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# The Veeda Newsletter

JUNE 2023: ISSUE 06

"Maturity & Quality of Indian Clinical Trial Ecosystem has been very well demonstrated through the successful & rapid conduct of large scale globally accepted COVID-related Clinical Trials"

**Ajay Tandon**
Managing Director,
Veeda Clinical Research Limited

Partners in Creating

## a healthier tomorrow

### Veeda News
News about our latest event, poster presentation and article.

### Regulatory
DCGI approves emergency use of Gennova's Covid-19 booster

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### Indian Pharma
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## VEEDA NEWS

### Veeda Clinical Research at the India Biopharma Leaders Conclave 2023

We participated in the third edition of the "India Biopharma Leaders Conclave" at Hyderabad. Dr. Kiran Marthak participated as a Moderator in the panel discussion on "Need for fostering collaboration and partnerships between industry, academia, and government in the biopharma".


Know More!

### Our Latest Poster Presentation at WRIB 2023

We are delighted to share a glimpse of our recent poster presentation at WRIB 2023, on Sensitive, Reproducible, and Simultaneous Bioanalytical method of Isosorbide Dinitrate and its metabolites Isosorbide 2-mononitrate and Isosorbide 5-mononitrate in human matrix samples for Pharmacokinetics Analysis by Ms. Swati Guttikar.


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### Our Latest Article on Chronic Myeloid Leukaemia

Chronic Myeloid Leukaemia is the commonest adult leukaemia, and its trials present unique challenges. CROs are expected to bring expertise and efficiency to the challenges related to designing & managing complex protocols, site monitoring difficulties, patient population identification, geriatric research, and many more.


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## FDA Issues Draft Guidance on Psychedelics

The FDA published its first draft guidance that presents considerations to industry for designing clinical trials for psychedelic drugs. In the guidance, the FDA says the term psychedelic includes classic psychedelics, typically understood to be 5-HT2 agonists such as psilocybin and lysergic acid diethylamide (LSD), as well as entactogens or empathogens such as methylenedioxymethamphetamine (MDMA).2Psychedelics have been evaluated as therapies for a number of conditions including depression, post-traumatic stress disorder, and substance use disorders


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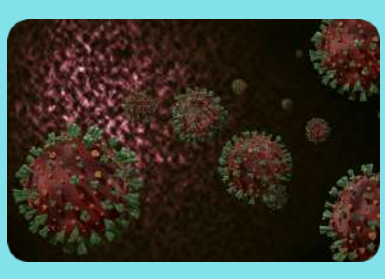
## DCGI approves emergency use of Gennova's Covid-19 booster

The Drug Controller General of India (DCGI) has granted emergency use authorisation (EUA) for Gennova Biopharmaceuticals' Omicron-specific mRNA-based Covid-19 booster vaccine, GEMCOVAC-OM.GEMCOVAC-OM was developed using indigenous platform technology. The project was supported under the Mission Covid Suraksha, which has been implemented by India's Biotechnology Industry Research Assistance Council (BIRAC).



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## DCGI streamlines cough syrup testing

To ensure timely testing of cough syrups at the government authorized laboratories, the Drug Controller General of India (DCGI) Rajeev Raghuvanshi has written to all drug manufacturers and exporters to submit cough syrups samples to the laboratory having lower workload and to ensure that no single laboratory gets overburdened.Also, to facilitate this, DCGI plans to publish the record of samples being tested in each lab for the manufacturers to plan their testing schedules. This is being done to avoid any delays in testing of cough syrups to prevent export delays.

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## CDSCO declares sample of Bharat Biotech's typhoid vaccine Typbar as NSQ

The Central Drugs Standard Control Organisation (CDSCO) has declared a batch of Typbar, the typhoid polysaccharide vaccine from Bharat Biotech International Ltd as not of standard quality (NSQ).The drug regulator, in a drug alert issued, said that a batch of Typbar, manufactured by Bharat Biotech International Ltd in Genome Valley in Hyderabad, Telangana, failed the standard quality test conducted by Central Drugs Laboratory (CDL), Kasauli, Himachal Pradesh, after the sample picked up and sent by Food and Drug Administration (FDA), Goa.

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## FDA approves Pfizer RSV vaccine for older adults

The Food and Drug Administration on Wednesday approved a vaccine made by Pfizer that protects adults ages 60 and older from respiratory syncytial virus, a common pathogen that kills and hospitalizes thousands of seniors every year.Pfizer, in a statement Wednesday, said it expects to have supply available in the third quarter of this year ahead of the RSV season. The Centers for Disease Control and Prevention's committee of independent advisors will meet on June 21 to make recommendations on the use of the vaccine.

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## NPPA fixes ceiling price of 18 scheduled formulations and retail price of 23 formulations

The National Pharmaceutical Pricing Authority (NPPA) has fixed the ceiling price of 18 scheduled formulations and the retail price of 23 new drugs based on applications from the company, through a recent meeting. The price regulator has fixed the price of an ophthalmic drug formulation based on an earlier order to fix the value of formulations where there is high inter brand variation in prices.

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## MDC recommends prices of anti-diabetic drugs with off patented molecules

The Multidisciplinary Committee (MDC) of Experts has recommended the prices of various fixed dose combinations (FDCs) containing dapagliflozin, sitagliptin, vildagliptin, pioglitazone, among others in tune with the recent amendments made by the Department of Pharmaceuticals (DoP) in the Drugs (Prices Control) Order (DPCO), 2013 related to fixing prices of drugs with off patented molecules. The MDC has recommended prices for almost 40 applications for these drugs, in a recent meeting.


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## Cytovation raises $8 mn in Series A extension financing round for clinical advancement of CyPep-1

Cytovation ASA, a clinical stage immune-oncology company focused on the development of its first-in-class targeted tumour membrane immunotherapy CyPep-1, announced the successful closing of its $8 million (NOK 85 million) Series A extension financing round. This new investment will support the progress of Cytovation's lead asset, CyPep-1 - a first-in-class targeted tumour membrane immunotherapy -into a full phase 2 programme for the treatment of solid tumours.

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## NPPA to fix ceiling prices based on existing methodology and add WPI for rest of the scheduled formulations

The National Pharmaceutical Pricing Authority (NPPA), which has fixed the ceiling price of 651 formulations till the end of March, 2023, has said that for the rest of the scheduled formulations for which prices are to be calculated, it will first compute the prices based on the methodology it has announced earlier and will arrive at a final ceiling price by applying the Wholesale Price Index (WPI) increase of 12.12 per cent on it.The Authority in its latest meeting, has fixed the ceiling prices of 20 scheduled formulations under the revised Schedule I of the Drugs (Prices Control) Order, 2013, based on this decision. It has also fixed the retail price of 15 new drugs based on applications from individual companies.


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## NPPA brings in various changes in IPDMS 2.0 version to help industry on online filings

The National Pharmaceutical Pricing Authority (NPPA) has made various changes in its Integrated Public Database Management System 2.0 (IPDMS), the cloud-based application to support the industry in statutory filings with the Authority, including a provision to add specific details of the bulk drug in the online product verification form based on the suggestions by the stakeholders.Many of the suggestions are related to the anomalies related to the existing forms and the Authority has said that they would be addressed once the forms are amended.The Authority said that several requests were received for the addition of the new bulk drug/formulation & strengths in the IPDMS 2.0.


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## CLINICAL RESEARCH

### JAMA Neurology unveils phase 1b/2a clinical trial results from neuroprotective drug ApTOLL forischemic stroke

The prestigious scientific journal JAMA Neurology has published the positive results from APRIL, the phase 1b/2a clinical trial from aptaTargets, which hasevaluated the safety and efficacy of the groundbreaking neuroprotective drug ApTOLL in combination with endovascular treatment (EVT) in patients with acute ischemic stroke.The results from the study have proven to be clinically relevant: the administration of 0.2 mg/kg of ApTOLL within 6 hours after acute ischemic stroke in combination with EVT was safe and well tolerated, and it was also associated with a reduction in mortality from 18% to 5% along with a reduction in functional disability at 90 days compared to the placebo. ApTOLL will enter in late-stage trials for ischemic stroke.

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### Sun Pharma presents data from first-in-human phase 1 studies of GL0034 at ADA 83rd scientific sessions

Sun Pharmaceutical Industries Ltd. announced results from two phase 1 studies evaluating the tolerability, safety, pharmacokinetics and pharmacodynamics of GL0034, a novel long-acting GLP-1 receptor agonist, in non-obese and obese adults without diabetes. The data highlighted in poster presentations at the American Diabetes Association's (ADA) 83rd Scientific Sessions held from June 23-26, 2023, in San Diego, California. In one of the studies, GL0034 reduced triglyceride levels and body weight by Day 8 after a single dose in obese individuals without diabetes.

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### BioCity begins phase 2 trial of ETA receptor antagonist, SC0062 for chronic kidney disease

BioCityBiopharma, a clinical-stage biopharmaceutical company, announced the initiation of a randomized, placebo-controlled phase 2 clinical trial of its novel, oral endothelin A (ETA)-receptor selective antagonist, SC0062, with the enrollment of two patients with IgA nephropathy (IgAN) in China (NCT05687890). This multi-center study will assess the safety and preliminary efficacy of SC0062 relative to placebo in patients with chronic kidney disease with albuminuria.The initiation of the phase 2 trial follows the successful completion of a phase 1, first-in-human (FIH) trial for SC0062 in healthy volunteers.

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### Escient Pharma announces positive results from phase 1 study of EP262 to treat mast cell mediated disorders

Escient Pharmaceuticals, a clinical-stage drug development company advancing novel small molecule therapeutics for systemic neuro-inflammatory disorders, announced positive results from a phase 1 first-in-human study of EP262, a potent, highly selective small molecule antagonist of MRGPRX2.By blocking activation of MRGPRX2 and degranulation of mast cells, EP262 has the potential to treat mast cell mediated diseases with an initial focus on chronic urticarias (hives) and atopic dermatitis (eczema). EP262 represents a new, targeted approach to the treatment of these disorders with the potential for once-daily oral administration without the serious side effects observed with other approaches.

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### NIH & US FDA leaders call for more research, lower barriers to improve and implement drug-checking tools amid overdose epidemic

In a new Commentary in the New England Journal of Medicine, leaders at the National Institutes of Health and US Food and Drug Administration highlight the urgent need to address current gaps in the research, development, and implementation of fentanyl test strips and other rapid drug-detecting tools that could help prevent overdose deaths. These tools have the potential to save lives and to serve as an important part of harm reduction toolkits but often remain inaccessible because of gaps in research and various other barriers, including state or legal prohibitions.This call to action encourages new collaborations among researchers and agencies to ensure the effectiveness of fentanyl test strips and promote the development of additional drug-checking technologies.

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## Quest Diagnostics completes acquisition of Haystack Oncology

Quest Diagnostics, the nation's leading provider of diagnostic information services, announced that it has completed its previously announced acquisition of Haystack Oncology.Haystack Oncology has developed a highly sensitive minimal-residual disease (MRD) testing technology, based on circulating tumour DNA (ctDNA), to aid in the early detection of residual or recurring cancer and better inform therapy decisions. Quest expects to incorporate this MRD technology into the development of new blood-based clinical lab services for solid tumour cancers available beginning in 2024.

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## Novo Holdings to acquire Denmark-based Ellab from EQT

Novo Holdings A/S, a leading global life sciences investor, announced that it has agreed to acquire Ellab from EQT.Headquartered in Hillerød, Denmark, Ellab (Ellab) provides validation and monitoring solutions and services for biotech and pharmaceutical processes. Its solutions and services measure and document parameters such as temperature, pressure and carbon dioxide, which helps clients to ensure consumer safety and regulatory compliance, while reducing time to market and the risk of product loss.

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## Lilly to buy biopharma company, DICE Therapeutics for $2.4 billion

Eli Lilly and Company and DICE Therapeutics, Inc. announced a definitive agreement for Lilly to acquire DICE.DICE is a biopharmaceutical company that leverages its proprietary DELSCAPE technology platform to develop novel oral therapeutic candidates, including oral IL-17 inhibitors currently in clinical development, to treat chronic diseases in immunology."In combination with its novel technology and expertise in drug discovery, DICE's talented workforce and passion for innovation will enhance our efforts to make life better for people living with devastating autoimmune diseases," said Patrik Jonsson, executive vice president, president of Lilly Immunology and Lilly USA, chief customer officer.

Lilly DICE Therapeutics

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## Ampath Labs inks strategic partnership with Emami Frank Ross

American Institute of Pathology & Laboratory Sciences has entered into a strategic partnership with Emami Frank Ross, a retail pharmacy chain in India. This collaboration aims to extend customer touch points in Bengaluru by offering high-quality pathology services through 10 Emami Frank Ross outlets. The partnership will enable individuals to access a wide range of services at Emami Frank Ross pharmacies, ensuring that healthcare services are readily available in their local communities.

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## Merck completes acquisition of Prometheus Biosciences

Merck, known as MSD outside of the United States and Canada, announced the completion of the Prometheus Biosciences, Inc. (Prometheus) acquisition. Prometheus is now a wholly-owned subsidiary of Merck and the common stock of Prometheus will no longer be listed or traded on the Nasdaq Global Market. “The Prometheus acquisition accelerates our growing presence in immunology, augments our diverse pipeline and increases our ability to deliver patient value. This transaction is another example of Merck acting strategically and decisively when science and value align,” said Robert M. Davis, chairman and chief executive officer, Merck.

MERCK

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## Novo Nordisk sees India as a key clinical trial hub for its range of novel therapies in lifestyle disorders and rare diseases

Novo Nordisk sees India to actively participate in its global clinical trials. India is an important destination for clinical trials because of several factors such an English speaking population, large-diverse patient pool, medical expertise, qualified research professionals, advanced healthcare infrastructure and a cost competitive advantage. On its centenary year, the Denmark-based Novo Nordisk which was founded on June 21, 2023 reinstates its research commitment to diabetes, rare diseases, obesity and serious chronic disease.

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## Mandatory test for Indian pharma products in Gambia after cough syrup deaths

Gambia will make it mandatory for all pharmaceutical products from India to be inspected and tested prior to shipment from July 1, according to Gambian government documents reviewed by Reuters, the first known restrictions on national exports following the deaths of dozens of children linked to Indian-made cough syrups.The new rule highlights how governments are reassessing their reliance on India's $42 billion pharmaceutical industry since the contamination came to light last year.

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## Lupin launches thiamine hydrochloride injection USP in US markets

Global pharma major Lupin Limited (Lupin) announced the launch of thiamine hydrochloride injection USP, 200 mg/2 mL (100 mg/mL) multiple-dose vials, after Lupin's alliance partner Caplin Steriles Limited (Caplin) received an approval for its ANDA from the United States Food and Drug Administration (FDA). Thiamine hydrochloride injection USP, 200 mg/2 mL (100 mg/mL) multiple-dose vials is therapeutically equivalent to the reference listed drug (RLD), thiamine hydrochloride injection USP, 200 mg/2 mL (100mg/mL) of Fresenius Kabi USA LLC.


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## Indian pharma sees the draft ICH norms for good clinical practices to boost better human studies outcome

Indian pharma is of the view that the draft of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) norms for good clinical practices (GCP) will boost better human studies outcome as India is the hub of global clinical trials.To this end, ICH GCP will ensure that safe, effective, and high-quality medicines are developed, registered, and maintained in the most resource-efficient manner. By harmonizing the regulatory expectations in regions around the world, the guidelines have considerably reduced duplication of clinical studies, prevented unnecessary animal studies, standardized safety reporting and marketing application submissions, and contributed to many other improvements in the quality of global drug development and manufacturing and the products available to patients.

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## Pristyn Care launches AI-powered medical trainer 'Mira.AI'

Pristyn Care, a leading healthcare services provider, has announced the introduction of its new AI-powered trainer Mira.AI. With Mira's arrival, Pristyn Care aims to revolutionize the training process for its care coordinators by incorporating highly engaging training modules.Mira is an advanced AI-enabled trainer designed to empower Pristyn Care's care coordinators with comprehensive knowledge and expertise across 13 medical categories.Mira will start delivering highly standardized and engaging training experiences to Pristyn Care's latest batch of 100 care coordinators. These coordinators will undergo an intensive training programme of 92 meticulously crafted modules.

Pristyn Care

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