substitutes heavily promoted from the non-scheduled formulations category.

AMR is a silent pandemic, a reminder that our actions today shape the future of medicine. To preserve the power of antibiotics, we must act responsibly and collectively, for a world where infections remain treatable and lives are safeguarded. BS

CSIR-IICT & GITAM sign pact to foster new research in Science and Technology

In a significant development, the Gandhi Institute of Technology and Management (GITAM), based in Visakhapatnam, has formally joined hands with the Council of Scientific and Industrial Research (CSIR)-Indian Institute of Chemical Technology (IICT). The collaboration was solidified through the signing of a Memorandum of Understanding (MoU) aimed at fostering collaboration in the realms of science and technology. The MoU paves the way for collaborative efforts in various scientific fields, including pharmaceuticals, biotechnology, chemical engineering, and medical research. Under this partnership, both institutions have committed to facilitating faculty exchanges, conducting joint research projects, and organising skill development initiatives such as workshops and training sessions. The collaboration will also feature invited lectures on shared interests, project proposals for funding, and opportunities for student internships and research exposure.

IIT-M offers seven new online courses on Sports Science

The Indian Institute of Technology Madras (IIT-M)-National Programme on Technology Enhanced Learning (NPTEL) is launching seven new online courses on Sports Science, which is a fast-growing field in India. The courses can be taken online free of cost. These comprehensive online courses are aimed at bridging the gap between theory and practical applications. The courses are tailored for the Indian and South Asian body structure and cultural aspects. NPTEL was initiated by seven Indian Institutes of Technology (Madras, Bombay, Delhi, Kanpur, Kharagpur, Guwahati and Roorkee) along with the Indian Institute of Science, Bengaluru in 2003. With a recommended Class XII Pass as qualification, learners can take this introductory NPTEL course to explore this growing field. The courses are relevant for students pursuing Bachelor's and Master's in Sports Sciences, Physiotherapy, and Physical Education, and other related areas.

IIM Nagpur, AIIMS Nagpur, TimesPro bring PG certificate programme in advanced healthcare management

The Indian Institute of Management Nagpur (IIM Nagpur) in collaboration with All India Institute of Medical Sciences Nagpur (AIIMS Nagpur) and TimesPro has announced the launch of the inaugural batch of the Post Graduate (PG) Certificate Programme in Advanced Healthcare Management.
The Post Graduate Certificate Programme in Advanced Healthcare Management is a one-of-a-kind joint certification programme with IIM Nagpur and AIIMS Nagpur that is designed for working professionals with approximately two years of experience, offering a transformative curriculum that combines the expertise of healthcare professionals from AIIMS Nagpur and management professionals from IIM Nagpur. The 12-month blended programme aims to equip healthcare and management professionals with the essential skills and knowledge to navigate the complex landscape of healthcare management. It offers an in-depth understanding of the industry through learning modules such as Healthcare Quality and Patient Safety, Information Systems and Technology, Financial Management, Marketing and Stakeholder Management, Leadership, Policy and Regulations, Technology, MIS, and Analytics, among others.

CitiusTech appoints Sudhir Kesavan as COO

CitiusTech, a leading provider of healthcare technology services, solutions, and platforms, has announced the appointment of Sudhir Kesavan as its Chief Operating Officer (COO). In his new role, Kesavan will be instrumental in steering CitiusTech towards the execution of its strategic vision and ensuring unparalleled service delivery excellence. Kesavan brings a wealth of experience to his new role, having spearheaded digital transformation initiatives for numerous enterprises across the US and Europe. His work involves customer-centric design exploration, resulting in innovative digital products. Kesavan is known for his consultative approach and collaboration with clients. He has successfully facilitated inside-out and outside-in transformations, optimising technology operations and promoting customer-driven business models for clients. Prior to CitiusTech, Kesavan served as Partner, Advisory - Cloud Transformation, responsible for PwC India's cloud business. He also has a rich experience working for large scale IT companies like Wipro and Tata Consultancy Services.

Sanofi India appoints Himanshu Bakshi as GM for Consumer Healthcare business

Sanofi India has announced the appointment of Himanshu Bakshi as General Manager (GM) for its Consumer Healthcare (CHC) business, effective January 15, 2024. With a vision of building the best Fast Moving Consumer Healthcare, (FMCH) company in the world and for the world, Sanofi earlier this year had announced that the company's Consumer Healthcare (CHC) business will be demerged into its wholly owned subsidiary, Sanofi Consumer Healthcare India Limited (SCHIL), subject to necessary approvals and sanction by the National Company Law Tribunal, Mumbai. Bakshi has successfully led organisations in the business of FMCG (Fast Moving Consumer Goods) and healthcare products, through many transformation journeys, from starting new businesses to scaling them up. In over two decades, he has worked in various roles across commercial, marketing, and general management in Indian and multinational companies. He has led large and diverse teams by fostering a culture of growth and development in Reckitt Benckiser, PepsiCo and Dabur.

Shweta Rai takes over as Managing Director of Bayer Zydus Pharma

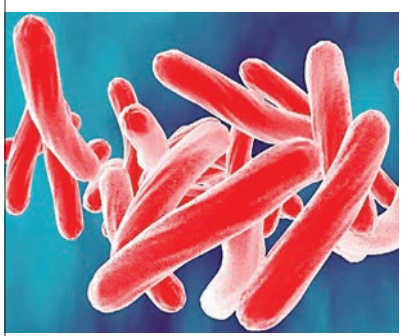
Shweta Rai has taken over as Managing Director of Bayer Zydus Pharma and Country Division Head (CDH) for Bayer's Pharmaceuticals Business in South Asia. Manoj Saxena has moved out of his present role to take on the role of CDH for Bayer's Pharmaceuticals Division and Senior Bayer Representative, Bayer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

IIT-Madras and -Mandi plant cells to increase production of anti-cancer drug Camptothecin

The Indian Institute of Technology Madras (IIT-M) and IIT Mandi researchers have metabolically engineered the plant cells of Nothapodytes nimmoniana to increase the production of Camptothecin, which is used to treat cancer. The researchers from the Plant Cell Technology Lab of IIT-M have developed a genome-scale metabolic model for N. nimmoniana plant cells using computational tools. This can be a major boost to produce cancer-treating drugs as Camptothecin, the third most in-demand alkaloid, is commercially extracted in India from Nothapodytes nimmoniana, which is an endangered plant. Camptothecin (CPT) is an important anti-cancer drug lead molecule for high-value drugs like Topotecan and Irinotecan. It is a potent topoisomerase I inhibitor extracted mainly from - Camptotheca acuminata (native to Eastern Asia) and Nothapodytes nimmoniana (native to India). However, the conjunction of climate change and extensive deforestation undertaken for CPT extraction has pushed these plants into the endangered species category.

IISc, NCBS and InStem suggest strategy for eradicating persistence of tuberculosis

Researchers at the Indian Institute of Science (IISc), in collaboration with the National Centre for Biological Sciences (NCBS) and the Institute for Stem Cell Science and Regenerative Medicine (InStem), have uncovered an important mechanism that allows the tuberculosis (TB) bacterium to persist in the human host for decades. They found that a single gene involved in the production of iron-sulphur clusters could be crucial for the persistence of the TB bacterium. Iron-sulphur clusters are mainly produced by the SUF operon in Mycobacterium tuberculosis (Mtb), a set of genes that get switched on together. However, there is another single gene called IscS that can also produce the clusters. The researchers observed that the absence of the IscS gene led to severe disease in the infected mice rather than a persistent, chronic infection typically seen in TB patients. This is because, in the absence of the IscS gene, the SUF operon is highly activated – albeit in an unregulated fashion – leading to hypervirulence. Depleting both IscS and the SUF system dramatically reduced the persistence of Mtb in mice. The IscS gene keeps the activation of the SUF operon in check, causing persistence in TB.



IISc & Aster-CMI Hospital design AI tool for screening nerve disorder

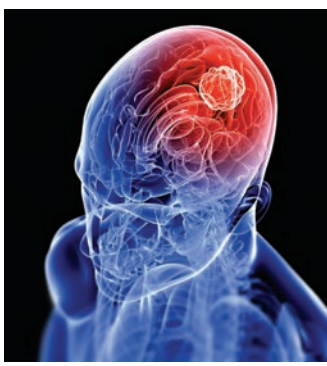
Researchers at the Indian Institute of Science (IISc), Bengaluru, in collaboration with Aster-CMI Hospital, have developed an artificial intelligence (AI) tool that can identify the median nerve in ultrasound videos and detect carpal tunnel syndrome (CTS). Doctors currently use ultrasound to visualise the median nerve, and assess its size, shape, and any potential abnormalities. But unlike X-rays and MRI scans, it's hard to detect what's going on in ultrasound images and videos. To develop their tool, the team turned to a machine learning model based on transformer architecture, similar to the one powering ChatGPT. The model was originally developed to detect dozens of objects simultaneously in YouTube videos. The team stripped the model's computationally expensive elements to speed it up, and cut down the number of objects it could track to just one – the median nerve, in this case. Once trained, the model was able to segment the median nerve in individual frames of the ultrasound video.

Indian researchers link ageing of cells with ovarian cancer spread

Researchers at the Indian Institute of Science (IISc) in Bengaluru have found that ovarian cancer cells can spread more easily in tissues that are senescent or aged because these tissues secrete a unique extracellular matrix that attracts the spreading cancer. During the study, the researchers observed that the cancer cells chose to settle down more on the aged tissues; moreover, they settled closer to the aged normal cells in the cell sheets. In particular, the researchers observed that it was proteins secreted by aged cells that settle down as the extracellular matrix (ECM), the base on which the cells adhere and grow, that were called the cancer cells. The team carried out experiments on human cell lines to replicate the predictions of the computer simulations. They noticed that the cancer cells stuck strongly to the extracellular matrix around the aged cells, and eventually cleared the aged cells away. They also noticed that the aged ECM had higher levels of proteins such as fibronectin, laminin and hyaluronan compared to the young cells' ECM, which allowed the cancer cells to bind more strongly. Researchers hope that future studies will build a strong case for using senolytics, drugs that kill senescent cells, as a combination therapy with chemotherapeutics to tackle cancer progression.

IIT-K offers new hope in cancer and brain disorders

The Indian Institute of Technology Kanpur (IIT-K) has achieved a breakthrough in biomedical research, with a study of G protein-coupled receptors (GPCRs) and chemokine receptor D6, shedding new light on the potential treatment of cancer and brain disorders such as Alzheimer's disease, Parkinson's disease and schizophrenia.



The researchers visualised the atomic details of the receptors. The information from this major advance opens up the possibility of designing new drug-like molecules to modulate these receptors under disease conditions. This landmark work has been recognised internationally with its publication in the prestigious international journal, Science. The researchers used a high-tech method called cryogenic-electron microscopy (cryo-EM) to create detailed three-dimensional images of the receptors. This allowed them to study the 3D images of the receptors at the molecular level in great detail, helping to identify and design new drug-like molecules to correct problems with these receptors that cause disease conditions.

IIT-M develops 3D-printed face implants for patients suffering from Black Fungus

Researchers at the Indian Institute of Technology Madras (IIT-M) have developed 3D-printed face implants for patients suffering from Black Fungus, which has been reported in COVID-19 patients as well as those with uncontrolled diabetes, HIV/AIDS and other medical conditions. Around 50 implants have already been done on patients from economically-weaker sections. The Institute has partnered with ZorioX Innovation labs, a startup founded by dental surgeons in Chennai, to implement this initiative, which is based on metal 3D printing or additive manufacturing. The outbreak of black fungus disease, also known as 'Mucormycosis', has been a cause of great concern in India. One of the most devastating effects of this disease is the loss of facial features, which can have a profound impact on the patient's mental and emotional well-being. Therefore, the reconstruction of faces lost due to black fungus is the need of the hour. Reports suggest that about 60,000 mucormycosis cases have been registered in India post-COVID.

HiMedia launches COVID-19 PCR Kit to detect JN.1 variant

Mumbai-based HiMedia Laboratories has announced that its RT-PCR kits are capable of detecting the recently discovered JN.1, SARS-CoV-2 variant.
The portfolio includes: MBPCR243 - Hi-PCR Coronavirus (COVID-19) Multiplex Probe PCR Kit; MBPCR255 - Hi-PCR Triplex COVID-19 Detection Kit; MBPCR262 - Hi-PCR COVID FLU Multiplex Probe PCR Kit; MBPCR270 - Hi-PCR COVID FLU RSV Multiplex Probe PCR Kit. JN.1 (BA.2.86.1.1) is a descendant of the BA.2.86 (Pirola). Pirola is the nickname of the BA.2.86 variant of Omicron, a variant of SARS-CoV-2. The number of cases caused by JN.1 and its close relative Pirola is on the rise all over the world. The first case of this variant was detected in Denmark in August and later in the USA. Cases of JN.1 have been found in some European countries, in Singapore, in China, and recently in Kerala, Maharashtra and in other states across India. The company has tested the impact of the variant on its Multiplex PCR Kit. Mutations, especially in RNA viruses like SARS-CoV-2 were expected and strain JN.1 is an example of the same. Its immune-escape capabilities have made it a variant of concern.

VFL Sciences announces cooperation with UVITEC, Cambridge

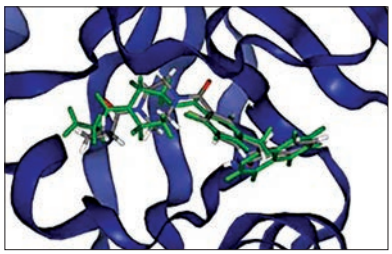
Chennai-based VFL Sciences and UVITEC, Cambridge, UK have signed an agreement to cooperate. As per the agreement VFL Sciences will sell the entire range of products from UVITEC. In addition, VFL sciences will also assemble select models of Gel doc line instruments from UVITEC in India. India is one of the largest markets for scientific instruments and UVITEC has planned this cooperation with VFL Sciences to grow its business further. The company believes that assembling some of its Gel doc models in India will allow the possibility to participate in more tenders and grab more market shares. With the Indian government's drive to promote Make in India, this cooperation will help VFL to create local value addition for some of UVITEC products. VFL's customers can experience the same world class products from UVITEC. This cooperation will further the company's focus on voice for locals.

Thermo Fisher and C-CAMP to establish Centre of Excellence in Bengaluru

Thermo Fisher Scientific and the Centre for Cellular and Molecular Platforms (C-CAMP) have announced a collaborative initiative to establish a Centre of Excellence in Bengaluru. This state-of-the-art facility will serve as a hub for fostering innovation, accelerating breakthroughs in the biotechnology sector and enabling researchers to enhance their expertise and achieve their entrepreneurial ambitions. As a part of this strategic partnership, C-CAMP will provide the necessary infrastructure at their premises to set up the Centre of Excellence. Thermo Fisher will equip the facility with advanced workflow-based solutions in flow cytometry and molecular biology and extend its expertise to offer research and training opportunities to scientists from startups under the C-CAMP umbrella, academia, and biopharma and biotech institutes.

Merck launches first ever AI Solution to integrate drug discovery & synthesis

Merck, a leading science and technology company, launched its AIDDISON drug discovery software, the first software-as-a-service platform that bridges the gap between virtual molecule design and real-world manufacturability through Synthia retrosynthesis software application programming interface (API) integration. It combines generative AI, machine learning and computer-aided drug-design to speed up drug development. Trained on more than two decades of



experimentally validated datasets from pharmaceutical R&D, AIDDISON software identifies compounds from over 60 billion possibilities that have key properties of a successful drug, such as non-toxicity, solubility, and stability in the body. The platform then proposes ways to best synthesize these drugs. Artificial Intelligence (AI) and machine learning models like AIDDISON software can extract hidden insights from huge datasets, thus increasing the success rate of delivering new therapies to patients. AI has the potential to offer more than $70 billion in savings for the drug discovery process by 2028, and to save up to 70 per cent time and costs for drug discovery in pharmaceutical companies.

Shimadzu releases OAD-TOF System, the first in the world to provide chemical structural analysis

Shimadzu Corporation, a precision tools and equipment maker from Japan announced the release of OAD-TOF system, a quadrupole time-of-flight mass spectrometer (Q-TOF MS), the first in the world to provide detailed structural analyses of lipids & other natural compounds. Oxygen attachment dissociation (OAD), an ion dissociation technology developed by Shimadzu, enables estimation of the position of double bonds between carbon atoms, a conventionally difficult task. OAD was developed at the Koichi Tanaka Mass Spectrometry Research Laboratory. In OAD, atomic oxygen is made to react with the ionized sample, and the double bonds between carbon atoms are selectively broken (dissociated). Information on the position of the double bonds between carbon atoms is then obtained from the ion fragments generated by the dissociation. A Q-TOF MS measures the size and amount of samples separated at the atomic & molecular levels, thereby obtaining precise information on compounds.

Agilent announces New ProteoAnalyzer System

Agilent Technologies Inc. that generated revenue of $6.83 billion in fiscal 2023 and employs approximately 18,000 people worldwide released a new automated parallel capillary electrophoresis system for protein analysis – the Agilent ProteoAnalyzer system – at the 23rd Annual PepTalk Conference, in San Diego. This new platform simplifies and improves the efficiency of analysing complex protein mixtures, a process central to analytical workflows across the pharma, biotech, food analysis, and academia sectors. Capillary electrophoresis (CE) has established itself as an indispensable tool for protein separation, as it offers rapid, high-resolution analysis with minimal sample consumption. The expanding interest of biopharma in monoclonal antibodies and other protein targets of potential therapeutic interest is driving the expected growth in demand for CE solutions. The Agilent ProteoAnalyzer system brings added efficiency, versatility, and reliability, particularly in protein QC workflows. Automating the separation, data processing, and simplifying sample preparation steps streamlines the analysis workflow, which improves efficiency and reduces training and related labour costs. The system also can analyse a wide range of sample types, from crude lysates to purified fractions.

Robust AI-driven Cancer Drug Development

In the recent past, many companies across the globe have increased their research and development efforts for anti-cancer drugs. Although the understanding of cancer mechanisms has advanced over the years, the process of cancer drug discovery continues to offer multiple challenges. It is especially difficult to design anti-cancer drugs due to factors such as undruggable targets, chemoresistance in oncology, metastasis, and tumour heterogeneity, to name a few. Thus, it calls for more effective anti-cancer drug design strategies to reduce the cost of drug development and the time required for clinical trials.

Artificial intelligence (AI) is being leveraged to address these challenges and increasingly explored by researchers in academia and the biotech industry to improve the anti-cancer drug design process. For instance, AI is being used to integrate data from multiple sources to help with anti-drug target identification, predicting druggability of anti-cancer drug targets, screening of anti-cancer drug hit compounds, de novo design of anti-cancer drugs, etc.

Researchers are using AlphaFold, an AI-powered protein structure database, to create a drug that could potentially treat hepatocellular carcinoma (HCC), or liver cancer. Another AI-driven cancer drug discovery engine called CancerOmicsNet can predict how a specific cancer would respond to a specific drug. Researchers are also applying AlphaFold to Pharma. AI platform to uncover a novel target for cancer and develop a "novel hit molecule" that could bind to that target without aid.

To quote a few examples, Australia-based QIMR Berghofer has recently partnered with Korean company Syntekabio to use their AI and high performance computing to accelerate potential new treatments for cancer and chronic inflammation. Likewise, University of Sydney and Pharos Therapeutics, the Australian subsidiary of Korean pharma company Pharos iBio are using AI to identify promising compounds for rapid development into treatments for cancer.

Swiss biopharma firm Debiopharm and ThinkingNodeLife.ai (TNL), a trailblazer in AI Digital Cells Lab in the US, are advancing the development of a cutting-edge cancer drug. ThinkingNodeLife.ai stands as the first AI Digital Cells Lab at scale generating any human digital cell clones within hours, with its Generative Distributed Reasoning AI (GDR-AI) that employs Distributed Reasoning AI instead of statistical correlation to generate causal reasoning models.

Then there is US-based biotech startup Absci recently signing a $247 million partnership with British pharma company AstraZeneca to focus on expediting the discovery of novel cancer treatments with the help of generative AI technology.

Another recent development that strengthens the association between AI and cancer treatment is the designing of an AI algorithm referred to as Substrate PHosphosite-based Inference for Network of KinaseS (SPINKS) by a group of scientists in the US. The algorithm offers applications to precision cancer medicine, giving oncologists a new tool to battle this fatal disease.

Scientists in the US and Europe are also utilising AI to identify dual-purpose target candidates for the treatment of cancer and ageing. In fact, this collaborative study is the first to show the feasibility of AI-driven approaches to identify potential dual-purpose targets for anti-ageing and anti-cancer treatment, and clearly demonstrates the value of such tools in addressing the complex challenges at the interface between ageing and carcinogenesis. AI can undoubtedly accelerate the discovery of new anti-cancer drug molecules and the synthesis of more desirable drug molecules. While AI is proving to be a powerful driving force for human cancer research and treatment in the future, it will offer some limitations too.

Over the coming years, we must ensure that we have solid data foundations and tight circles of model validation to leverage our data resources. Moreover, in the drug development process, predicting the underlying logic behind a model is critical to designing the right drug molecules. Interpretable AI models will be the new development direction, and the close combination of data and computation will be a feature of AI-assisted cancer drug development. BS

Dr Manbeena Chawla
Executive Editor
manbeena.chawla@mmactiv.com

Spectrum Hired

Connecting Careers, Empowering Industries

Introducing Spectrum Hired - Your Gateway to Industry Success!

www.spectrumhired.com

Join the

Spectrum Hired revolution at www.spectrumhired.com and discover a world of career opportunities tailored just for you.

- Unearth the latest Agricultural roles.
- Explore groundbreaking Biotech positions.
- Dive into the world of MedTech innovation.
- Savor the flavor of Food & Beverage careers.
- Contribute to cutting-edge Academic Research.
- Harness your potential in the dynamic Agritech sector.
- What makes Spectrum Hired your ultimate job portal?
- Unmatched Industry Focus: We specialize in your
- industry, ensuring you find the perfect match for your skills and aspirations.
- Cutting-Edge Job Listings: Discover the hottest job openings before anyone else.
- Personalized Alerts: Get tailored job
- recommendations straight to your inbox.
- Easy Navigation: Our user-friendly platform makes job searching a breeze.

Don't let your dream job slip away. Visit www.spectrumhired.com today and embark on your journey to industry excellence. Your future is waiting!

Spectrum Hired – Where Your Career Begins!

poonam.bhosale@mmactiv.com

ankit.kankar@mamctiv.com

RNI TC No. MAHENG14628
Date of Publication - 30.1.2024

RNI NO. DELENG/2004/13061
Date of Posting - 1.2.2024