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The Veeda Newsletter

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DCAT Week

Veeda Experts at DCAT Week 2023

Partners in Creating

a healthier tomorrow

Veeda News
Update on our latest case study and recently concluded event

Regulatory
FDA Authorizes Bivalent Pfizer-BioNTech COVID-19 Vaccine as Booster Dose for Certain Children 6 Months through 4 Years of Age

Financial
Sanofi cuts US price of its most-prescribed insulin, Lantus by 78%

Clinical Research
AbbVie Advances Upadacitinib (RINVOQ®) to Phase 3 Clinical Trials in Systemic Lupus Erythematosus

Merger and Acquisition
Pfizer acquires ADC pioneer Seagen for $43bn

Indian Pharma
HIV self-testing to take off in India: Findings from the STAR Initiative

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Bioequivalence Study of an Oncology Drug

Read to learn more about how Veeda assisted an Indian pharmaceutical company conduct a bioequivalence study for a complex Oncology drug candidate used to treat Advanced Ovarian and Breast Cancer

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A glimpse of Veeda Experts at BioEurope Spring 2023

We are excited to share a glimpse of our team who attended BioEurope Spring 2023, to discuss drug-development of generics, complex generics, and innovator drug molecules with various global pharma and biopharma companies.

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Lupin's partner Caplin receives US FDA approval for rocuronium bromide injection

Global pharma major Lupin Limited (Lupin) announced that its alliance partner Caplin Steriles Limited (Caplin) has received final approval from the United States Food and Drug Administration (FDA) for its Abbreviated new Drug Application (ANDA) rocuronium bromide injection, 10mg/mL in 5 mL and 10 mL multi-dose vials, to market a generic version of Zemuron bromide injection, 50 mg/5 mL and 100 mg/10 mL of Organon USA Inc. Rocuronium bromide injection (Zemuron) had an annual sale of approximately USD 53 million in the US (IQVIA MAT December 2022).

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SAGO statement on newly released SARS-CoV-2 metagenomics data from China CDC on GISAID

WHO was made aware of new SARS-CoV-2 sequences and metagenomics data associated with samples collected in the Huanan Seafood Wholesale Market, Wuhan, China, from January 2020, that became available on GISAID for a short period of time. The data had subsequently been downloaded by a number of researchers from several countries. Access was restricted shortly after, apparently to allow further data updates by China CDC. WHO then immediately reached out to China CDC and to the Chair and Vice-Chair of SAGO. Upon discussions between WHO and Chinese colleagues, it was explained that the genomic data are the basis for an expected update to the existing Liu et al. 2022 preprint (1), which is in the process of being re-submitted for publication to Nature by China CDC.

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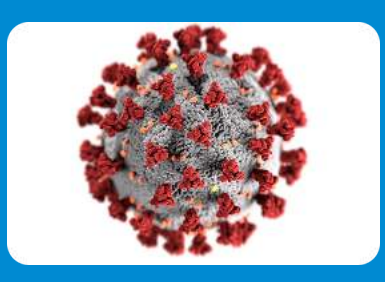
WHO updates tracking system and working definitions for variants of SARS-CoV-2

WHO has updated its tracking system and working definitions for variants of SARS-CoV-2, the virus that causes Covid-19, to better correspond to the current global variant landscape, to independently evaluate Omicron sublineages in circulation, and classify new variants more clearly when required. SARS-CoV-2 continues to evolve. Since the beginning of the Covid-19 pandemic, multiple variants of concern (VOCs) and variants of interest (VOIs) have been designated by WHO based on their assessed potential for expansion and replacement of prior variants, for causing new waves with increased circulation, and for the need for adjustments to public health actions.



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FDA Authorizes Bivalent Pfizer-BioNTech COVID-19 Vaccine as Booster Dose for Certain Children 6 Months through 4 Years of Age

The U.S. Food and Drug Administration amended the emergency use authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to provide for a single booster dose of the vaccine in children 6 months through 4 years of age at least 2 months after completion of primary vaccination with three doses of the monovalent (single strain) Pfizer-BioNTech COVID-19 Vaccine.

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CDSCO approves two more medical devices testing laboratories

The Central Drugs Standard Control Organisation (CDSCO) has approved two more Medical Device Testing Laboratories (MDTL) to carry out tests or evaluation of a medical device on behalf of the manufacturers under the provisions of the Medical Devices Rules (MDR), 2017. With this, the total number of MDTLs approved by the regulator is 30 across the country. The newly added laboratories are Bharat Test House Pvt Ltd situated in North West Delhi and Manisha Analytical Laboratories Pvt Ltd in Mumbai. Bharat Test House has approval to conduct tests on 20 devices including surgical luminaries and luminaries for diagnosis, operating tables, ultrasonic physiotherapy equipment, baby incubators, and medical electrical equipment in various classes under the MDR, 2017.

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Sanofi cuts US price of its most-prescribed insulin, Lantus by 78%

Sanofi announces that it will cut the list price of Lantus (insulin glargine injection) 100 Units/mL, its most widely prescribed insulin in the US, by 78 per cent. The company also will establish a $35 cap on out-of-pocket costs for Lantus for all patients with commercial insurance, underscoring its longstanding commitment to offer affordable access to medicines. These moves, which go into effect January 1, 2024, will come in addition to decisions taken in June 2022 to lower diabetes medicines costs: the launch of an unbranded Lantus biologic at -60% versus Lantus list price, and a cap on out-of-pocket costs on insulin to $35 for all people without insurance.

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Pharma exports register growth of 4.72% to $2.05 billion in February

Pharmaceutical exports from the country have seen a growth of 4.72 per cent during the month of February, 2023, compared to the same month of previous year after registering a year-over-year decline in the two previous months. The 11 months of the fiscal year 2022-23, ended February, reported a growth of 3.14 per cent in exports compared to the same month of previous fiscal year. The exports of drugs and pharmaceuticals, according to the data from the Ministry of Commerce and Industry, for the month of February stood at $2.05 billion as compared to $1.48 billion reported in the same month of last year, with a growth of 4.72 per cent..

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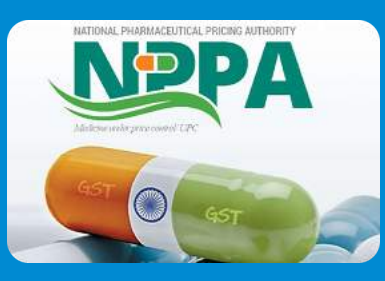
NPPA fixes new ceiling prices for 33 scheduled formulations under revised Schedule I

The National Pharmaceutical Pricing Authority (NPPA) has released the draft ceiling price calculation sheets for 33 scheduled formulations under the Schedule I of the Drugs (Prices Control) Order, 2013, which has been revised last year with replacing the National List of Essential Medicines (NLEM), 2015 with the NLEM, 2022. The latest set of calculation sheets, which is the 14th lot released by the NPPA so far as part of the fixation of ceiling prices under the revised Schedule I, has revised ceiling price for 24 scheduled formulations, while for the rest of the nine formulations, the ceiling price has been fixed afresh since they are new additions to the NLEM, 2022.



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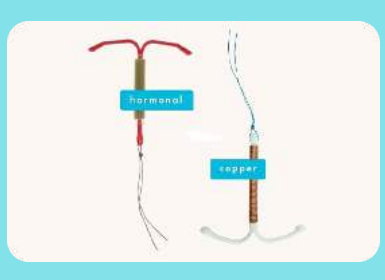
NPPA fixes ceiling price of hormone releasing IUDs and IUDs containing copper

The National Pharmaceutical Pricing Authority (NPPA) has fixed the ceiling price for two medical devices - hormone releasing intrauterine devices (IUDs) and IUDs containing copper - under the Schedule I of the Drugs (Prices Control) Order, 2013, which was revised to include in the National List of Essential Medicines (NLEM), 2022.The draft calculation sheet for these two device formulations was released on January 12, 2023 and the same was finalised in an Authority meeting held on February 21, after considering one representation received against the draft working sheet, said the drug price regulator.



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Practo launches cashless OPD services for corporates in India

Practo, an integrated healthcare company, has launched Practo Plus Health Credits as part of its Corporate Health Benefits (CHB) Program. A source told Financial Express.com that Practo Plus Health Credits will offer their employees cashless outpatient department (OPD) healthcare services by adding a fixed amount to their accounts.

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AbbVie Advances Upadacitinib (RINVOQ®) to Phase 3 Clinical Trials in Systemic Lupus Erythematosus

AbbVie (NYSE: ABBV) today announced topline results from a Phase 2 study of upadacitinib (RINVOQ®, 30 mg) given alone or as combination therapy (ABBV-599) with a Bruton's Tyrosine Kinase inhibitor (elsubrutinib, 60 mg), once daily in patients with moderately to severely active systemic lupus erythematosus (SLE).1 The SLEek study met the primary endpoint of SLE Responder Index (SRI-4) and steroid dose less than or equal to 10 mg prednisone equivalent once per day at week 24 in the upadacitinib 30 mg group.1,2 Based on the results, AbbVie is advancing its clinical program of upadacitinib in SLE to Phase 3.

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Dupixent demonstrates potential to become first biologic to treat COPD by showing significant reduction in exacerbations in pivotal trial

The primary and all key secondary endpoints were met in a phase 3 trial evaluating the investigational use of Dupixent (dupilumab) compared to placebo in adults currently on maximal standard-of-care inhaled therapy (triple therapy) with uncontrolled chronic obstructive pulmonary disease (COPD) and evidence of type 2 inflammation. Dupixent is the first and only biologic to demonstrate a clinically meaningful and highly significant reduction (30%) in moderate or severe acute exacerbations of COPD (rapid and acute worsening of respiratory symptoms), while also demonstrating significant improvements in lung function, quality of life and COPD respiratory symptoms.

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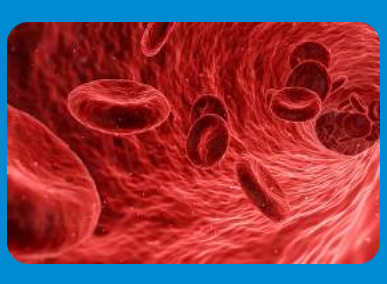
Disc Medicine collaborates with NIH for phase 2 study of bitopertin in patients with Diamond-Blackfan anaemia

Disc Medicine, Inc., a clinical-stage biopharmaceutical company, announced a collaboration with the National Heart Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH) to evaluate bitopertin, a therapeutic candidate designed to modulate heme biosynthesis, in a phase 2 clinical study of patients with Diamond-Blackfan anaemia (DBA). The study will be conducted and funded by the NIH under a Cooperative Research and Development Agreement (CRADA) and is expected to initiate mid-year 2023.



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Jacobio enters clinical collaboration with Merck to evaluate CD73 monoclonal antibody JAB-BX102 in combo with Keytruda for patients with cancer

Jacobio Pharma announced it has entered into a clinical collaboration with Merck & Co., Inc., Rahway, New Jersey, USA to evaluate the combination of Jacobio's CD73 monoclonal antibody JAB-BX102 in combination with Merck & Co., Inc., Rahway, NJ, USA's anti-PD-1 therapy, Keytruda (pembrolizumab). The clinical study will evaluate the clinical effect of JAB-BX102 in combination with Keytruda for the treatment of advanced solid tumours. Under the terms of the agreement, Merck & Co., Inc., Rahway, NJ, USA will provide Keytruda.

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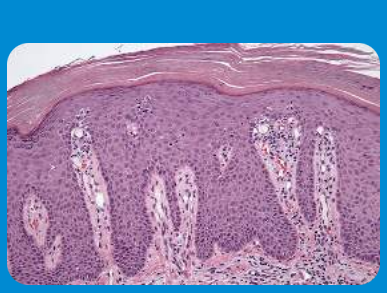
Takeda's Phase IIb TAK-279 trial meets primary and secondary endpoints

Takeda has reported positive data from a Phase IIb clinical trial of TAK-279 (NDI-034858) in moderate-to-severe plaque psoriasis patients.The double-blind, randomised, multiple-dosed, multicentre, placebo-controlled Phase IIb trial has been designed for assessing TAK-279's tolerability, efficacy, and safety in the indicated patients.In the trial, 259 participants were randomised in a 1:1:1:1:1 ratio to receive either a 2mg, 5mg, 15mg, or 30mg dose of TAK-279 once-a-day or a placebo for 12 weeks.



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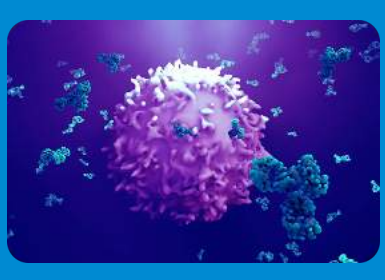
Pfizer acquires ADC pioneer Seagen for $43bn

Pfizer recently announced an agreement to acquire Seagen, a biotech company based in the US with four marketed oncology therapeutic agents and a rich pipeline.The deal, expected to be completed by the end of 2023, will see Pfizer pay $229 per Seagen share in cash for a total of $43bn, the largest deal for the sector in the past three years.Seagen specialises in developing antibody-drug conjugates (ADCs) which will complement Pfizer's oncology portfolio.



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Integra Biosciences acquires California-based Miroculus to accelerate genomics

Integra Biosciences, a leading provider of high-quality laboratory tools and consumables for liquid handling and media preparation, announced that it has acquired Miroculus, a biotechnology specialist focused on developing hands-off automation solutions for next generation sequencing (NGS) protocols. This acquisition will allow Integra to expand its product range for library preparation, offering significant time savings to academic, research and diagnostics laboratories using NGS and, ultimately, accelerating discovery in this dynamic field.

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ACKO acquires digital health platform, Parentlane to strengthen its content and healthcare delivery capabilities

ACKO has acquired Parentlane, a leading digital health platform in the maternity & child health space. The technology platform empowers young millennial parents with proactive healthcare solutions from preconception to the most critical early childhood development phase. The platform, combined with ACKO's core insurance offering, will deliver personalised content and services to enable better healthcare choices, informed decisions, and improved outcomes. For young millennial parents, who comprise most of ACKO's customer segment, maternal care is the first in-depth hospitalisation or healthcare experience.

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Sumitovant Acquires Myovant for $1.7 Billion

Sumitovant Biopharma announced on March 10, 2023 that it has completed its acquisition of Myovant Sciences. Sumitovant has acquired all outstanding shares of Myovant not already owned by Sumitovant in an all-cash deal with a total transaction value of approximately $1.7 billion. Myovant will now be delisted from the New York Stock Exchange, and its shares will no longer by publicly traded.

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Sun Pharma Completes Acquisition of Concert Pharmaceuticals

Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715 (together with its subsidiaries and/or associated companies, "Sun Pharma")) today announced the successful completion of its acquisition of Concert Pharmaceuticals, Inc., a late-stage clinical biopharmaceutical company that is developing deuruxolitinib, a novel, deuterated, oral JAK1/2 inhibitor, for the potential treatment of adult patients with moderate to severe alopecia areata. "We are excited to add deuruxolitinib, a late-stage, potential best-in-class treatment for alopecia areata, to our growing global dermatology portfolio and expand our presence in the Boston biotech hub," said Abhay Gandhi, CEO North America, Sun Pharma.

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Indian healthcare providers and pharma companies speed up to combat TB as drug resistance concerns emerge

Indian healthcare providers and pharma companies pace up their efforts with early detection and research for new medicines to combat the spread of tuberculosis as drug resistance concerns emerge. TB is a significant public health threat, with an estimated 10 million annual cases. India shares the highest TB burden with 2.69 million cases and 4.5 lakh fatalities every year. On the occasion of the World TB Day observed annually on March 24, this year's theme is 'Put a Full Stop on TB'. Medical experts and pharma industry see the need to research for new drugs and accurate point-of-care diagnostics.

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Quantumzyme receives patent for development of green catalyst in India

Quantumzyme, a biotransformation company, focused on clean and green chemistry has recently been granted a patent for the transaminase enzyme by applying its revolutionary technology QZyme Workbench in India. The patent was granted for creating a green catalyst for one of the world's most significant chemical reactions, which can be useful for pharmaceutical industries. Quantumzyme focuses on research to enhance enzyme activity, selectivity and specificity by applying novel quantum mechanics, molecular modelling and engineering approaches that might help the world attain sustainability and save resources efficiently.

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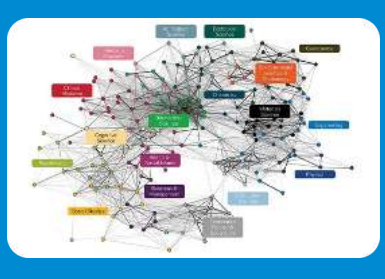
Indian pharma gearing up for interdisciplinary research for medicines to combat diseases

Indian pharma is now accelerating its pace towards interdisciplinary research for medicines to combat diseases. In this regard several collaborations for the integration of knowledge from different academic disciplines to address common complex problems that cannot be solved by any individual researcher from a single area of research are already underway. Even as the Union government is supporting research and innovation for pharmaceuticals, there are several interdisciplinary research efforts that are going on like the Bengaluru-based Institute for Drug Delivery and Biomedical Research (IDBR) which is a non-profit research organization with an objective to foster research in the field of drug delivery and biomedical sciences



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Gujarat FDCA soon to move from e-governance to m-governance to enhance ease-of-doing-business

The Gujarat Food and Drug Control Administration (FDCA) is all set to graduate from its e-governance model to m-governance model as it is likely to launch a mobile application for all the stakeholders including the manufacturers and retailers towards ease of doing business. As per the m-governance, all applications will be on mobile which will also include mobile testing to bring in effectiveness of governance/vigilance at grass root level, effective utilization of capacity and instruments and real-time connectivity for monitoring and governance. "The programme which will be launched in a month's time is currently undergoing safety audit and will benefit over 5,000 licensees which includes allopathic, ayurvedic and cosmetics manufacturers," informed Dr HG Koshia, Gujarat FDCA Commissioner.

FDA

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HIV self-testing to take off in India: Findings from the STAR Initiative

World Health Organization (WHO) recommends HIV self-testing (HIVST) as an important approach to address gaps in HIV diagnoses including among key populations (sex workers, men who have sex with men, transgender people, people who inject drugs, and people in prisons other closed settings). Globally, 98 countries now have policies supportive of HIVST and 52 are routinely implementing, yet many countries have not yet introduced HIVST as a routine approach. A report launched at a national event held in New Delhi last year showed HIVST is acceptable to key populations and their partners in India. As part of Unitaid-funded STAR Initiative, PATH led the implementation of HIVST project in India.

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