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SEPTEMBER 2023: ISSUE 09

ATAL INCUBATION CENTRE
CENTRE FOR CELLULAR & MOLECULAR BIOLOGY

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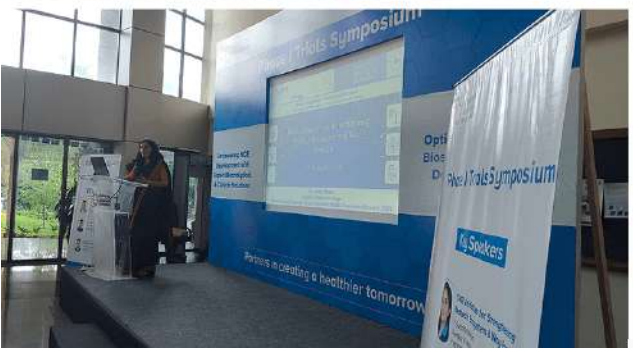
Veeda team at the Hybrid Symposium on Integrated Phase I Trial Solutions



Partners in Creating

a healthier tomorrow

Veeda News
News about our upcoming event, award win, and our latest webinar

Regulatory
Updated Covid-19 vaccines for 2023-24 approved by US FDA

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Pharmaceutical exports grow 4.53% in August, imports grow 20%

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Clinical trial of HIV vaccine begins in United States and South Africa

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VEEDA NEWS

Veeda Experts at the ISCR Clinical Research Conclave 2023

Veeda is proud to be represented as event partners at the ISCR Clinical Research Conclave 2023.

Know More!

Webinar: Generating Patient Narratives in the Clinical Trails by Using SAS Programming | Veeda

In this informative webinar, viewers will gain insights into the use of SAS programming for creating patient narratives in the context of clinical trials. The session is led by an experienced Principal Statistical Programmer with a decade of expertise in statistical programming for clinical development.

Watch Now!

Veeda Clinical Research conferred Gujarat's Best Employer Brand Award for 2023

The vibrant and dynamic team at Veeda Clinical Research Limited is conferred the "Gujarat Best Employer Brand Award" for 2023 by CHRO Asia and World HRD Congress.

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FDA shares draft medical device harmonization plan to meet MDUFA V goal

Through MDUFA V, the FDA committed to several international harmonization initiatives and secured additional resources to support the work. The publication of a draft strategic plan was the first item on the MDUFA V convergence and reliance agenda. The FDA recently delivered on that commitment, releasing a document that sets out how it aims to meet its other MDUFA V harmonization obligations. The draft document describes five strategies to align regulatory guidelines across multiple countries.

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Updated Covid-19 vaccines for 2023-24 approved by US FDA

The US Food and Drug Administration (FDA) recently approved two updated Covid-19 vaccines.The new mRNA (messenger ribonucleic acid) vaccines from Moderna and Pfizer/BioNTech are formulated to better target SARS-CoV-2 viral variants that are currently circulating and will replace outdated vaccines.“The new vaccine that was just approved by the FDA is essentially a Covid vaccine targeting a different strain of the Covid virus than was in the original vaccine or in the bivalent vaccines that came out last year (2022).

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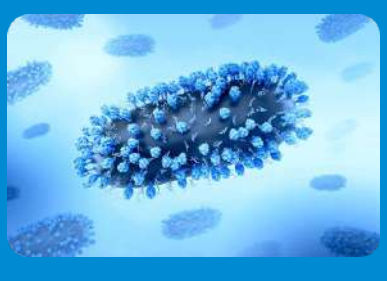
CDC recommends new vaccine to help protect babies against severe respiratory syncytial virus (RSV) illness after birth

CDC recommended the first respiratory syncytial virus (RSV) vaccine for pregnant people to protect their newborn from severe RSV illness. RSV is the leading cause of hospitalization for U.S. infants. This new vaccine, Pfizer’s bivalent RSVpreF vaccine (trade name Abrysvo TM), has been shown to reduce the risk of RSV hospitalization for babies by 57 percent in the first six months after birth.To maximize protection for babies after birth, CDC recommends seasonal administration of one dose of RSV vaccine for pregnant people during weeks 32 through 36 of pregnancy.



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CDSCO approves nine more MDTLs taking total labs to test medical devices to 39

The Central Drugs Standard Control Organisation (CDSCO) has approved nine more Medical Devices Testing Laboratories (MDTL) applied during this year, including the laboratory of public sector undertaking HLL Lifecare Ltd and Atal Incubation Centre (AIC), Medivalley at Andhra Pradesh MedTech Zone (AMTZ).The addition takes the total number of laboratories to conduct tests under the provisions of the Medical Devices Rules (MDR), 2017 from 30 applied till last year to 39 across the country at present. The laboratories are registered to carry out test or evaluation of a medical device on behalf of the manufacturer applied under Form MD-40, under the MDR, 2017, said the CDSCO.

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Moderna’s updated COVID-19 vaccine approved by MHRA

Moderna’s updated COVID-19 vaccine has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) for use in individuals aged six months and older.In line with previous recommendations from regulators and global public health bodies, the company’s monovalent ‘Spikevax’ vaccine has been adapted to target the XBB.1.5 Omicron variant. In addition to XBB sublineages, the vaccine has also demonstrated an 8.7 to 11-fold increase in neutralising antibodies against other currently circulating variants, including BA.2.86, which is currently being tracked by global health authorities, and the EG.5 strain.

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CDC announces $262M funding to support National Network for Outbreak Response and Disease Modeling

CDC announced the recipients of 13 funding awards to establish a first-of-its-kind national network, the Outbreak Analytics and Disease Modeling Network (OADMN). The awards, totaling $262.5 million in funding over a five-year period, will support state and local decision-makers in developing and implementing new tools to detect, respond to, and mitigate public health emergencies more effectively. The program will support building and scaling needed capabilities best suited for their respective jurisdictions, based on the best available information.Reflecting representation from state health departments, tribal organizations, academic and private sector partners

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Pharmaceutical exports grow 4.53% in August, imports grow 20%

Exports of pharmaceutical products from the country have reported a 4.53 per cent growth during the month of August compared to the same period of previous year. For the five months of the current fiscal year has posted a 4.18 per cent growth.According to data from the Central Government, the exports during the month of August, 2023 stood at $2.24 billion as compared to $2.14 billion during the same month of last year.The growth compared to the exports of $2.12 billion in the previous month of July is around 5.66 per cent.For the five months from April to August, 2023, the exports were at $10.96 billion as compared to $10.52 billion reported during the same period of previous year.

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NPPA fixes separate ceiling prices for Gufic Bioscience's two Tazofic injection formulations

The National Pharmaceutical Pricing Authority (NPPA) has notified separate ceiling prices for antibiotic scheduled formulations Tazofic injection 2.25 gm and 4.5 gm packs from Mumbai-based Gufic Biosciences Ltd on account of special packaging in dual chamber bag.Any other manufacturer claiming separate ceiling price having special feature of dual chamber bag helping in reduction of administration time, reconstitution of the drug with distilled water in accurate dose with reduction in possibility of contamination, shall apply to NPPA for separate ceiling price approval, said the Authority.

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Novo Nordisk Foundation to invest €127 million to establish world-class cell therapy facility

The Novo Nordisk Foundation has committed up to DKK 950 million (EUR 127 million) to establish a world-class facility for the final development steps and upscaling of cell therapies for testing in humans. The Novo Nordisk Foundation Cellerator will fill a critical gap in the Danish cell therapy ecosystem, helping to translate breakthroughs in cell therapy research into real-world treatments for people with diseases such as chronic heart failure, Parkinson's, kidney disease, type 1 diabetes and several forms of cancer.

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Glenmark Pharma to divest majority stake in Glenmark Life Sciences to Nirma Limited for Rs. 56,515 million

Glenmark Pharmaceuticals Limited, a research-led, integrated, global pharmaceutical company, has entered into a definitive agreement with Nirma Limited to divest 75% stake in its subsidiary, Glenmark Life Sciences Limited (GLS), at a price of Rs. 615/- per share for an aggregate consideration of Rs. 56,515 million, subject to closing adjustments.Glenmark Pharma own 7.84% in GLS after the divestment. The transaction is subject to customary closing conditions precedent, including receipt of regulatory and shareholder approvals.Pursuant to the transaction, Nirma Limited will make a mandatory open offer to all public shareholders of GLS.

Glenmark
A new way for a new world

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Alkem Labs collaborates with Biosergen to develop anti-infective for severe fungal infections

Alkem Laboratories and Biosergen AB have inked a co-development and license agreement for BSG005, an innovative polyene macrolide, through phase II and phase III trials for sale in the Indian market. Biosergen AB is developing BSG005 for the treatment of severe and difficult-to-treat invasive fungal diseases. After the successful completion of two phase I studies, the first patient trial will be conducted in India on patients with severe fungus disease who are intolerant or resistant to treatment with amphotericin B.

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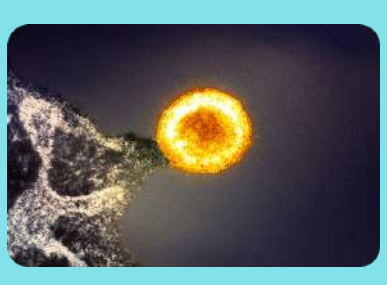
Clinical trial of HIV vaccine begins in United States and South Africa

A trial of a preventive HIV vaccine candidate has begun enrollment in the United States and South Africa. The phase 1 trial will evaluate a novel vaccine known as VIR-1388 for its safety and ability to induce an HIV-specific immune response in people. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, has provided scientific and financial support throughout the lifecycle of this HIV vaccine concept and is contributing funding for this study.



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SEC recommends permission for phase I trial of Cadila Pharma's VZV vaccine

The Subject Expert Committee (SEC) on vaccines, which reviews proposals and advice the Drugs Controller General (India) (DCGI) in matters for biologicals and post approval change proposals, has recommended to grant permission to Gujarat-based Cadila Pharmaceuticals to conduct phase I clinical trial for its chicken pox vaccine.The decision was taken in a recent meeting after the company submitted a revised phase I clinical trial protocol for grant of permission to conduct the trial for Varicella-Zoster Virus (VZV) vaccine.

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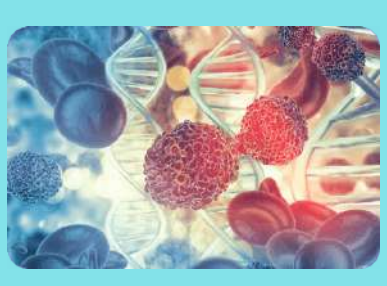
IISc develops novel approach to detect and kill cancer cells with hybrid nano particles

Researchers at the Indian Institute of Science (IISc) have developed a new approach to potentially detect and kill cancer cells, especially those which form a solid tumor mass. They have created hybrid nanoparticles made of gold and copper sulphide, which can kill cancer cells using heat, and enable their detection using sound waves.Early detection and treatment are key in the battle against cancer. Copper sulphide nanoparticles have previously received attention for their application in cancer diagnosis, while gold nanoparticles, which can be chemically modified to target cancer cells, have shown anticancer effects. The current study, according to the IISc team, decided to combine these two metals into hybrid nanoparticles.



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Hutchmed's savolitinib receives breakthrough therapy designation from China NMPA for gastric cancer

Hutchmed (China) Limited, an innovative, commercial-stage, biopharmaceutical company, announces that the Center for Drug Evaluation of China's National Medical Products Administration (NMPA) has granted Breakthrough Therapy Designation (BTD) to savolitinib for the treatment of locally advanced or metastatic gastric cancer or gastroesophageal junction (GEJ) adenocarcinoma patients with mesenchymal epithelial transition factor (MET) amplification who have failed at least two lines of standard therapies.

HUTCHMED

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Abbott completes acquisition of Bigfoot Biomedical

Abbott announced it has completed the acquisition of Bigfoot Biomedical, a leader in developing smart insulin management systems for people with diabetes.The transaction expands Abbott's presence in diabetes care, building on its world-leading FreeStyle Libre portfolio of continuous glucose monitoring technology and furthering the company's efforts to develop connected solutions for making diabetes management even more personal and precise.Pursuant to the terms of the merger agreement, upon completion of the acquisition, Bigfoot became a wholly owned subsidiary of Abbott. Financial terms were not disclosed.

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Lupin buys five brands in gastroenterology, urology & anti-infectives from Menarini

Global pharma major Lupin Limited (Lupin) announced that it has signed an agreement to acquire five legacy brands in strategic therapy areas - gastroenterology, urology and anti-infectives from Menarini (A. Menarini India Private Limited and A. Menarini Asia-Pacific Holdings Pte. Ltd.), along with the associated trademark rights. The brands are Piclin (picosulphate sodium), Menoctyl (otilonium bromide), Sucramal O (sucralfate + oxetacaine), Pyridium (phenazopyridine) and Distaclor (cefaclor). Lupin has been exclusively marketing these brands in the Indian market since July 2021 under a distribution and promotion agreement with A. Menarini India Private Limited.

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Abbott to acquire Milpitas, California-based smart insulin management systems developer, Bigfoot Biomedical

Abbott and Bigfoot Biomedical announced a definitive agreement for Abbott to acquire Bigfoot, a leader in developing smart insulin management systems for people with diabetes.The transaction is subject to customary closing conditions and is expected to close in the third quarter of 2023. Financial terms were not disclosed.Abbott and Bigfoot have worked together on connected diabetes solutions since 2017. Bigfoot developed Bigfoot Unity, a smart insulin management system that features the first and only FDA-cleared connected insulin pen caps that use integrated continuous glucose monitoring (iCGM) data along with healthcare provider instructions to provide insulin dosing recommendations.

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HiRO acquires US-based full-service clinical research provider Courante Oncology

Harvest Integrated Research Organization (HiRO), an innovation global CRO, announced the successful acquisition of Courante Oncology, a US-based full-service clinical research provider specializing in oncology product development.As a reputable boutique CRO with a strong track record of delivering high-quality, expedited clinical trials in the Asia-Pacific, HiRO's acquisition of Courante Oncology marks a significant milestone in its global expansion. This strategic move further strengthens HiRO's capabilities in managing global studies, extending its presence into the US market.

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Biocon Generics acquires Eywa Pharma's oral solid dosage manufacturing facility in New Jersey for US$ 7.7 million

Biocon Limited, an innovation-led global biopharmaceutical company, announced that its step-down, wholly-owned subsidiary, Biocon Generics Inc., has acquired Eywa Pharma Inc.'s oral solid dosage manufacturing facility, located in Cranbury, New Jersey, US, effective 1st September, 2023.The facility is acquired for a total consideration of US$ 7.7 million. As part of the acquisition, the existing workforce of the facility will transition to Biocon Generics Inc. The facility has a potential for capacity expansion up to 2 billion tablets/capsules per year. Siddharth Mittal, managing director and CEO, Biocon Limited said, "The acquisition of this US FDA approved facility, our first in the US, will complement Biocon's existing manufacturing capabilities and strengthen our foothold in the United States.

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Union health minister launches National Policy on Research and Development and Innovation in Pharma-MedTech Sector in India

"Today is a historic day, an inflection point in the journey of "Atmanirbharta" in the pharma and medical devices sector. We need to transform Indian Pharma and MedTech sectors from a cost-based to a value-based and innovation-based industry," stated Dr. Mansukh Mandaviya, Union minister of chemicals and fertilizers and minister of health and family welfare, Government of India while launching National Policy on Research and Development and Innovation in Pharma-MedTech Sector in India and Scheme for promotion of Research and Innovation in Pharma MedTech Sector (PRIP) today.

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Kerala DCA prepares new guidelines to collect drug samples as the number of DTLs increases

Since the state has four drug testing laboratories and one more in the pipeline, the drug control administration (DCA) in Kerala has prepared new guidelines to drug inspectors for drawing drug samples from industry and retail shops.As per the new guidelines, one drug inspector has to collect 23 samples per month and this will likely increase when the fifth lab becomes operational. Kerala DCA is the only drug regulator in India having this much number of drug testing laboratories and large collection of drug samples. Sources said the department wants that the quality of all the medicinal products circulated in the market, whether locally manufactured or imported, should be free from all sorts of defects, deficiencies and variations.

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Gujarat FDCA attributes 45% of drug samples failing quality tests due to dissolution testing failure

The Gujarat Food and Drug Control Administration (FDCA) has attributed 45% of drug samples failing quality tests due to dissolution testing failure.The state drug regulator collects 15, 000 drug samples annually of which 2% samples fail quality tests related to content, disintegration, dissolution, description, variation in weight and sterility. Out of the failed samples, 45% alone are due to failure in dissolution testing. Dissolution testing determines the drug absorption rate in the human body and hence helps determine its efficacy. Dissolution testing is a requirement for all solid oral dosage forms and some other category products.

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Single-use systems are increasingly used in pharma as market trend shifting to biosimilars, cell therapy: Expert

Single-use systems are increasingly used in pharma manufacturing due to market trend shifting from APIs and complex generics to biosimilars, cell therapy and gene therapy, informs Ritesh Patterson, general manager, Performance Plastics, Saint-Gobain India.Saint-Gobain India provides silicone and thermoplastic tubing for pharma, biopharma, medical, molded parts for medical devices and equipment, single use bags, liners and assemblies for biopharma and pharma industries and also filters for pharma and industrial applications. The company offers a complete range of silicone tubing accompanied by well-formulated documentation providing customers with both information and assurance.

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Indian pharma considering manufacturing of nutraceuticals under Atmanirbhar Bharat

Going by its ability to formulate products with advanced technologies including modified drug delivery systems, sterile parenteral nutrition as well as sterile parenteral nutrition for administration through IV, blended granules and powders, Indian pharma is considering to manufacture nutraceuticals under Atmanirbhar Bharat.According to DBA Narayana, the Indian pharma industry has the capability in improving the palatability of such products better than the imported current offerings, develop stable products for Indian and Asian population and the measurement science ability to guarantee presence of desired nutrients and absence of undesired nutrients are known. Industry can also look at producing some of these individual nutrients in a commercial scale indigenously, he added.

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