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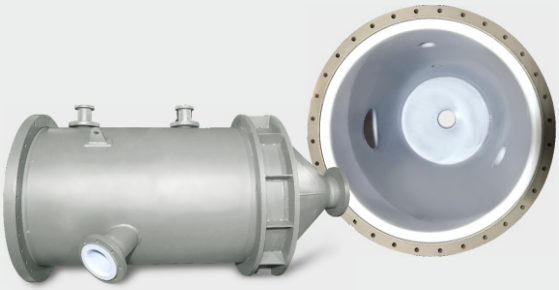


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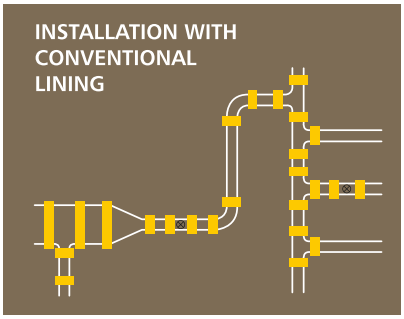

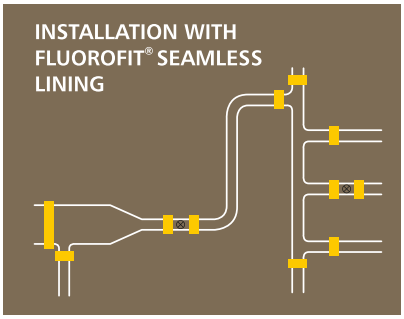

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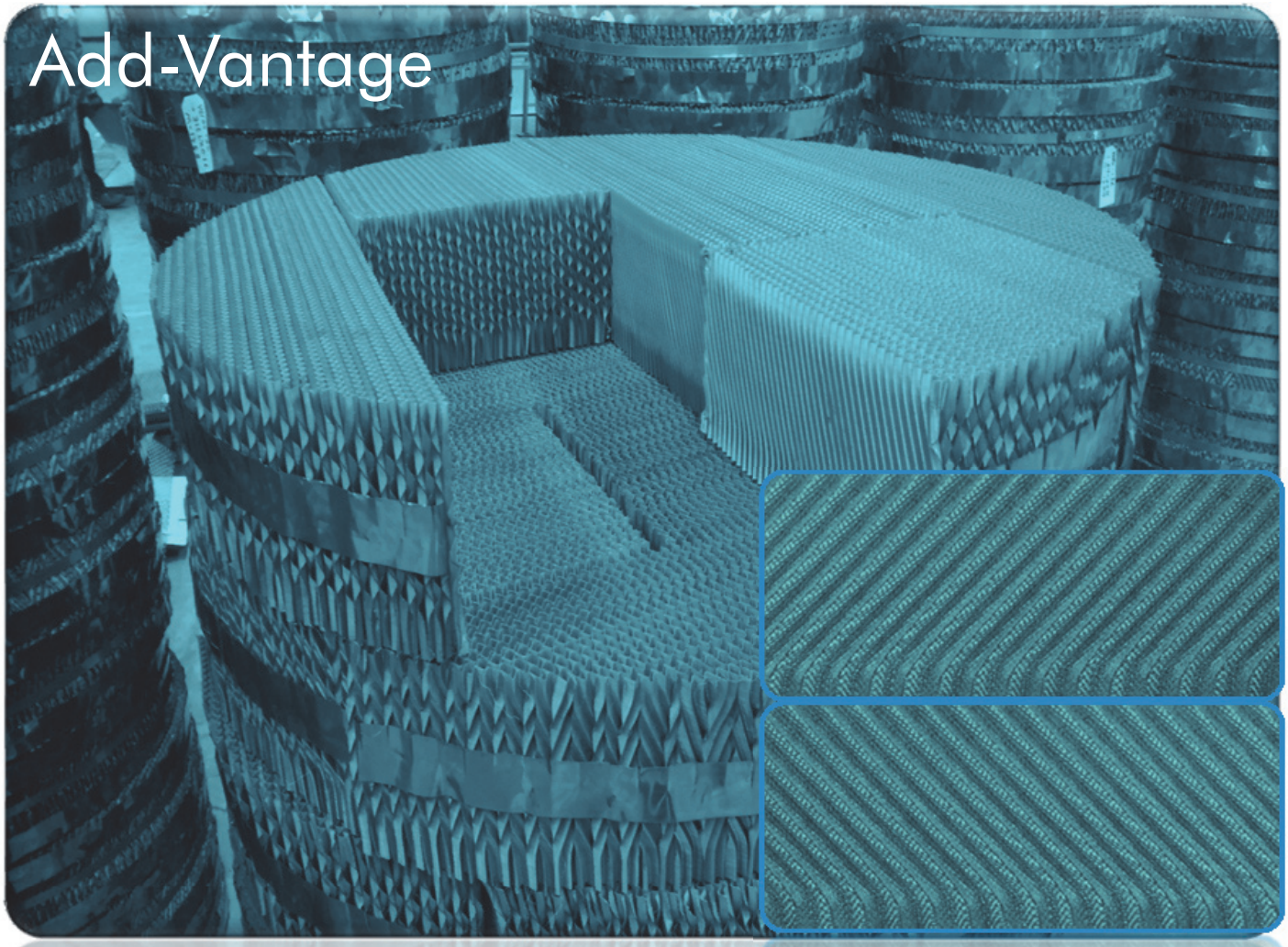

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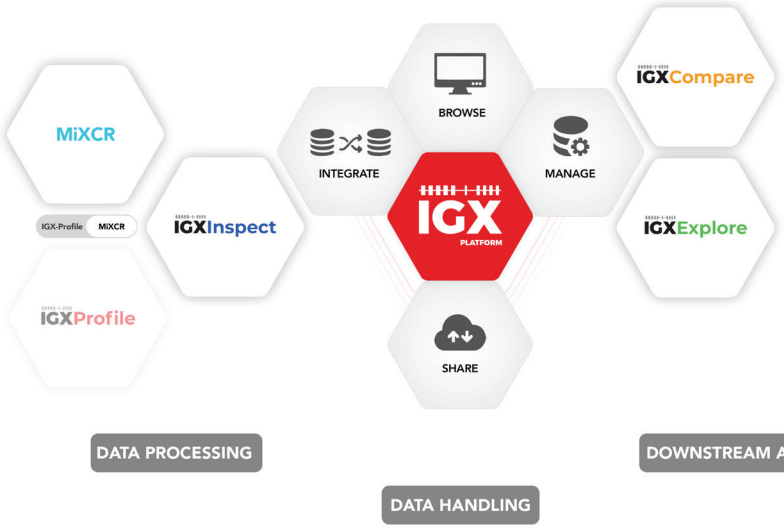
ENPICOM and MiLaboratories join forces



ENPICOM BV, an innovative bioinformatics software engineering company, and MiLaboratories LLC, a technology leader in profiling the mammalian adaptive immune system, announced a strategic partnership to enable efficient MiXCR integration into ENPICOM's cloud-based IGX Platform.

Combining the best of both software solutions within a single platform

MiXCR is a universal, state-of-the-art software solution for annotation and quantification of large-scale immunomics data. MiLaboratories serves a rapidly growing customer base and a wide range of Repertoire Sequencing (Rep-Seq) applications with this profiling tool. ENPICOM's IGX Platform comes with powerful data management features and an intuitive user interface out of the box for the same type of data. Its modular, flexible structure allows for further enhancements and customizations. IGX-Profile is a specialized App engineered to annotate clones with advanced error correction and clone identification. With this partnership, MiXCR will be fully integrated into the IGX Platform, allowing users to choose their preferred profiling solution.

In August 2020, ENPICOM already announced support for annotated clone files generated using MiXCR, in addition to clone tables from commercial platforms such as Adaptive Biotechnologies and 10x Genomics. Since that moment, MiXCR users can continue their downstream analysis workflow in the IGX Platform, leveraging its intuitive user interface, ability to integrate sequencing data from different sources, and compare their clones with publicly available databases using IGX-Compare.

Sygnature Discovery invests £3m to expand high-throughput

Sygnature Discovery, a leading independent integrated drug discovery and pre-clinical contract research organization, is

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strengthening its high-throughput screening (HTS) and translational oncology service-offerings by investing £3 million in new instrumentation and equipment.

Sygnature's Translational Oncology department at Alderley Park is currently focused on in vivo services for cancer drug discovery with in-house expertise to design, conduct and interpret pivotal oncology in vivo pharmacology experiments to identify promising pre-clinical candidates. These assessments help define the path to the clinic and identify the anticipated patient populations who might best respond to treatment. Detailed tumour analysis is an important aspect of pre-clinical in vivo research to measure target engagement and impact on tumour biology. A significant component of the £3M investment will be used to establish internal flow cytometry support for ex-vivo tumour analysis to enhance Sygnature's integrated oncology capabilities and provide a more comprehensive, competitive and integrated service offering to customers.

In November 2019, Sygnature added in-house HTS to its comprehensive range of hit identification solutions, underpinned by a novel compound library of 150,000 lead-like molecules, carefully curated by a team of experienced computational and medicinal chemists. At a cost of £1.3M, this service has proven to be such a phenomenal success with clients that the company is now being asked to store and screen external compound collections. To accommodate this increased customer demand and planned expansion of Sygnature's compound library, an automated plate and tube storage system with the capacity to hold over 2 million plated compounds and 135,000 in tubes will be installed at BioCity Nottingham from early 2021.

Eli Lilly to Acquire Prevail Therapeutics

Eli Lilly and Company announced on Dec. 15, 2020 that it will acquire Prevail Therapeutics, a US-based gene therapy company, for $1 billion.

Through the acquisition, Lilly will have access to Prevail's portfolio of clinical-stage and preclinical neuroscience assets that include PR001 for patients with Parkinson's disease with GBA1 mutations and neuronopathic Gaucher disease, PR006 for patients with frontotemporal dementia with GRN mutations, PR004 for patients with specific synucleinopathies, and possible gene therapies targeted at Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis, and other neurodegenerative disorders, Lilly said in a company press release. With Prevail's pipeline, Lilly will work to create a new gene therapy program.

"Gene therapy is a promising approach with the potential to deliver transformative treatments for patients with neurodegenerative diseases such as Parkinson's, Gaucher, and dementia," said Mark Mintun, MD, vice president of pain and neurodegeneration research at Lilly, in the press release. "The acquisition of Prevail will bring critical technology and highly skilled teams to complement our existing expertise at Lilly, as we build a new gene therapy program anchored by well-researched assets.

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We look forward to completing the proposed acquisition and working with Prevail to advance their groundbreaking work through clinical development."

"Lilly is an established leader in neuroscience drug development and commercialization who shares our commitment to patients with neurodegenerative diseases, and I'm excited for Prevail to join the Lilly family," added Asa Abeliovich, MD, PhD, founder and CEO of Prevail, in the press release. "With its global scale and resources, Lilly will be the ideal organization to maximize the potential of our pipeline and accelerate our ability to bring these therapies to as many patients as possible. We look forward to working together to advance our shared mission."

Genentech and Relay Therapeutics Announce Potent Inhibitor Development Collaboration

The companies are entering into a license and collaboration agreement for the development and commercialization of Relay's investigational cancer treatment, RLY-1971, a potent inhibitor of SHP2, a molecule that plays a role in cancer cell survival.

Genentech, a member of the Roche Group, and Relay Therapeutics, a clinical-stage precision medicine company located in the US, announced they are entering into a license and collaboration agreement for the development and commercialization of Relay's RLY-1971, a potent inhibitor of Src homology region 2 domain-containing phosphatase-2 (SHP2), found to be a critical signaling node and regulator that promotes cancer cell survival and growth and that plays a key role in therapy resistance by cancer cells.

Under the terms of the agreement, Relay will receive an upfront payment of $75 million and will be eligible to receive $25 million in additional near-term payments, Relay said in a company press release. Genentech will develop RLY-1971 with the hope of expanding it into multiple combination studies, including with Genentech's investigational inhibitor of KRAS G12C, GDC-6036.

Samsung Biologics Appoints New President and CEO

Samsung Biologics announced on Dec. 16, 2020 that John Rim, the company's former executive vice-president, has been named its new president and CEO.

Rim has more than 30 years of experience in the biopharmaceutical industry and previously held senior global leadership roles at Genentech/Roche and Astellas Pharmaceuticals after starting his career at Booz, Allen & Hamilton as a management consultant, Samsung said in a company press release.

"I am deeply grateful and excited by the opportunity to lead Samsung Biologics into the next decade," said Rim in the press release. "This is an extraordinary company, unparalleled in its phenomenal growth and dedication to client satisfaction, made possible by the company's unrelenting vision and passion, and business execution by great people whom I will have the privilege to lead as CEO."

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Nordic Capital and Astorg invest in pharmaceutical technology and advanced analytics company Cytel

Nordic Capital and Astorg today announced an agreement to jointly acquire Cytel Inc. ("Cytel"), from New Mountain Capital. Cytel is one of the largest providers of statistical software and advanced analytics for clinical trial design and biometrics execution. Building on Cytel's advanced software platform and leading biometrics services offerings, the new owners will invest in the continued development of the business and its software. Cytel's mission is to continue providing life sciences companies with cutting-edge clinical trial optimization technologies and harness the full value of their clinical and real-world data. Cytel's management team, led by CEO Josh Schultz, will continue to lead the organization, building on a strong track-record of organic growth and strategic acquisitions.

Cytel is recognized as an industry pioneer of adaptive clinical trials and other innovative quantitative methods, helping biotech and pharmaceutical companies to reduce risk, increase R&D productivity and support medical innovation, improving speed, productivity and efficiency of clinical trials. The Company was founded over 30 years ago by renowned statisticians Cyrus Mehta and Nitin Patel, thought-leaders in statistical science, who will continue to be active in the Company.

Headquartered in Waltham, Massachusetts, Cytel has more than 1,500 employees across North America, Europe and Asia. Cytel's software and services are used by over 500 life sciences customers, including the world's 30 top pharmaceutical companies, as well as regulatory bodies such as the FDA.

The terms of the transaction were not disclosed. The transaction is subject to customary regulatory approvals. Barclays and Rothschild & Co served as financial advisors to New Mountain Capital.

UFlex to double its aseptic liquid packaging plant's capacity

UFlex Limited, India's largest multinational flexible packaging and polymer science company and first Indian manufacturer of aseptic liquid packaging, announced to double its aseptic plant's production capacity from 3.5bn to 7bn packs per annum, in Sanand, Gujarat. The capacity expansion will be completed within the next 10 months approximately.

The expansion is in response to the new contracts and increasing demand for the company's aseptic packaging laminates. Driven by a strong and healthy order book and consistent market growth, this initiative doubles the production capacity and will allow creating company's expanding operations team by adding more workforce, which will strengthen the company's expansion plan.

The first phase of expansion will focus on adding new machines to the existing line i.e., the best-in-class new generation Gallus printing line (M/S Heidelberg Web Carton GmbH) from Germany. The new-age machine has progressive features, loaded

with sophisticated technologies that make it extremely efficient and sound in operation. The machine prints at a speed of 500MPM (Meters Per Minute). An ideal choice for UFlex' aseptic liquid packaging business growth strategy.

The Slitting Line is high -performance machine from IMS technologies S.P.A- Italy, which is super-fast giving output at a speed of 1200MPM. In addition to increasing the capacity, the company has also added Doctoring Line and over 8 new tools/formats as part of its expansion. This is targeted to be completed within approximately ten months, adding Asepto's capacity to address the increasing demands.

EC Grants License for siRNA Cholesterol-Lowering Treatment

The European Commission has granted a license for the use of inclisiran (Leqvio) as a treatment of primary hypercholesterolemia or mixed dyslipidaemia in adult patients. Inclisiran is a first-in-class small interfering RNA (siRNA) treatment that aids in the reduction of low-density lipoprotein (LDL) cholesterol. Administered as a single injection initially, then at three months and six month intervals, inclisiran is indicated as an adjunct to diet, in combination with a statin, or statin with other lipid-lowering therapies for patients not reaching their LDL cholesterol target with the maximum tolerated dose of a statin, or alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant or for whom a statin is contraindicated.

The EC based its decision to grant a license for inclisiran on the results of the ORION clinical research program, which assessed the safety, efficacy, and tolerability of the therapy in over 3600 patients. The granting of the European license follows the company's announcement in early 2020 that the United Kingdom (UK) will initiate a population health model, making inclisiran available through a population-level agreement.

Medovate announces new agreement for SAFIRA™ in the USA

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Medovate is proud to announce conclusion of an agreement with Mercury Medical to

distribute its medical device SAFIRA™ (SAFer Injection for Regional Anesthesia) – a move that will now provide 100% coverage across the United States of America.

Despite the ongoing global COVID-19 pandemic which has closed many country borders, Medovate has successfully secured a deal with one of the United States' largest distribution partners for their FDA-cleared device.

Developed in collaboration with clinicians from the National Health Service (NHS) in the UK, SAFIRA™ is a revolutionary Class II medical device set to transform regional anesthesia around the world by making it a one-person procedure. It puts control of the injection in the hands of the anesthesiologist, therefore freeing up their assistants to carry out other tasks and the device helps to improve patient safety by reducing the risk of nerve damage as it prevents injection above 20psi. For hospitals, economic modelling has shown it also has the potential to generate cost savings.

Headquartered in Clearwater, Florida, Mercury Medical is a company with more than 50 years of experience developing medical device innovation, focusing heavily on keeping healthcare ahead of the curve with novel technologies. They have positioned themselves as a US leader in providing technological advances for clinicians in both airway solutions and anesthesia – a philosophy that aligns with Medovate and SAFIRA™. Mercury Medical also has very high quality standards and are ISO 13485 and ISO 9001 certified.

Mercury Medical will distribute SAFIRA™ throughout 28 US States. This will cover the East Coast, the Southern states and the West Coast including the states of New York, Delaware, Florida, New Jersey, North Carolina, South Carolina, Texas, Mississippi and California.

Amid the current COVID-19 pandemic SAFIRA™ has the potential to make a significant impact by turning regional anesthesia into a one-person procedure. Recent publications, including a joint statement by the American Society of Regional Anesthesia and Pain Management (ASRA) and the European Society of Regional Anaesthesia and Pain Therapy (ESRA), have recommended regional anesthesia be considered whenever surgery is planned for a suspected or confirmed COVID-19 patient. This is because it preserves respiratory function and avoids aerosolization and the potential for transmission of COVID-19 compared to general anesthesia.

Lonza's MODA-EM™ Paperless Solution to be Implemented at the UK's New Vaccines Manufacturing and Innovation Centre

Lonza and the Vaccines Manufacturing and Innovation Centre (VMIC), a not-for-profit organization established to provide the UK's first strategic vaccine development and advanced manufacturing capability, announced a project to implement the MODA-EM™ Solution to automate quality control (QC) in the new facility.

VMIC plans to implement the MODA-EM™ Solution as part of its strategy to develop

a state-of-the-art manufacturing center due to open in 2021 – fast-tracked to open a year ahead of schedule. The MODA-EM™ Solution is a comprehensive informatics platform that automates QC processes for regulated manufacturing in the Life Sciences industry. This fully digital QC system enables companies to reduce the time needed for validation and qualification and provides a forward-thinking paperless solution.

The ongoing COVID-19 pandemic has accelerated multiple industry trends, including digitalization and automation. Implementing paperless solutions can help researchers meet aggressive timelines and fit into Industry 4.0 initiatives. Lonza's comprehensive, next-generation solution for pharmaceutical QC will allow paperless management of a wealth of microbiological data. The electronic approach reinforces data integrity compliance, enables real-time access to data, and provides fast input necessary to make informed decisions.

The automation of the QC laboratory has seen slow adoption by organizations due to cost constraints and flexibility concerns. The MODA-EM™ Data Acquisition Platform for automated and paperless QC processes is changing this, thanks to the ease of implementation to achieve regulatory compliance and maximize employee utilization.

SpiceHealth signs MoU with CSIR-CCMB

SpiceHealth has signed a Memorandum of Understanding (MoU) with CSIR - Centre for Cellular and Molecular Biology (CCMB), India, a constituent lab of Council of Scientific and Industrial Research. This MoU with CCMB, a premier research organization in frontier areas of modern biology, is for conducting dry swab Direct Real-Time Polymerase Chain Reaction (RT-PCR) tests in its mobile testing laboratories.

The Indian Council of Medical Research (ICMR) recently granted approval to CSIR-CCMB to commercially use the game changing technology of dry swab RNA-extraction free Covid testing method that has the potential to scale up testing by 2 to 3 fold with no additional resources and significantly reduce the time and costs of such tests.

SpiceHealth is a health care company founded by the promoters of SpiceJet and led by Avani Singh. SpiceHealth's first mobile testing laboratory was inaugurated by Hon'ble Union Home Minister, Sh. Amit Shah and Hon'ble Union Minister for Health & Family Welfare, Dr. Harsh Vardhan, at ICMR, AIIMS on November 23.

The Company's pioneering and first-of-its-kind initiative follows the successful launch of its first mobile testing facility offering the most affordable RT-PCR testing at Rs. 499/ only. SpiceHealth currently has 5 functioning labs at government requested locations around Delhi NCR, conducting 10,000-15,000 tests per day.

The ICMR recently gave permission to CSIR-CCMB to conduct dry-swab testing method after successful trial runs and SpiceHealth's mobile testing laboratories will become the first to incorporate this testing method. CSIR-CCMB centre conducts high quality basic research and training in frontier areas of modern biology, and promotes centralized national facilities for new and modern techniques in the inter-disciplinary areas of biology.

The dry-swab direct RT-PCR method is easy to implement as it eliminates the requirement of new kits and doesn't require any additional training to be provided to the persons conducting the test. Generally, the swab samples are placed in a liquid called Viral Transport Medium (VTM). The samples are packed heavily to avoid leakage which increases sample processing time at both the sample collection and testing centres. However, dry-swab testing eliminates this process and also doesn't require RNA extraction.

In order to fight the Covid-19 virus, SpiceHealth had launched SpiceOxy – a compact, portable, non-invasive ventilation device, which is an effective solution for patients with mild to moderate breathing issues. Additionally, SpiceHealth had also introduced fingertip pulse oximeter, a handy device making it easier for people to measure the oxygen level of the blood.

APIS Assay Technologies Ltd. and Moffitt Cancer Center sign Master Collaboration Agreement

APIS Assay Technologies Ltd. has entered into a Research & Development agreement

with the Laboratory of Elsa Flores, Ph.D., and Marco Napoli, Ph.D. characterising the suitability of TROLL-2 and TROLL-3 as predictive biomarkers of cancer progression with the goal to assess the role of TROLLs as markers of response to chemotherapy.

Cancer is a multi-pathway disease, whereby it is now clear that personalised genomic medicine is required in the diagnosis and stratification of treatment, and in the prediction and prevention of the disease. There is a real clinical need for validated biomarkers that can demonstrate clinical impact in the decisions made for cancer treatment pathways.

The most frequent genetic alterations across multiple human cancers are mutations in TP53 and the activation of the PI3K/AKT pathway, two events crucial for cancer progression.

The laboratory of Dr. Elsa R. Flores has recently demonstrated that the crosstalk between p53 mutations and the AKT pathway is mediated by two long non-coding RNAs (lncRNAs), called TROLL-2 and TROLL-3, which promote tumor formation and progression in several orthotopic models of human cancers. (Nat Commun. 2020 Oct 14;11(1):5156. doi: 10.1038/s41467-020-18973-w)

The published and patented data provide preclinical rationale for the implementation

of these lncRNAs and WDR26 as novel therapeutic targets for the treatment of human tumors dependent upon mutant TP53 and/or the PI3K/AKT pathway.

The first target of the R&D collaboration will be Triple-negative breast cancers. TNBCs are among the most therapeutically challenging human cancers and are frequently characterized by the hyperactivation of the PI3K/AKT pathway and the gain-of-function mutation of the tumor suppressor TP53.

TNBCs have higher levels of both lncRNAs compared to non-TNBC cases. A pan-cancer analysis of TCGA datasets and human cancer tissue microarrays showed that these two lncRNAs are prognostic in breast cancer and that they are novel biomarkers of cancer progression in at least 6 different tumor types, underlying the relevance of TROLL-2 and TROLL-3 across multiple human tumors.

The aim of the research collaboration between APIS and Moffitt will be to determine the feasibility of these lncRNAs as a diagnostic tool for the prediction of efficacy of treatment pathways and prognosis of treatment outcome in chemoresistant TNBCs and further analysing NSCLC and melanoma as potential diagnostic targets for the TROLL Biomarkers.

Romaco Innojet IGL 100 granulation line: As versatile as a Swiss pocketknife

The IGL 100 granulation line from Romaco Innojet is suited for a wide range of production-scale processing applications. The technology impresses with up to 25 percent shorter process times.

Romaco Innojet's IGL 100 granulation line is designed for production-scale use and combines the five main processing functions in one unit: high-shear mixing and granulation, fluid bed drying, fluid bed granulation, fluid bed pellet coating and fluid bed hot melt coating. The granulation lines in the Innojet IGL series can process a wide variety of bulk materials such as fine powders, crystals, granules or pellets with a bulk density ranging from 0.2 up to 1.2 g/m^3. Batch sizes from 30 up to 600 kg are possible depending on the size of the equipment.

Five in one

The IGL 100 is a multipurpose unit consisting of a high-shear mixer and an integrated VENTILUS® fluid bed system. The bottom driven high-shear mixer ensures that the raw materials are homogeneously mixed and granulated, while the fluid bed processor allows for an efficient drying of the batch to a very low final moisture content. This method is particularly widespread in the pharmaceutical industry.

The Innojet IGL 100 can also be upgraded for fluid bed granulation or coating of fine powders and pellets. In this case, the VENTILUS® fluid bed processor is equipped with a top or bottom spraying nozzle. The bottom spray system with the central ROTOJET® nozzle is especially suited for high performance pellet coating. By simply adding the Innojet IHD, the IGL 100 granulation line is also capable of hot melt coating formulations. If required, the various processes can be combined to get the maximum benefit from the unit's capabilities, for example in order to apply a hot melt coating to granules that have previously been manufactured using the high-shear mixer. By doing so, material transfers can be eliminated, which saves time,

increases the yield and avoids unnecessary product exposure of the operator.

Space-saving GMP design

The compact and closed design of the Innojet IGL 100 granulation line with built-in wet and dry mills enables fast, clean and dust-free operation. The transfer of the finished wet granulate from the high-shear mixer into the fluid bed processor is carried out gravimetrically and without external air supply. The integration of all the Innojet IGL 100's line components in a centrally controlled WIP (washing in place) system conforms to cGMP standards. Furthermore, all inner surfaces in contact with the product are easily inspectable and if necessary, quickly removed for a final offline manual cleaning.

Efficient and sustainable

When manufacturing compact granules with the Innojet IGL 100, users benefit from up to 25 percent shorter drying times. The reduction of the process duration is mainly due to the air flow guided ORBITER® booster system, through which the process air is introduced into the VENTILUS®. The air flow bed ensures accurate control of the product movement, which significantly accelerates the drying of the granulate. At the same time the gentle guidance of the particles minimises the breaking of soft granules as well as the abrasion of pellets. This lower product loss leads to significant cost economies, especially when processing high-priced active pharmaceutical ingredients (API). In addition, the SEPAJET® filter system of the VENTILUS® fluid bed unit also contributes to a reduction in product loss. Particles retained during production by the rotating filter system are not removed from the process. These measures not only improve the overall equipment effectiveness (OEE); they also support sustainable production as part of Romaco Innojet's efforts to reconcile commercial and ecological interests.

- Image for online use: Romaco Innojet IGL 100 granulation line
- Image for online use: Romaco – a sustainability enabler
- Image for print use: Romaco Innojet IGL 100 granulation line
- Image for print use: Romaco – a sustainability enabler

Research reveals portable digital chest drainage systems

Pioneering research, which reveals digital chest drains generate and distribute less aerosol generated particles compared to traditional water seal systems, has been published in the Seminars in Thoracic and Cardiovascular Surgery journal.

The research was led by a team of thoracic consultants from Guy's and St Thomas' NHS Foundation Trust – home to one of the largest lung cancer practices in the UK.

At the start of the pandemic there was limited

evidence about the spread of COVID-19 via chest drains which led to uncertainty within the thoracic community about the best medical device to use.

To understand this area further, the researchers reviewed three different types of chest drainage systems – single chamber, 3 compartment wet-dry suction and digital drainage system.

The aim was to establish the best way to prevent transmission of COVID-19 to patients, as well as protecting healthcare workers. While the transmission of COVID-19 is primarily through droplet spread, new research shows that SARS-CoV-2 can survive in smaller aerosols that remain suspended in the air for several hours. These infective airborne particles may travel greater distances and be inhaled, increasing the risk of transmission.(1)

The results of this study showed that the 3-compartment wet-dry suction system and the digital drainage system did not generate any identifiable aerosolised particles at any of the air leak or drain output volumes considered.

During the same period Medela also carried out tests at Nelson Labs, a global microbiology testing lab for medical device, pharmaceutical, tissue and biologics companies. This showed that Thopaz+ can effectively retain pathogen-sized particles and hence prevent them from subsequently exiting to the environment via the exhaust. Drained air passes through a hydrophilic 3-D protection filter with the adaptation of filter performance to retention rate of 99.925% to 99.999(2) for 25nm particles. Both sets of research were presented at this year's European Society of Thoracic Surgeons conference.

Thopaz+ is designed to increase patient mobility and is supported by clinical evidence from the National Institute for Health and Care Excellence (NICE), which recommends the system for its ability to reduce drainage time and length of stay in hospital, as well as improve safety for patients and cut hospital costs.

Guidance published by the National Health Service (NHS) now advises hospitals against using piped vacuum to support infectious disease units (IDU) to reduce the risk of virus spread and cross-contamination(3).

Used worldwide, Medela's portable medical suction machines are designed to provide crucial suction and fluid removal during respiratory treatment provided with ventilators. Their pioneering Thopaz+ digital system is clinically proven to improve outcomes, ensuring a safe and continuous drainage independent of a wall vacuum to provide safer patient care while minimising the risk of cross-contamination.

GLocalMind, global healthcare fieldwork and analysis company from India completes 10-year milestone

GLocalMind, a leading healthcare fieldwork and analysis company serving the healthcare ecosystem has successfully completed 10 years in the business. With its global headquarters in the US and operations headquarters in India, GLocalMind

has access to healthcare professionals in 57 Countries across 86 Specialties and 60 Medical Conditions and over 1.5 million panellists, making them a familiar name in the healthcare research sector the world over.

They provide access to healthcare stakeholders including physicians, patients and payers by way of their panels, partners and custom recruitment. Their client base includes top Global Market Research Companies, Hospitals, Pharma Companies, Healthcare Consulting Companies, Life Sciences Companies and Medical Device Companies.

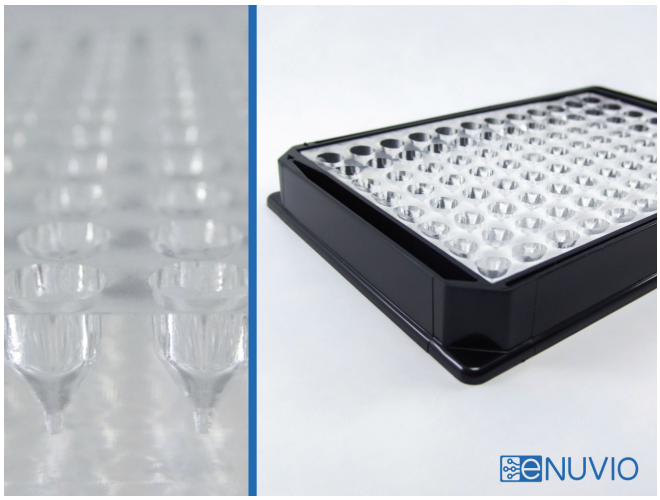
GLocalMind was launched in 2010 with a vision to provide easy access to high quality healthcare professionals in a timely manner to the healthcare industry. They aimed to leverage the power of technology in reducing time to insights and in stakeholder research. Today they have offices in India, USA and Europe along with a wide network of panellists present in most cities around the world.

GLocalMind's supports research studies which includes Market Evaluation, KOL Research, Patient Pathways, Concept Testing, Market Access, Product Usage, Communication Testing, Current and Future Therapy Trends, Packaging Testing, Prescription Habits and Reimbursement Studies.

With COVID-19 being the biggest healthcare crisis faced by the world in many decades, the medical community has been working on a vaccine as well as to understand the impact on the healthcare system. GLocalMind has conducted various market research studies including studying the Impact on healthcare practices, Impact on hospital operations, Adoption of tele-medicine, pricing perceptions for Covid Vaccine, healthcare innovation and transformation etc.

Known for their focus on technology, Glocalmind has successfully conducted over 200,000+ surveys globally to date. Armed with their GLocalSMART suite of products, their proprietary panel and project management software, they are well on their way to transitioning from being an independent healthcare research facilitator to a larger aggregator model. This is in line with their vision to play a bigger role by creating a larger ecosystem for healthcare research studies globally by the end of 2021.

eNUVIO is Launching the EB-Plate



eNUVIO announced the release of the first completely reusable 3D cell culture microplate on the market. Scientific research currently consumes high-volumes of single-use plastics - from serological pipettes and pipette tips to vials and culture microplates - these are just a few of the many plastic items thrown in the garbage in labs everyday. eNUVIO's completely reusable EB-Plate comes to the market at the right time as the demand for 3D cell culture microplates is high, conventional

plastic plates are currently in short supply, and the zero waste movement is becoming increasingly popular in laboratories. As with many emerging environmentally friendly options, it's no surprise that the reusable and virtually indestructible EB-Plate comes in at a higher cost compared to its plastic counterparts. According to the company, the new plates pay for themselves after approximately 5-8 uses, and can be reused many times more.

eNUVIO understands the hesitation to switch from tried-and-true devices to new tools, but asserts that in the case of the EB-Plate, scientists don't have to compromise quality when switching from conventional single-use microplates to a greener choice. This new plate allows researchers to generate embryoid bodies, the necessary first step to growing larger self-assembled 3D cultures known as spheroids or organoids from stem cells. Owing to the unique geometry of each microwell, uniformly-sized spheroids can be generated with high reproducibility, and the high-transmissive plate bottom enables high-quality optical observation. The company anticipates that researchers will benefit from this environmentally-friendly device for a long time, both scientifically and economically.

3D cell cultures are quickly emerging as the next generation tools of choice for safety pharmacology and drug screening purposes. As such, conventional single-use plastic 3D cell culture microplates are increasingly being used in CROs, biotech and pharmaceutical companies as well as for fundamental research in academic and government laboratories. eNUVIO opens the door to researchers around the world to access the first, completely reusable and environmentally-friendly 3D cell culture microplate on the market. The company is banking on labs embracing greener choices in their workflows, and is working to expand their environmentally-friendly product offerings.

EB-PLATE Specifications:

- 96 microwells/plate
- Microplate outer dimensions: 127.7 x 85.4 mm
- Chamber material: Polydimethylsiloxane (PDMS), biologically inert, non-degradable
- Microplate height (w/o lid): 14.2 mm
- Microwell opening diameter: 6 mm
- Microwell diameter at base: 900 µm
- Microplate bottom thickness: 1 mm
- Chamber volume: 250 µl
- Chamber pitch: 9 mm
- Shipped sterile, ultra low attachment (ULA) surface
- In-house production ensures high quality at all times
- Sold directly through enuvio.com or via scienceexchange.com

New-Generation, High-Precision Isotope Ratio Mass Spectrometry System Delivers Analysis for Geosciences, Nuclear Safeguards and Medical Research Applications

A new inductively coupled plasma mass spectrometry (ICP-MS) instrument has been designed to enable scientists working in earth sciences, nuclear safeguards and biomedical research to conduct reliable, high-precision

isotope ratio analysis across a wide range of applications, without compromising sensitivity, stability or ease-of-use.

The Thermo Scientific Neoma Multicollector ICP-MS (MC-ICP-MS) system combines innovative features from the field-proven technology of existing Thermo Scientific variable multicollector instrumentation. A new level of automation with the integration of peripherals makes access to reliable, high-precision isotope ratio data easier and more efficient, leading to enhanced research productivity and novel applications. The new instrument offers the flexibility to quickly change between a broad range of isotopic systems, which is a key consideration for productivity in multi-user facilities.

"High quality isotopic data enables scientists to better understand the processes that shape our environment and that control the distribution of mineral resources," said Fabrizio Moltoni, vice president and general manager, applied analytical technology, chromatography and mass spectrometry, Thermo Fisher Scientific. "These data also shed light on events in earth's history and our understanding of climate change, as well as underpinning nuclear safeguards and providing novel tools for metallomics and biomedical research. The Neoma Multicollector ICP-MS system builds on our experience with the market-leading Thermo Scientific Neptune Series MC-ICP-MS instrument and represents a major step forward in flexibility and ease-of-use, without compromising performance. The Neoma ICP-MS greatly increases accessibility to the wealth of information that isotope ratio data can provide, which will benefit geoscientists as well as researchers from numerous scientific disciplines."

Designed with learnings from 20 years of experience in high resolution MC-ICP-MS and feedback from customers, the system incorporates new software and hardware technologies. The new modular concept is designed to integrate future developments.

Users of the Neoma Multicollector ICP-MS system will benefit from:

- The ability to extract the finest detail of isotopic information from samples, utilizing the highest sensitivity ICP interface, and the lowest noise detectors available.
- The most flexible MC-ICP-MS instrument available; a new detector array that covers the broadest range of isotopic applications with uncompromising accuracy.
- Productivity stemming from the combination of modern hardware design with intuitive, easy-to-learn Qtegra Intelligent Scientific Data Solution (ISDS) software.

Neuberg Diagnostics announces appointment of A Ganesan as Group Vice Chairman

Neuberg Diagnostics, India's fourth largest diagnostics chain, today announced the appointment of Mr. A Ganesan as the Group Vice Chairman of Neuberg Diagnostics. In his new role, Mr. Ganesan will continue to play a key role and be actively involved in the business

expansions.

Mr. Ganesan is a Chartered Accountant with over 33 years experience in Assurance and Advisory practice and also a veteran in healthcare field having handled in the past M&A deals for Metropolis group , Trivitron group and Maxivision Eye Hospitals At Neuberg, in his previous role as Director of Finance, his broad vision and pro-active efforts have enabled the company to win several accolades and making it one of the top 4 diagnostics companies in the country.

DT-109 Significantly Prevents Progression of Diet-Induced Non-Alcoholic Fatty Liver Disease

Rom et al report today that the oral administration of the simple tri-peptide, DT-109 (Patent US8664177B2), prevents both development of non-alcoholic fatty liver disease (NAFLD) and late stage fibrosis in a murine model of diet-induced non-alcoholic steatohepatitis (NASH). The study titled, "Glycine-based treatment ameliorates NAFLD by modulating fatty acid oxidation, glutathione synthesis, and the gut microbiome" was published in Science Translational Medicine on December 2, 2020.

About DT-109 Development for Human NASH

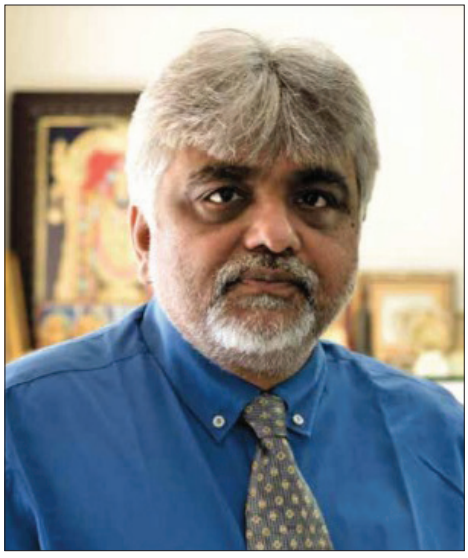
DT-109 is a 3 amino acid, orally active peptide, that stimulates release of intestinal GLP-1. Dr. Eugene Chen and his team at the University of Michigan identified DT-109 as having dual glucose/lipid-lowering effects and potently lowering steatohepatitis and fibrosis in a long-term pre-clinical NASH model. Applying advanced multi-omics approaches, the team identified underlying mechanisms by which DT-109 protects against NAFLD. These included modulation of the gut microbiome, stimulation of lipid utilization in the liver and the production of one of the most protective antioxidants, glutathione.

Dr. Oren Rom, the study lead author stated "We thought outside the box and focused on understudied aspects linking dysregulated amino acid metabolism to NAFLD. Our studies not only provided metabolic explanations for impaired glycine metabolism in NAFLD, but also identified a novel glycine-based treatment".

DT-109 has been licensed from the University of Michigan by Diapin Therapeutics LLC. Dr. Bruce Markhan, CEO of Diapin stated "DT-109 has been designated as a lead NASH compound and is currently being evaluated in preclinical IND enabling studies and developed in chemical manufacturing control. We see this as a breakthrough molecule for the treatment of NASH and other co-morbidities associated with metabolic syndrome." ■

Sticking to the core strengths will immensely benefit the pharma industry

Mr. Dharmesh Shah, Chairman and Managing Director of the BDR Pharmaceuticals *is recognized as a 'niche' player in manufacturing of pharmaceutical APIs and new age formulations. In an exclusive interaction with PBW, Mr Shah talks about his journey, BDR Pharmaceutical's drive for innovation, development and the continuous endeavor to make high cost medicines available to masses at affordable prices.*



Mr. Dharmesh Shah
Chairman and Managing Director,
BDR Pharmaceuticals

BDR Group is recognized as a "niche" player in manufacturing of Pharmaceutical APIs. What is the story of BDR Group and how BDR Pharmaceuticals International Pvt Ltd and BDR Life sciences Pvt. Ltd aided the journey to build undeniable reputation that the Group enjoys?

The role of BDR Group is working on niche molecules. When we say "niche" we have been focusing on life threatening diseases like cancer, critical care, hepatitis, and gynecology and off late COVID-19. We normally chase the disease pattern and hence look forward to a complex molecule. BDR Pharma primarily takes care of the formulation, development along with the regulatory compliance and putting the product in the market as a first generic.

BDR Life Science is an arm that helps in the backward integration like developing the raw material in-house that makes us self-reliant than competitive by making the product accessible and affordable.

BDR's specialization is in early identification, development and introduction of new molecules. Gives us an insight.

BDR's way of approaching the business is quite different than other large players in India. We don't follow the IMS data, we don't chase the value of the product created by the originator. We chase the disease pattern and look for innovative molecules in order to bring more sophisticated molecules or complex molecules at an affordable and accessible price. Our expertise when we say "early identification", is we chase the disease pattern and always look forward to something more advanced which can help patients with early recovery as well as less of side effects. Even though IMS data shows that the value of products can be insignificant but if they are complex, niche and small we still venture in and become the first generic.

Innovation and development are the inalienable cornerstones of BDR group. BDR invest heavily in R&D activities, possess state–of-the-art API and Formulation development centers accredited by the DSIR, Government of India. Tell us more about BDR's endeavors in research & innovation.

When I started my journey, my motto used to be "Spend peanuts and earn diamonds." As we advanced, we started realizing that there is a lot to do in terms of complex molecules, and for that, we need a more significant research team. That's how we invested heavily in an R&D center. Probably in India, it's one of a kind with 70,000sqt built up that can accommodate up to 550 scientists only in the finish formulation segment. We have been upgrading and modernizing ourselves according to the need to deal with the challenging chemistry, enhance and ensure that we invest adequately to gear up to counter any challenging chemistry and delivery systems. For any pharma company, the heart to its success is on R&D, and that's where we are highly emphasized. We are also blessed with a team that also works meticulously to take our vision forward.

BDR's philosophy of sustained growth and consolidation is achieved by strategic tie-ups with several globally renowned players. Could you elaborate how this philosophy has helped the group?

Unlike majority or large Indian companies that have their own subsidiaries and manpower in different geographical locations outside India we always believe to align with a strong national player in a country we plan to penetrate in. They need to be right with the job in terms of having a bigger field force and potentially reaching the markets. When it comes to India, it is a

country with 1.3billion people, and I don't believe it's a game of an individual to make a new product available and accessible across pan India. Hence, we look at like-minded partners who have a strong presence in these segments and have a bigger filled force to ensure upon like tier 2 & 3 cities apart from metro cities with a fair distribution and marketing network. And as a result, global alliances are concerned. It's better to have a strong alliance partner internationally who has a strong national presence, which benefits their rapport with the regulatory authorities and the distribution networks. I'd call it a win-win situation for both.

Congratulations on BDR's ambitious plans to manufacture specialized Oncological Injectable dosage forms as the next giant step, which once operational will target for approval from various international accreditation agencies, including from US, Europe, African and Asian Health Authorities. Could you elaborate?

There was a need of the moment to expand ourselves beyond India and the ROW market. We believe with the new delivery systems that we are creating, even in oncological injectable, to improve the bioavailability and reduce the toxicities. We needed a different kind of setup. Hence we decided to set up a world-class facility in oncology, which will have no restriction in accreditation, be it any regulatory or emerging market. With the kind of product portfolio and many of our pipelines going forward in the coming five years, we have the world market as our horizon and not stay limited to only India and emerging ROW markets.

What impacts and / or transformations do you see digitization and digitalization making in the healthcare and Pharmaceuticals + Biotechnology industry?

Every modernization, advancement, new technologies takes time to be adopted. We are moving towards a new environment, a new healthcare system. I believe it will be quite positive and companies will adopt to it according to the need of the moment.

Mr Shah, you are credited with identification and launching of more than 140 molecules for the first time ever in India and 2nd time in the world market after the Originator. Readers would like to know your story. Could you tell us journey?

My journey began way back in 90s when I identified HIV as a segment when there was hardly any presence of generic players. We saw HIV as an epidemic which was spreading world-wide. That's where I realized there was a need for accessibility and affordability. That's where I started my journey with the first generic in HIV. We believe we contributed a lot and made it very affordable. Some of the classic example was when crixivan was sold by the originator for an unaffordable price per unit we could bring it to almost

1/4th of the price as a generic and made it accessible. Moving ahead from HIV in 2003-04, I saw that cancer is another area which was becoming almost like an epidemic where the presence of a generic player was insignificant and markets were dominated by the originators and the costs was prohibitive. That's where we decided to start our journey in oncology. To mention about it on a personal front my father who was living with cancer fought the disease for almost 5 years and during chemotherapy he lost his zeal apart from the side effects like loss of hair and skin rashes. The doctor asked me to use a product from the originator which was costing almost a lakh per vial and about 30 vials had to be given to help him get back his zeal. When I looked at the chemistry involved around the product I realized that the generic would not cost most than INR 500 a vial that's where the journey began.

As I have already mentioned, we don't chase the IMS data; we chase the disease pattern. We work closely with the medical fraternity and have studies that happen globally. Based on the disease pattern, we define the molecules of our interest. Let's say, for example, I enter into a molecule for the treatment of blood cancer for a pediatric patient. If we look at the IMS data as an entrepreneur, it does not become an economically feasible project. But we realized that if a vial will cost about INR 1,25,000, then definitely a pediatric patient who has blood cancer will never be able to afford it and cannot be treated in a country like India and many other emerging countries. Even if it was economically not feasible, we decided to calculate the patient population and ventured into it. We witnessed a lot of patients who benefitted from this due to the accessibility and affordability criteria. This makes us different from others.

Can you provide our readers an overview on what is the company's current strategy during this pandemic crisis?

We have been observing and studying the disease pattern when it broke out in China. Since then, our research team started working on possible avenues to treat Covid-19. Of course, the time available is short as nobody had the time to conduct the phase three studies. Based on our research, we realized that products like remdesivir and favipiravir help reduce the viral load and speed recovery. That's where we can say historically, in less than 70 days, we developed the molecule, took regulatory support, aligned ourselves with companies like Cipla and Sun Pharma, and were instrumental in making these products available to Indian Patients. I am happy to state that it helped a large number of the Indian population who were critical but were timely provided with a cure.

What is your message for boosting the Pharma & Healthcare Sector to emerge through this tough time?

I particularly feel that it is time that the Indian companies realize that they need to master what they are good at rather than be a jack of all. I would always say that sticking to the core strengths will immensely benefit the pharma industry and avoid unhealthy competition for dependence, which could see a different horizon. The fact of the pharma industry is that there is a large dependence on China. As our Prime Minister says that we need to be atmanirbar, we will need to start expanding ourselves to be basic, intermediate producers, which will help us be self-reliant and focused.

Make in India is a major new national program of the Government of India designed to gain momentum for investment, innovation and enhance skill development and build best in class manufacturing in the country. What is the impact of this program on Pharma sector?

It's a very welcomed initiative by our Prime Minister Shri. Narendra Modi. It's the need of the moment that India needs to be self-reliant, and it has all the potential. With the government's initiative to be atmanirbar, it will help the Indian Pharma Industry master what they are good at and be at par in competition with the world market with limited dependence on China. This will help to be cost-effective and dominate the world market.

The pandemic was unprecedented and has stopped the world at its feet. What are your views on finding a cure for the current pandemic and how will technology help us prepare for the next one (if at all it hits us)?

The pandemic was a sudden setback for the whole world and brought us to a pause as nobody was prepared; neither did anybody foresee the same. But since the pandemic broke, there have been many studies on synthetic chemistry and the vaccine front. It is too early for anybody to say that they have found a cure. Until vaccines hit in the market and become available and accessible to all, existing products like remdesivir played a significant role in the early treatment and reduction of viral therapy. A product like favipiravir also helped asymptomatic and mild patients for an early cure. During these testing times where all the efforts are on vaccines, there is an equal amount of pressure mounting on developers concerning conducting trials through phases to check the safety, efficacy, and adverse effects. I believe that we all will work together to find a permanent solution to overcome the pandemic. ■

How is Artificial Intelligence (AI) driving Drug Discovery and Development?

Artificial intelligence (AI) is a trending and sizzling topic in the world of pharma and medical industry. Recent advances in high-performance computing, the availability of large annotated data sets and new frameworks for implementing deep neural networks (DNNs), which has surpassed human accuracy, has resulted in an unprecedented acceleration of the field. This article is discussing about application of AI in drug discovery and development. Implementation of AI can give better results than traditional method of drug development. Discovery of a new drug is a complex and expensive process which costs about 2.6 billion USD and take an average of 12 years. Application of AI technology in medical field is very important in this modern era of 4th industrial revolution where innovations and development in medical field are growing rapidly. Use of AI technology will improve efficiency of drug discovery and drug development processes. It will reduce cost, time and efforts.

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The last 25 years has seen an explosion in the availability of data relating to the properties of drugs that are efficacious in human as well as those drugs that have failed in clinical trials. The availability of this data has opened up unprecedented opportunities for understanding critical drug features that may allow the drug to be successful or fail against a particular disease. The understanding of such properties enhances the identification of new therapies.

For a long time, the discovery of a drug has been a "hit or miss" approach. In general, the approach has been to screen as many compounds using high thru put robots and find hits. In addition, with genomics, thousands of potential targets have been revealed adding another layer of high thru put screening against these targets. The result is an explosion of classic hit or miss misleads with actually very little productive data to show for. As an example of this lack of productivity despite the high thru put approach, the actual numbers of drugs approved over the last decade have actually been steadily declining.

A better way to design new drugs is to use more rational approaches. To this end the plethora of information available publicly in publications data bases etc. can be exploited to formulate a strategy to find drugs. However, the sheer volume of such data is overwhelming such that the data cannot be accessed and correlated in an efficient and effective manner manually.

Compounding the problem is that the data are in disparate sources making it extremely hard to piece together in order to derive a fuller picture. Thus, it is near impossible to sift thru these data manually. Similarly, the data in the publications and the databases are not structured in a way that allows easy analysis of what drug properties are needed to make it a candidate for cancer therapy.

Fortunately, data extraction, curation and recognizing patterns and insights can now be better utilized by using Artificial Intelligence (AI) in drug discovery and development.

AI has the potential to:

- **Reduce timelines for drug discovery and improve the agility of the research process:**
  The successful application of innovative technologies could speed up the discovery and preclinical stages by a factor of 15.
- **Increase the accuracy of predictions on the efficacy and safety of drugs:**
  Currently, only one out of thousands of drugs are approved after clinical trials. Most fail due to efficacy and safety issues. Given the growing cost of bringing a drug to market, even a ten per cent improvement in the accuracy of predictions could save billions of dollars spent on drug development
- **Improve the opportunity to diversify drug pipelines:**
  AI-enabled prediction tools could improve the speed and precision of discovery and preclinical testing, opening up new research lines and enabling more competitive R&D strategies. Failure to demonstrate value compared to available therapies is a key factor undermining clinical trial progression. Finding new niches of competitive advantage could reduce withdrawals and improve asset sale.

A case study in application of AI in drug discovery that we recently utilized is presented here. Despite all of our knowledge and scientific progress we still do not have drugs to treat all cancers. Chemotherapy, which is use of cytotoxic drugs continues to be the gold standard as first line therapy for most cancers. Cytotoxic drugs work by simply killing all cells, normal and cancerous cells without showing any differentiation. As a result of which they have unacceptable side effects like hair loss, body weight loss, nausea etc. The side effects are so severe that the cytotoxic drugs have to be administered in cycles, where the drugs are given to the patient and then there is a period of recuperation before another round of treatments. Often times the patients are unable to tolerate the drugs and discontinue the treatment. New immunotherapies are currently being used as combination therapy with cytotoxic

drugs but these new therapies are un-affordable to most patients in India (cost is US $200,000 per treatment course).

The situation is worse in children because their tolerance to such drugs is even lower than adults. The most frequent cancer in children (also in India) is leukemia. Pediatric lymphocytic leukemia (PLL) is a rare disease for which the treatments are not optimal. We wish to identify non-cytotoxic drugs for treatment of pediatric lymphocytic leukemia.

We utilized AI to not only improve the speed and probability of finding new therapy for PLL but also reduce the cost. AI utilizes the vast amount of data sets available for all marketed drugs and up to 12000 drug like compounds. We could extract the most desirable properties needed for a cancer drug using this massive data using AI. Rather than use the traditional steps used to discover new drugs, we used AI to find drugs that are currently approved for other diseases and to see if they can be used for PLL. This process is called re-purposing of drugs, in which successful drug for one indication is used for another indication. Using AI we designed a process to use AI in successfully finding drugs that could be repurposed for PLL

1. Creation of Drug Database of drugs that are successful in treating cancer and those that have failed
2. Training AI model with Drug Database
3. Validation/Testing of the model with unknown drugs
4. Testing selected drugs in in vitro and in vivo models of disease

While AI/ML (Machine Learning) as describe above is being to be used

Use of AI guided model for identifying leukemia drugs

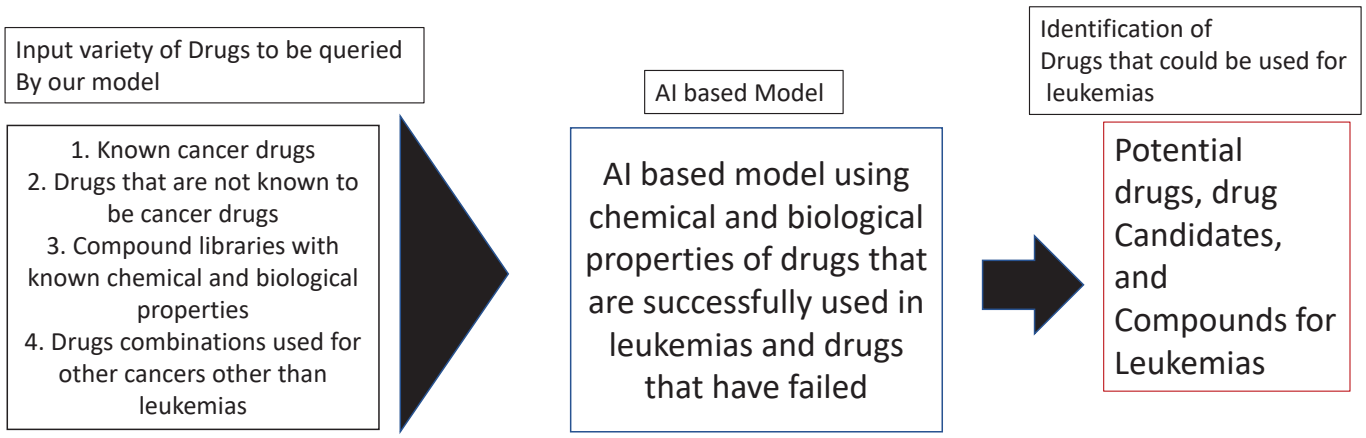


Figure 1

frequently in drug discovery, this whole approach also has application to clinical trials and safety as well. Specifically, blockchain which is known for its immutability, security and transparency is also aiding drug discovery and development in many ways such as data management, drug authenticity, Intellectual property authentication. Clinical Trials is a complex exercise and involves various stakeholders making the process error-prone. Blockchain provides a single sharing platform for all parties ensuring proof-of-existence, authenticity, efficient data sharing and data security leading to effective clinical trials. The Mediledger project was designed to apply blockchain to track and trace prescription medicines and prevent drug counterfeiting.

Drug Safety is of utmost importance in current era of patient centricity. Increasing regulatory reporting requirements, stringent timelines, exponential rise in adverse event cases is complicating the pharmacovigilance process multifold. Pharmacovigilance involves repetitive, manual and mundane tasks which are highly time-consuming making it a perfect case for RPA. As most of the business logic and conventions are clearly defined in the pharmacovigilance processes, RPA for data entry processes serves as excellent means to overcome common issues like oversight errors and helps generate quality reports within a short time. Machine learning can be useful in handling mailboxes of the safety team, identification of adverse event reports, categorization of adverse event emails into expedited, and non-expedited and prioritization of emails based on the seriousness, initial receipt date, and reporting country. NLP plays an important role in handling unstructured data by converting it into structured data. NLP techniques can be applied to extract information from various fields of source documents, including reporter information, narrative, autopsy data, etc.

In summary, AI/ML/Blockchain technologies are slowly but steadily transforming the pharma traditional paradigm of drug discovery and development. This augurs well for the future of this industry which traditionally has had the lowest rates of productivity. ■

Portable chiller for last-mile delivery

Blackfrog Technologies Pvt. Ltd. is a Manipal, KA based technology start-up company that seeks to improve the efficiency of immunization supply chains. We have developed precision cold-chain and vaccine traceability systems with support from BIRAC (DBT) and leading impact investors in the nation including Venture Centre (NCL, Pune) and Social Alpha to provide logistical support in the last-mile delivery of vaccines.

The safety and efficacy of vaccines depend largely on efficient cold-chain management. In remote, low-income settings that rely on ice-based technologies, compliance issues and lack of temperature control and monitoring are significant problems. According to the Immunization Technical Support Unit (ITSU) of the Indian Health Ministry, 25% of all vaccines are wasted due to suboptimal cold-chain management practices. Further, a recent study found that nearly 65% of all vaccine vials across 10 Indian states showed evidence of freezing in storage[1]. With the COVID-19 vaccine in the horizon, it is imperative to ensure the vaccines do not lose their efficacy in the last mile of delivery, which is when they are most susceptible to thermal degradation. This is where our flagship device, Emvólio comes in.

Ergonomic & Fits into a Backpack

Emvólio: Product Overview

Emvólio is a portable, battery-powered refrigeration device that will strictly maintain any preset temperature for over 12 hours for last mile transport of vaccines+. Emvólio's 2-litre capacity enables it to carry 30-50 vials, which is standard for a daylong immunization campaign. Further device capabilities

include continuous temperature monitoring, location tracking, state-of-charge indication, communication with headquarters via live tracking, and vital statistics for improved coverage. This system, at a pilot scale, has been helping remote hospitals relieve the economic burden of wasted vaccines. Further, it helps optimize human resources in vaccine delivery by removing the need for repeated immunization visits to account for the administration of unviable vaccines. Most importantly, our battery-powered device stands apart from the competition with its unmatched portability and ease of charging.

Emvólio's role in mitigating vaccine wastage

A group of researchers from the UK and Thailand conducted a study in 2017 on the 'Cost, health impacts and cost-effectiveness of ice-less refrigeration in India's vaccine cold chain'[2] to better understand the economic benefits of using a battery-operated device as a replacement for conventional iceboxes. The team concluded that the costs of wastage in the context of just rural India alone of the ice-based cold chain system is USD 7,512,930 and that even at a unit cost-price of USD 2000 (INR 1,47,420) for an iceless, battery-powered vaccine carrier, the cost-benefit ratio that avoids this wastage would 0.28, indicating that this is cost-beneficial.

With NOC from CDSCO, we have deployed 11+ units at pilot capacity across hospitals & PHCs in 3 states of India.

Emvólio costs INR 54,000 (plus applicable taxes) and has been purchased by multiple hospitals and non-profit organizations engaged in improving healthcare and livelihood (SELCO Foundation, CInI TATA Trusts, Support Jharkhand, etc.).

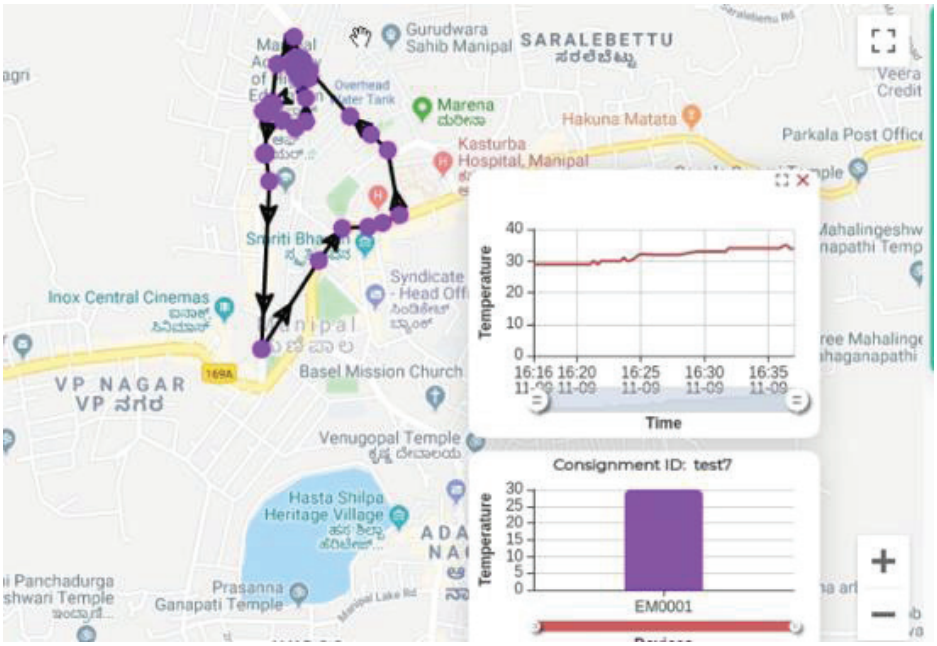
One of Blackfrog's clients, SVYM Hospital in Sargur, near Mysore (Karnataka) have used Emvólio for a full year now. They report saving INR 13,000 every month as a direct consequence of not having to discard unused vaccines at the end of the day's field trip. The field doctors report that with Emvólio's battery performance, they are now able to immunize twice as many children in tribal regions as they were previously able to with ice-based systems.

With NOC from CDSCO, we have deployed 11+ units at pilot capacity across hospitals & PHCs in 3 states of India.

Emvólio: Technology

Emvólio's patented technology ensures that all contents in the cold chamber are

blanketed in strictly temperature-controlled air. The underlying refrigeration mechanism is solid-state cooling with a smart PID (Proportional Integral Derivate) controller, which guarantees precise temperature maintenance without the risk of noxious refrigerant leakage or cross-contamination. The lack of motors/ compressors or any moving parts enables low-maintenance operation. The unique design of Emvólio promises:



Remote Temperature and Vital Statistics monitoring

1. Uniform cooling: No hot spots/cold spots within the cold chamber.

2. Minimal freeze-thaw cycles: This means every time a user opens the lid to retrieve a vial and subjects the cold-chamber to ambient air, the rapid-cooling system onboard Emvólio brings the cold-chamber back to safe limits (i.e. 2-8 degrees Celsius) over 96% faster than an ice-based product would

Emvólio - IoT and eVIN

The eVIN (Electronic Vaccine Intelligence Network) program adopted by MoHFW provides live intelligence on vaccine availability and status until the last point of storage. However, the accountability ends when the vaccines leave the storage facilities and head into the field. Emvólio is a battery-powered system that carries vaccines until the point of administration, implying there is now unprecedented potential to bring traceability in the last mile of the supply chain.

The GSM-GPS system onboard transmits live vital statistics like temperatures, location, and usability patterns to the cloud, which Blackfrog provides as a service to the client via an online dashboard at a nominal cost. This system is easily integrated into the existing eVIN system using APIs, thus providing MoHFW end-to-end visibility of all vaccines.

Remote Temperature and Vital Statistics monitoring

In-house manufacturing being scaled-up for up to 5000 units by March 2021. Discussions ongoing with contract manufacturers for 100k+ units

As part of next steps, with funding support from BIRAC, Blackfrog Technologies is currently building a platform to integrate QR-code/barcodes on individual vaccine vials against each recipient's vaccine schedule data (immunization card). This will provide clarity at the level of individual patients and vials, enabling timely and enhanced pharmacovigilance in case of adverse reactions to medication. This is beneficial especially during COVID-19 vaccine delivery to prevent full batch write-offs, curb black market activities and counterfeits.

In-house manufacturing being scaled-up for up to 5000 units by March 2021. Discussions ongoing with contract manufacturers for 100k+ units

Emvólio is a portable active cooling (battery-powered) device that will provide a platform for delivery of vaccines and all other biologicals like blood, serums, viral culture which require to be kept strictly between 2°C and 8°C for up to 12 hours in the field. The product has been designed in accordance with WHO PQS E003 draft specifications.

Alternatives			
Product	Origin	Stage	Current status & procurement
Indigo Cooler	Gates Foundation (Seattle, US)	Developed till field-trials demonstrated long cold life of 20+ days.	Project likely discontinued
Isobar	James Dyson Foundation (UK)	Ergonomic Industrial Design developed with Ammonia & Propane as mechanism of Refrigeration.	Available in the UK (Price Unknown)
Zedblox	Hyderabad, India	Conventional Vapor Compression technology with promising trial results.	Refrigerants & risk of leakage from underlying technology is conceivable

Dimensions	35cm x 22cm x 38cm
Weight	6Kg
Payload Capacity	2L
Battery	350Wh Li-ion
Operating ambient Temperature	-15°C to 50°C
Operating Humidity	Up to 100%
Adjustable internal chamber Temperature Range	-10°C to 20°C
Accuracy of maintained Temperature	±0.5°C
IP Rating	IP66
Operating Time	12+ Hours
Charging Time	4 Hours
Initial cool down time	< 20 minutes
Device Life	5+ Years

- Food grade SS304 Chamber for easy sterilization
- Ergonomic Backpack and Shoulder strap to carry the device
- GPS tracking and Cloud data monitoring with detailed report generation
- Audio and visual alarms for temperature excursions
- Vial holder compatible with all shapes and sizes of vials
- User interface to change/ monitor temperature, battery, and other vitals

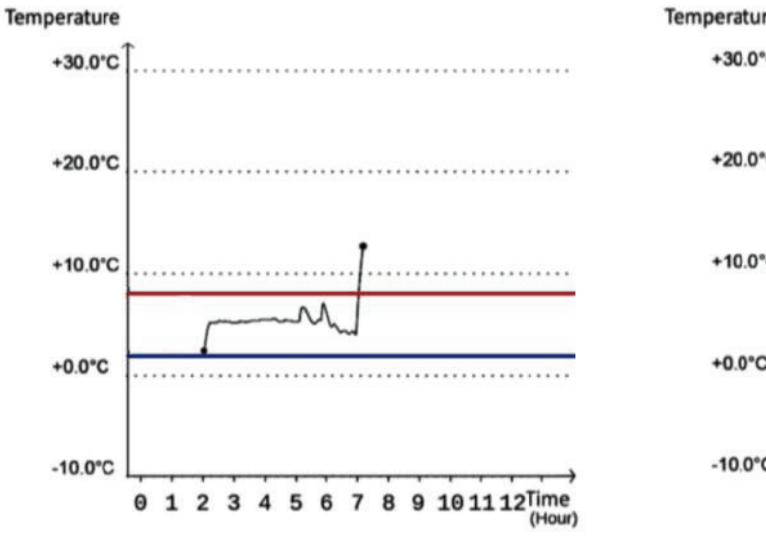
Field Trial Data

Following are results from a simulated field-trial for Emvólio against current practice of using Iceboxes in a Vaccine outreach programme (Routine immunization campaign) held at Kapu RMCW (Rural Maternity & Child-Welfare) home in February 2019.

Ambient Temperature: Ranging from 27° C to 34° C

Temperature Sensor used (for both systems): Berlinger Q-tag Wireless (WHO PQS Certified)

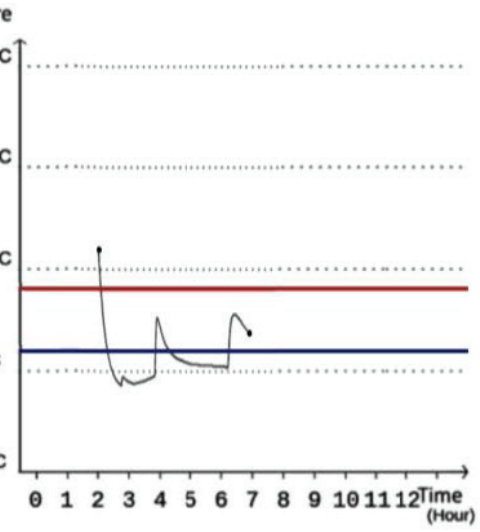
Emvólio performs significantly better



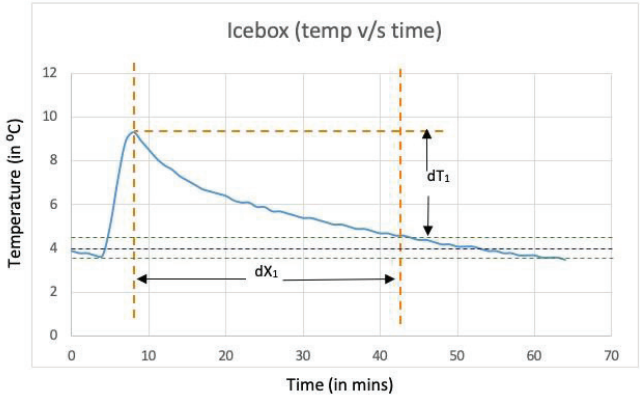
than the ice-based option in terms of temperature control. Our device can maintain a stable 4° Celsius platform, with a 0.1° Celsius error margin. On the other hand, the temperature within the icebox is radically variable (often freezing the samples), and this is potentially the single most serious threat to the efficacy of temperature-sensitive vaccines. Emvólio's stable temperature platform ensures absolute accountability for the efficacy of vaccines, and minimizes human error, thanks to the novel design that does away with repeated freeze/thaw cycles.

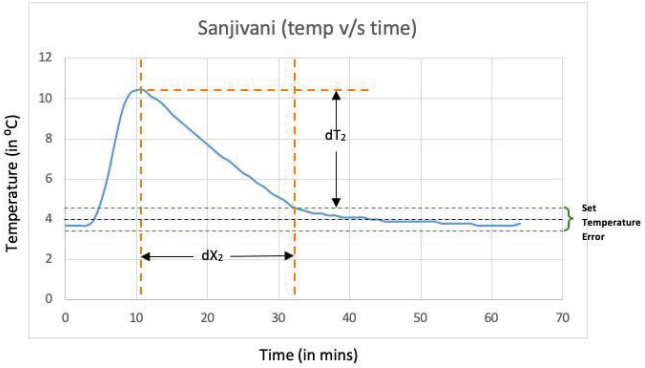
Interference Testing (Emvólio – Rapid stabilization of Temperature)

When vaccines are taken to the field for administering, the device is opened multiple times to retrieve the vials. This is usually when the temperatures shoot above the recommended 8 degrees Celsius higher limit and thus degrade the efficacy. It is imperative for any refrigeration mechanism to bring the temperature down to the safe limits in the least possible amount of time.



We simulated these human-interference by opening both the systems (icebox and Emvólio containing same volume and density of load) for a period of 3 minutes (as per WHO PQS guidelines for testing refrigeration). The temperatures went above the set-temperature and they were placed back inside the respective devices for stabilization. Temperature versus Time curves were plotted for both the systems and compared.





Ta = 34.03 °C is the Average Ambient Temperature during Test

T0 = 4.6 °C is the Set-temperature / optimal temperature for cold-chain

Parameters	Ice Box	Emvólio
Peak Temperature (T1)	9.3°C	10.4°C
Temperature change brought about by Refrigeration (dT)	4.7	5.8
Time taken to reach 4.6°C (T0) in minutes (dX)	35	22
Rate of cooling R = dT/dX	0.13429 °C/min	0.26364 °C/min

Improvement in rate of cooling = (REmvólio – Ricebox)/ Ricebox

= (0. 26364 - 0. 13429)/0. 13429

= 96.33%

Emvólio is able to refrigerate (stabilize temperature to recommended levels) at a rate of 96.33% faster than the icebox. ■

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An Overview on Biosimilars: A Review of Literature

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The risk of chronic diseases like diabetes, cancer, rheumatoid arthritis, etc. has been increasing considerably at the global level. Biologics have been used for many years in treating chronic diseases, but their high cost leads to high financial burden on healthcare systems. This calls for affordable treatment, contributing to the development and commercialization of biosimilars across the world. The patent cliff of many biologics has provided opportunities for pharmaceutical companies to develop, manufacture, and market biosimilars. A biosimilar can be defined as "copied" and licensed versions of approved and authorized biologic products that have undergone patent expiration. It takes around 8-10 years to develop a biosimilar, at a cost of between $100 million to $250 million. According to the published reports, it is expected that sales of biologic drugs may lose up to $197 billion after the entry of biosimilars. Various regulatory bodies such as European Medicines Agency (EMA), US Food & Drug Administration (FDA), World Health Organization (WHO), etc. actively regulate biosimilars development and ensures that only high-quality, safe, and efficacious biosimilars are available on the market. Each country has its regulatory guideline for biosimilar drugs. The regulatory authorities play an important role in the success of the biosimilar development as they closely monitor the viability and balance between the reference product and biosimilar product. This article summarizes the approved status, market size, and comparison of the regulatory guidelines of biosimilars in Europe, the United States (US) & India.

1. Introduction:

The existence of biopharmaceuticals has been in the market for more than 20 years and Humulin was the first drug to be approved in 1982. There are nearly 300 biopharmaceutical products that have been approved and are available in the market. The global biopharmaceuticals market was at the value of $186,470 million in 2017 and is projected to reach $526,008 million by 2025, at a compound annual growth rate (CAGR) of 13.8% from 2018 to 2025. [1] Biosimilars are considered to be the new category of biotechnological drugs and represent a significant opportunity for healthcare systems to deal with the rising cost of biologics and access issues faced by patients. The biosimilar can be defined as an official approved medical drug that shares the same amino acid sequence but can never be identical. A biosimilar registration follows strict guidelines based on a totality-of-evidence approach emphasized on stepwise development. The initial development of biosimilar requires extensive studies and in-depth analysis to confirm that the product is identical to the originator in terms of structure, composition, and in-vitro activity. After the bio-similarity is confirmed, regulatory authorities may allow extrapolation to other licensed reference biotherapeutics (bio-originator) indications. Hence, a biosimilar may be approved in all indications (without multiple trials) for which the bio-originator has been approved. [2]

2. WHO Regulations:

According to the WHO, the biosimilar can be defined as "A bio-therapeutic product which is similar in terms of quality, safety and efficacy to an already licensed reference bio-therapeutic product." In 2009, WHO followed the guidelines on the evaluation of Similar Biotherapeutic Products (SBPs) and aligned its guidelines with those from the EMA. Most countries rely on WHO guidance to assure the safety and efficacy of biosimilars. [3] In 2019, WHO prequalifies its first biosimilar medicine i.e. trastuzumab which comes in the WHO Essential Medicines List. The global average cost of the trastuzumab innovator product is ~ $20,000, a cost that is too much of an expense for many women and healthcare systems in most countries. Hence, the biosimilar version of the trastuzumab has enabled women and healthcare systems to afford the drug as it is ~ 65% cheaper than the originator. It is expected that many products will come into the prequalification pipeline, as it assures countries of purchasing quality health products. [4]

3. Biosimilars in Europe:

3.1 Overview & Approved Status:
Europe was the first country to introduce regulatory guidelines for examination and approval of biosimilars via an abbreviated registration process from 2005 to 2006. After 2006, many guidelines were developed and released for biosimilars. Omnitrope (somatropin) was the first biosimilar to be approved in Europe in 2006. To-date approval of 64 biosimilars has been recommended by EMA within the product classes of human growth hormone (HGH), granulocyte colony-stimulating factor (G-CSF), monoclonal antibodies (mAbs), anticoagulants, erythropoietin, insulin, follicle-stimulating hormone (FSH), parathyroid hormone, and tumor necrosis factor (TNF)-inhibitor. Out of 64 approved biosimilars, six biosimilar approvals have been withdrawn after approval, leaving a total of 58 biosimilars approved for use in Europe. [5]

3.2 Biosimilar Market Size: Biosimilars have been on the market in Europe for more than 15 years. The biosimilar market in Europe reached a worth of $ 2,934.6 million in 2018. The market is further projected to reach a value of $ 11,663.1 million by 2024, growing at a CAGR of 24.9% during 2019-2024. [6] Europe has the world's largest biosimilar market accounting for approximately 87% of global biosimilars sales of $5 billion as compared to just 2% from the US [7].
In late 2018, the EU patent of Humira (adalimumab) got expired, opened the door for sponsors to develop cheaper biosimilars to hit the market. The originator product, AbbVie's Humira was one of the world's best-selling drugs, had worldwide sales of $18.4 billion in 2017, before the arrival of biosimilars. The global sales of Humira got to drop by 33.5%, after facing competition from biosimilars. [8] As per published reports, adalimumab has gained a high of 57% uptake across the European Union (EU) 5 nations, and discounts have reached levels of 70% to 80%. The total sales of Samsung Bioepis's three autoimmune biosimilars (i.e. Benepali, Imraldi, and Flixabi) in Europe alone accounted for $738.3 million (~35 % profit) in 2019. [9]

4. Biosimilars in US:

4.1 Overview & Approved Status: The regulatory framework for approval of biosimilars was established in 2009, via the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). To date, the USFDA has approved 28 biosimilars within the product classes of TNF- α, monoclonal antibodies (mAbs), GCSF, and insulin. The USFDA approves its first

biosimilar product Zarxio (filgrastim-sndz) in 2015. The penetration of biosimilars in the US biosimilar market is very slow and is limited. Currently, there are only nine approved biosimilars in the US biosimilar market because anti-competitive behaviors, other markets, and regulatory dynamics discourage market uptake of biosimilars in the US. [10]

4.2 Biosimilar Market Size: Biosimilars currently make up only 2.3% of the US biologicals marketplace. On average, the biosimilars can cost 30% less than reference biologicals, with the potential to save the US up to $71 billion in the next 10 years. Also, the US could have saved $7.2 billion annually if the biosimilars penetration grew to 75% in the biosimilar market and even more savings could have been figured out if more categories of biosimilars are approved. [10] The US biosimilar market was valued at $737.2 million in 2019 and is projected to reach $ 22,966 million by the end of 2027. [11]

5. Biosimilars in India:

5.1 Overview & Approved Status: India released the draft of regulatory guidelines for 'similar biologics'(or biosimilars) at the BIO industry conference in Boston, USA, in June 2012, and implemented the same from September 2012. The Central Drugs Standard Control Organization (CDSCO) is responsible for the approval, i.e. marketing authorization of medicinal products, including biosimilars in India. The CDSCO introduced the revised biosimilar guidelines in August 2016. The first biosimilar was approved and marketed in India for a hepatitis B vaccine in 2000, well ahead of Europe which approved its first biosimilar in 2006. The number of approvals for biosimilars in the last 5 years represents a robust opportunity for biologics and biosimilars. Currently, more than 98 biosimilars have been approved in the domestic market of India. There are more than 2700 biotech startups, 600 biotech companies, and 100 biotech incubators in India which will be going to increase by 4-5 times in the next five years. [12]. The pipeline for biosimilars in India is robust because Indian government provides subsidies to Indian biosimilar manufacturers. In addition, global biopharmaceutical manufacturers are increasingly partnering with Indian biopharmaceutical producers. For example, Apotex (via its European marketing arm, Accord Healthcare) partnered with Intas Biopharmaceuticals Limited (IBPL) such that Apotex received the rights to market the product in North America (US and Canada), Europe, and selected other countries whereas IBPL expanded its ability to commercialize its products in Western markets. [2]

5.2 Biosimilar Market Size: The global biosimilar market will be worth of $240 billion and Indian biosimilars market will reach the value of $40 billion by 2030. India is considered to be one of the emerging hub for biologics and biosimilars. After CDSCO revised the biosimilar guidelines in 2016, several Indian pharmaceutical companies are making significant investments into biosimilar development and production into global markets. For example Cipla have made huge investments in India and abroad to acquire manufacturing facilities and potential product pipelines in the biosimilar segment in other countries like China [13]. Also, India is providing an affordable place to carry out research and development, more international players are partnering with Indian companies. India has shown that biosimilars have the potential to capture as much as 75 % of the available volume share. [2]

6. Comparison of Legal framework of biosimilars in Europe, US & India: The regulatory authorities play a significant role in enabling many biosimilar products to gain regulatory approval around the world. They develop a specific, appropriate, regulatory framework for approving biosimilars that is different from the previous regulatory policies applied to copy-version products, where the regulatory assessment was not well defined. [14] The summary of the comparison of the legal framework of biosimilars in Europe, the US & India is tabulated in Table no. 1.

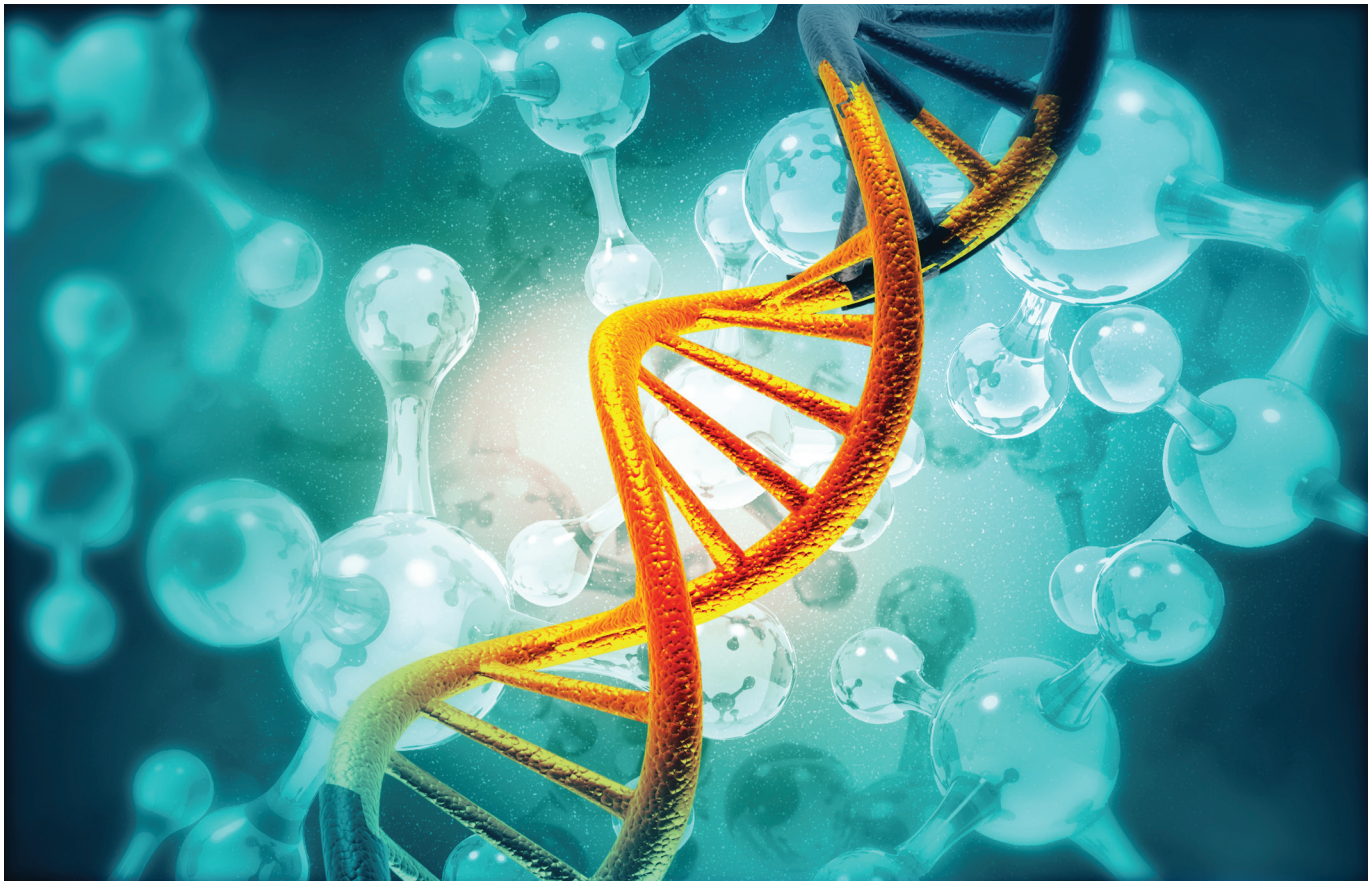
7. Discussion & Conclusion: The development of biological medicines has experienced continuous growth over the past three decades and it has transformed the treatment for several severe chronic diseases. Biosimilars are drugs that contain similar active components as biologics. The development of biosimilar drugs is a cumbersome process and the main driving force behind its development is the expiry of patents for approved biological products worldwide.

Table 1: Sum

S.No	Parameters
1.	Reference Pro (RP)
2.	Pharmacokinetics (PK) Studies
3.	Pharmacodynami (PD) Studies
4.	Safety (Immunogenicity)
5.	Extrapolation
6.	Exclusivity Period
7.	Interchangeability
8.	Post Marketing Surveillance (PMS

mmary of the comparison of the legal framework of biosimilars in Europe, US & India [2] [3]

	Europe	United States	India
oduct	RP which is not authorized in European Economic Area (EEA) can be used for certain clinical & in vivo non–clinical studies based on similar scientific and regulatory as per the EMA guidelines (CHMP/437/04 Rev Effective date: April 30, 2015) and representative of the reference.	As per 351(k) of the Public Health Service (PHS) Act, a sponsor must demonstrate the biosimilarity between the proposed product and single RP that previously has been licensed by FDA.	As per section 6.1 of the CDSCO & Department of Biotechnology (DBT) revised guidelines, biologics approved/licensed and marketed in a member country of The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human use (ICH) countries like EU, USA, Japan, Canada, and Switzerland can be used as reference biologic in India.
	PK studies are applicable to homogeneous and sensitive population (healthy volunteers or patients) to detect any possible differences between the proposed biosimilar and its reference medicine.	The sponsor should conduct comparative PK studies between proposed biosimilar and RP to measures of peak concentration (Cmax) and total area under the curve (AUC) in a relevant biological fluid.	Comparative PK studies should be conducted between proposed biosimilar and RP in normal healthy volunteers & patients and should consider some factors like half- life, linearity of PK parameters, route of administration and indications.
cs	The end points measuring PD activity ('PD endpoints') can be used when available and when relevant for the medicine's clinical effect.	In PD studies, PD biomarker(s) evaluated for the proposed biosimilar product and the RP and are compared by determining the area under the effect curve (AUEC).	Comparative PD studies are conducted between proposed biosimilar and RP in healthy volunteers when the PD properties of the RP are well characterized with at least one PD marker validated for a clinical outcome of the molecule.
)	Immunogenicity studies are mandatory for biosimilars as per EMA Guidelines.	Immunogenicity studies are compulsory and should able to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and for which licensure is sought for the biosimilar product.	Both pre-approval and post-approval assessment of safety is mandatory which has to be conducted for a biosimilar.
	Extrapolation is allowed and requires sufficient scientific justification in comparability studies (quality, non-clinical and clinical).	USFDA view is same with that of EMA in context of extrapolation of data to other indications.	As per section 8.5 of the CDSCO & DBT guidelines, both old & revised guidelines have the provision for approval of biosimilar for all the indications as that of the RP. However, the introduction of detailed description of "quality" and "clinical" similarity is an additional feature in the revised guideline.
	10 years of exclusivity to pioneered product.	12 years of exclusivity to pioneered product.	The concept of exclusivity period is not mentioned in the guideline.
y	EMA does not regulate interchangeability of a product. It is left up to the member states of EU.	The biological product may be substituted for the RP without the interference of the healthcare provider who prescribed the RP.	The concept of interchangeability is not mentioned in the guideline.
S)	PMS permits monitoring of knowns risks and detection of rare adverse drug reactions that arises when large numbers of patients have been treated for a long period.	PMS allows safety monitoring of all products with unknown safety risks as mentioned in Good Pharmacovigilance Practice guidance.	As per Section 10.3 of CDSCO & DBT guidelines, in PMS additional safety data may be collected by conducting a pre-defined single arm study of more than 200 evaluable patients and compared with historical data of the RP product.



Biosimilars have a product lifecycle that starts with inception (R&D) continues through manufacturing to regulatory approval and as well as post-approval in the form of pharmacovigilance. As a new wave of biosimilars is in the pipeline for development, and regulations in the EU and the US are simultaneously becoming increasingly more complex, manufacturers working on biosimilar development will need increasing guidance. Also, to establish a global strategy for biosimilars, sponsors/manufacturers have to make future strategies including "where to play" and "how to win".

The uptake and adoption of biosimilars in the EU vary greatly not only by country but by therapeutic area as well. The involvement of government, reimbursement systems, the regulatory and payer environment, and tender procurement policies also varies greatly among EU member states, the US, and India. In Europe, major awareness-raising initiatives have been taken on biosimilar drugs mainly focusing on physicians rather than on the patient perspective. Also, education remains a priority in the EU, which in turn will help healthcare members and patients to get updated information on the decisions related to

treatment options. The emendation of several biosimilar guidelines by EMA shows that the EU legal structure is moving stepwise in the direction of reducing the clinical requirements for biosimilars with the aim to have timely access to safe and efficacious biological medicines in Europe.

In the case of the US, USFDA is in continues to develop guidance on biosimilars, intentional educational efforts with various stakeholders, including continuous engagement of providers, payers, and patients will remain critical. It is estimated that the availability of biosimilars in the US could increase access to biological medicines and lowering out-of-pocket costs of ~1.2 million patients over the next 10 years, benefitting women, lower-income, and elderly individuals. Currently, the biosimilar market has been much slower in the US. It is expected that as more products get penetrated to the US biosimilar market, physicians will get more familiar with these products, resulting in a much larger uptake in the next 5-10 years. As more products get penetrated to the US biosimilar market, physicians will get more familiar with these products, resulting in a much larger uptake in the next 5-10 years.

India is emerging fast as a significant biotechnology sector across the world. In recent years the biotechnology sector has seen remarkable growth in terms of new companies registered, larger product pipelines, increased patent filings, and several product launches. The advent of biosimilars created huge opportunities for all stakeholders both in oncologic and non-oncologic disease areas. The Indian government took the steps to support the biopharmaceutical industry with the necessary infrastructure, funding, and global collaboration to bridge the technical knowledge gap, and further revision in regulatory policies of a biosimilar will help to capture the opportunity. As per published reports, India is likely to accomplish a $12 billion market size for biologics and biosimilars by 2025 and will grow at a CAGR of 22% [15]. This indicates that the Indian biosimilar market is lucrative, full of potential, and is always bullish for biosimilars. ■

SARS-COV2 Vaccine-
A ray of hope for billion Indians

The fore-running vaccine candidates across the world are reaching the core human trials stages. But that ray of hope needs to reach everyone. The announcements about the vaccines and their potential availability for use among the general population in the coming weeks and months has offered hope to millions around the world in a year that has seen the COVID-19 pandemic devastate lives and economies with no signs of abating. In this article, the authors is giving an overall view on vaccine production and how government is preparing for the distribution.

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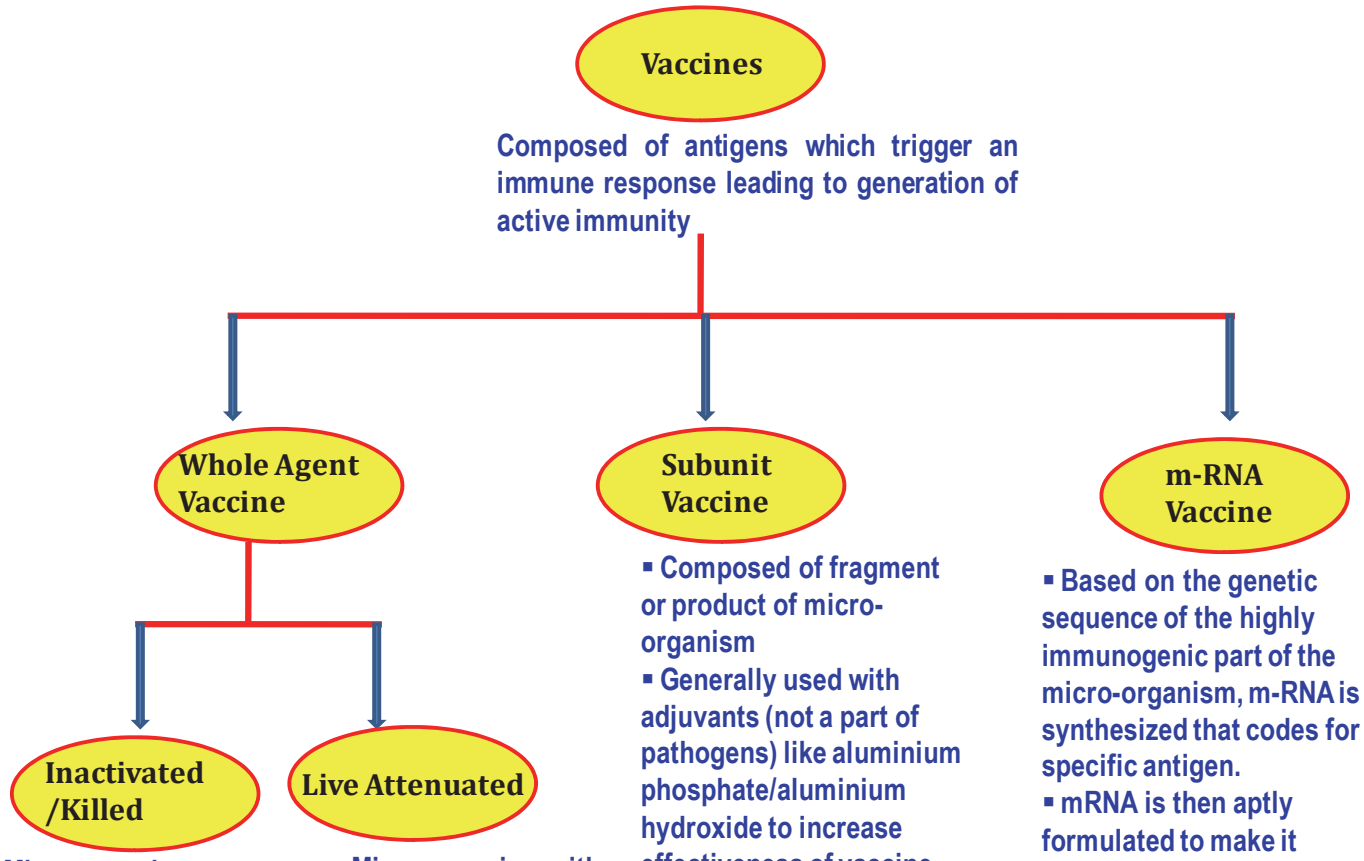
The whole world is eagerly waiting for the day when the effective vaccine against SARS-COV2 becomes available to everyone in need, and help controlling the corona virus pandemic. Vaccines, as we all know, have been the best solution to curb the endemics / pandemics e.g. small pox, avian flu, influenza, measles, chicken pox and reducing incidences in the disease such as polio vaccine for poliomyelitis.

If we go in the history of the development

of vaccines, the optimal time required to bring a vaccine out from lab to market varies from 10-15 years (~ 12 years on average). While approximately 198+ candidates are in development; more than half a dozen of vaccines against SARS-COV2 are almost on the verge to hit the market in next few weeks. In backdrop of same, one cannot stop thinking and congratulating the scientists around the world, who have made it possible in unprecedently short time frame (less than a year) against the unparalleled corona virus pandemic, which is spreading continuously even as of today since there is no available treatment to contain it.

A vaccine is an attenuated/weakened form of micro-organisms or fragments or a sub-unit thereof injected in the humans to allow their immune system to recognize and develop active immune response against it. The active immunity may comprise of humoral, cell mediated or both. However, the SARS-COV2 vaccine "Tozinameran" (BNT162b2) developed by Pfizer- BioNTech and "mRNA-1273" vaccine developed by Moderna for COVID-19 are based on a new concept wherein m-RNA, which encodes for a prefusion stabilized form of the Spike (S) protein, is injected in the humans. Humans mount an effective immune response against the in-vivo translated S-spike protein, and thus acquire protection against SARS-COV2. m-RNA vaccine approach thus evades the costly production and purification of viral proteins, is fast and flexible, and can be executed the moment genetic sequence is out.

Pfizer- BioNTech has sought emergency use authorization (EUA) from Drugs Controller General of India {DCG(I)}. Bharat Biotech Ltd (BBL) and Serum Institute of India (SII) too submitted the application to DCG(I) for EUA. However, SII and BBL's EUA request has been turned down by DCG(I) citing inadequate Phase II/III clinical trial safety data of Covishield and insufficient Phase III data of Alhydroxiquim-II adjuvanted Covaxin, respectively. Deficient cold chain infra, high price and lack of ethnic bridging studies in Asians may dissuade DCG(I) to grant EUA to Pfizer- BioNTech vaccine. Logistics, cold chain, storage at site are the main challenges to execute effective vaccination campaign, especially for Pfizer- BioNTech vaccine which requires subzero storage temperature. The impact of temperate excursion on Pfizer-BioNTech vaccine efficacy has not yet been fully ascertained and to the best of our understanding, without the availability of -80oC storage system, the Pfizer-BioNTech vaccine may become ineffective


Vaccines
Composed of antigens which trigger an immune response leading to generation of active immunity
Whole Agent Vaccine
Subunit Vaccine
m-RNA Vaccine
Inactivated /Killed
Live Attenuated
Micro-organisms are killed using formaldehyde, β-propiolactone, or ethylenimines and therefore pose no risk of infection in immunized individual. e.g. Rabies Vaccine.
▪ Micro-organism with DNA mutations accumulated through serial cell culture passages leading to loss of virulence.
▪ However, may revert to wild type in immunized individuals & increase the possibility of infection due to activation of pathogen.
▪ Primary advantage, no booster required and one shot is generally sufficient to confer protection. e.g. MMR vaccine containing live attenuated measles, mumps and rubella viruses.
▪ Composed of fragment or product of micro-organism
▪ Generally used with adjuvants (not a part of pathogens) like aluminium phosphate/aluminium hydroxide to increase effectiveness of vaccine
▪ These are way safer than attenuated vaccines as there is no risk of acquiring infection in immunized individuals. Hepatitis B vaccine comprising of HepB surface antigen (HBsAg vaccine) is an example of this class
▪ Based on the genetic sequence of the highly immunogenic part of the micro-organism, m-RNA is synthesized that codes for specific antigen.
▪ mRNA is then aptly formulated to make it stable and deliverable inside the cells.
▪ Once inside, the cells decode the m-RNA's genetic information to produce the antigen.
▪ The antigen is then displayed on the cell surface, where it is recognized by the immune system.
▪ Immune response is generated against the antigen, and thus the targeted microorganism. e.g. SARS-COV2 .

within two days. DRL- Gamaleya Research Institute's "Sputnik V" too needs low-temperature storage at -20°C. BBL and SII candidates, however, can be stored at refrigerated temperature 2-8°C, obviating the need to install deep freezers at immunization centers. Zydus ZyCov-D can be stored at room temperature. However, the vaccine requiring one shot to confer protective titres, coupled with transmission blocking efficiency may eventually have edge over others.

Vaccines are obviously critical; however, the primary healthcare workforce, ample disposables and proper record maintenance are tantamount to bring this pandemic to halt. Indian government has launched "Co-WIN", a mobile app to self-register for Covid-19 vaccine. It is noteworthy that the Case Fatality Rate (CFR) is below 1.45% and current recovery rate in India is 94.59% which is close to Pfizer-BioNtech and Moderna vaccine efficacy (95% and 94.5% respectively). SII's (Oxford/AstraZeneca) Covidshield has exhibited 70% efficacy and BBL's covaxin is expected to be atleast 60% effective. In light of above, the safety of vaccine becomes equally important to that of efficacy.

Both, BBL's Covaxin and SII's Covidshield are undergoing extensive clinical evaluation in 18-99 year old adults. Given that proper long-term safety clinical trials are usually required for a vaccine to get regularity approval for marketing, let's hope that the vaccines approved under EUA do not end up in creating long term side effects like the "narcolepsy" which Sweden, Finland and other European countries witnessed in children and adolescents post Pandemrix Influenza Vaccination or life threatening allergic reactions, and are efficient enough to develop effective immunity against SARS-COV2 in the population most vulnerable i.e. geriatrics and co-morbids. ■

The Evolution of Law and Ethics in Pharma Sector an Analysis of the Statutory Framework in India

In the last issue, we have seen how revised guidelines influenced various policy formulations in the pharma sector. In this month's edition, we examine in detail the regulatory bodies and the statutory framework that is present in our country.

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India plays a pivotal role because of its geo-strategic location, its population, low cost of living and better medical infrastructure. Back in 1969, global pharmaceutical companies had a lion's share in the Indian market; however cut to the year 2020 and the trend has completely changed!

Studies suggest that the local pharmaceutical companies today hold a whopping 85% stake and the remaining 15% only is held by foreign companies. A study conducted by Grand View Research valued 'global clinical trial market' size to be at $46.8 Billion in the year 2019 and pegged the expected growth rate at a compounded annual growth rate (CAGR) of 5.1% between 2020 and 2027.

The same study also estimated the Indian clinical trial market's size to be at $1.6 billion back in the year 2017 and an anticipated CAGR of 8.7% upto the year 2025.

India an enticing choice for clinical trials:

With 17% of world's population and one-fifth of global burden of diseases, India is a top-choice for clinical trials. Already we contribute about 20% by value and 40% by volume to the global generic drug production. In addition, our big number of English-speaking population and diverse pool of talented medical professionals make us even more attractive.

Regulatory Framework in India:

In India, the Ministry of Health and Family Welfare (MoHFW) and the Central Drugs Standard Control Organization (CDSCO) are the main regulatory bodies responsible for overseeing pharmaceutical production and medical devices.

The CDSCO exercises regulatory control over the import of drugs and devices as also approves new medical products and clinical trials. The CDSCO also oversees the Drugs Consultative Committee (DCC), the Drugs Technical Advisory Board (DTAB) and the Central Licensing Approving Authority (CLAA) which is the body responsible for ensuring medical device compliance.

Drugs Controller General of India:

The Drug Controller General of India (DCGI) is a body responsible forgiving regulatory permissions for the conduct of clinical trials and is also responsible for approving marketing licenses to drugs. There are also some other governmental bodies namely the Department of Biotechnology, the Genetic Engineering Approval Committee (GEAC) and the National Pharmaceutical Pricing Authority

that are involved with regulating new drugs.

Applications filed and reviewed in the office of the DCGI under two main categories, A and B.

- Category A includes clinical trials whose protocols have been approved by European Medicines Evaluation Agency (EMEA) or regulatory agencies in the US, UK, Switzerland Australia, Canada, Germany, South Africa or Japan. For such studies, permission is granted after accepting the protocol approval of those countries. For category A applications, review and approval usually take two to four weeks.
- Category B trial applications are reviewed by an expert committee that follows a regular system of approval. It usually takes eight-twelve weeks for a grant of approval to an application. Along with the application, a summary of information comprising detailed pharmacology, toxicology and clinical experience data needs to be submitted.

The DCGI also seeks expert guidance from other independent government agencies viz., ICMR or Department of Biotechnology (for biotech products) on case to case basis.

Statutory Framework:

1. The Drugs and Cosmetics Act, 1940 (revised in 2005) and Drugs and Cosmetics Rules, 1945

The Act regulates import; manufacture and distribution of drugs in the country to ensure that drugs and cosmetics sold are not just safe and effective but also conform to the requisite quality standards. Schedule Y of Drugs and Cosmetics Rules, 1945 along with the following special provisions, namely Rules 122A, 122B, 122D, 122DA, 122 DAC &122 E lay down a solid foundation for the guidelines for clinical trials.

The expansion of clinical trials in the country and the entry of foreign pharmaceutical companies have prompted the government to introduce several changes in Schedule Y to ensure ethical and regulatory guidelines relating to clinical trials.

2. The Drugs Price Control Order (DPCO)

The Drugs Prices Control Order has been issued by the Government of India under Section 3 of Essential Commodities Act, 1955 mainly to regulate the prices of drugs. It interalia provides:

- A list of price controlled drug
- The procedure for fixing the price of drugs

- The method of implementation of the price that is fixed by the government and
- The penalties in case of contravention of its provisions.

For the purpose of implementing provisions of DPCO, all the powers of Government have been vested in National Pharmaceutical Pricing Authority (NPPA).

3. National Pharmaceutical Pricing Authority (NPPA):

The National Pharmaceutical Pricing Authority was established on 29th August, 1997 as an independent body of experts per decision taken by the Cabinet committee that met in September of 1994 to review the Drug Policy. This authority has been entrusted with the task of:

- fixing/revising of prices of pharmaceutical products (bulk drugs and formulations),
- enforcement of provisions of the Drugs (Prices Control) Order and
- Monitoring prices of controlled and decontrolled drugs in the country.

The rationale behind controlling the price of drug entries is to determine their essentiality. The drugs are consequently found on the National List of Essential Medicines (NLEM) 2011. The DPCO, 2013 contains more than 600 Scheduled Drug formulations spread across 27 therapeutic groups and 348 drugs that are found on the NLEM 2011 list. The prices of all other drugs are possible to be regulated in 'public interest.'

4. The Drugs And Magic Remedies (Objectionable Advertisement) Act, 1954

The Act prohibits the advertising of remedies alleged to possess magical qualities. It also deals with the levy of taxes on medicinal and toilet preparations containing substances such as alcohol, opium, Indian hemp, or any other narcotic drugs.

5. The Pharmacy Act, 1948

The Act regulates the profession of pharmacy and deals with various pharmacy issues such as professional education and requirements f or registration. ■

(More legislation will be dealt with in the next part of this series)

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