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The Veeda Newsletter

JUN 2021: ISSUE 06

VEEDA CLINICAL RESEARCH RAISES $16 MN FROM SABRE PARTNERS

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Our latest webinar and new investmest round

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First cell-based gene therapy to treat adult patients with multiple myeloma

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Merger and Acquisition
Icon to raise $2bn to help fund major clinical research merger

Indian Pharma
Indian pharma market: Emerging medico-legal issues in COVID era

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CX partners backed Veeda Clinical raises $16 mn from Sabre partners, others

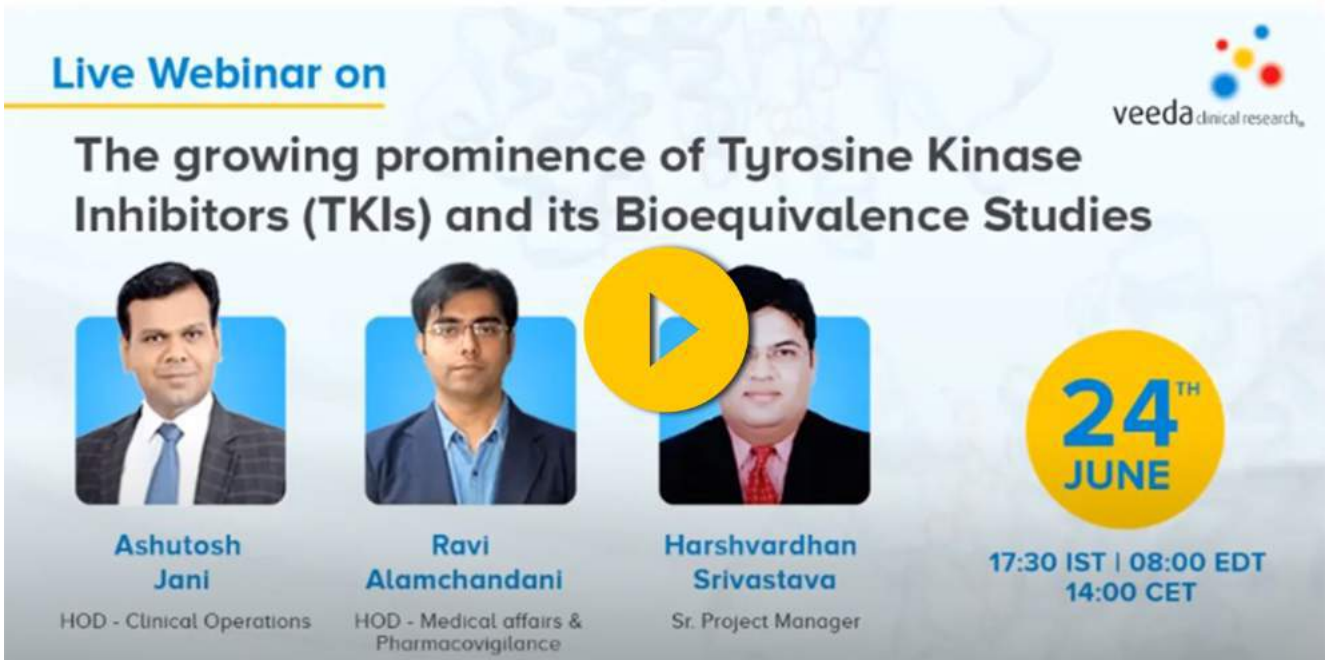
In March, Veeda Clinical Research, acquired a significant minority stake in Bengaluru-based pre-clinical research firm Bioneeds India Pvt. Ltd. **(HT)**

We are delighted to be featured on LiveMint

Veeda raised USD 16 million (~118 cr) in a round led by the private equity fund, Sabre Partners. This is a huge step for us in our growth plans and achieving our vision of being the preferred research partner offering a broad range of drug development, pre-clinical and clinical research services to our global brands.

Missed attending our webinar?

We conducted a webinar on "The growing prominence of Tyrosine Kinase Inhibitors (TKIs) and its Bioequivalence Studies" on 24th June, 2021. If you missed attending it, below is the link to access the complete recording.



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First cell-based gene therapy to treat adult patients with multiple myeloma

EMA has recommended granting a conditional marketing authorization in the European Union (EU) for Abecma (idecabtagene vicleucel) for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least three previous therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody, and whose cancer has worsened since receiving the last treatment.

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New treatment for people with dwarfism

EMA has recommended granting a marketing authorization in the European Union (EU) for Voxzogo (vosoritide) for the treatment of achondroplasia, a condition that impairs bone growth and causes dwarfism. The medicine is intended for use in patients 2 years and older whose epiphyses (growth plates of the bones) are not yet closed. The condition must be confirmed by genetic testing before patients can start treatment with Voxzogo.

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FDA Approves First Oral Blood Thinning Medication for Children

Today, the U.S. Food and Drug Administration approved Pradaxa (dabigatran etexilate) oral pellets to treat children 3 months to less than 12 years old with venous thromboembolism (a condition where blood clots form in the veins) directly after they have been treated with a blood thinner given by injection for at least five days.

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FDA In Brief: FDA Issues Draft Guidance on Remanufacturing and Discussion Paper Seeking Feedback on Cyber security servicing of Medical Devices

The following quote is attributed to William Maisel, M.D., director of the Office of Product Evaluation and Quality in FDA's Center for Devices and Radiological Health. "Many medical devices are reusable and need preventative maintenance and repair during their useful life; therefore, proper servicing is critical to their continued safe and effective use.

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FDA releases new draft guidance on sponsor role for safety reporting requirements

The US Food and Drug Administration (FDA) has released a new draft guidance for sponsors on safety reporting requirements and assessments for investigational new drug application (IND) and bioavailability/bioequivalence (BA/BE) studies. In a notice announcing the availability of the draft guidance, FDA said this latest version iterates on the "Safety Assessment for IND Safety Reporting" draft guidance released in 2015, and "provides recommendations related to the two IND safety reporting provisions.

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Indian pharma evinces interest on supply chain trade finance to enable easier global trade: Swati Babel

India's pharmaceutical supply chain is complex. There are always concerns about safety and product quality of the product in global trade. Sometimes there is lack of integration across the network having to deal with large number of players at every stage. Now Indian pharma is evincing interest in supply chain trade finance (SCTF) that is seen to break the traditional method of funding through Letter of Credit (LC) which is complex in nature, said Swati Babel, CEO, and PrimaDollar India.

CHRONICLE PHARMABIZ

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U.S. to buy another 200 million doses of Moderna's COVID-19 vaccine

Shares of Moderna Inc. MRNA, -0.09% were down 1.2% in premarket trading on Wednesday after the company said the U.S. has agreed to buy an additional 200 million doses of its COVID-19 vaccine. This agreement includes the option to purchase other COVID-19 vaccine candidates that Moderna is developing. This could include booster shots, Moderna executives said in a news release. In total, the U.S. has ordered 500 million doses of the company's mRNA vaccine. Moderna's stock has soared 92.9% this year, while the S&P 500 SPX, +0.33% is up 13.0%.

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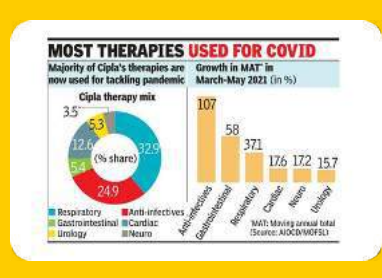
Cipla to tap foreign cos for large-scale vax play

Cipla, one of India's top 3 drug firms, is readying a larger play in the Covid therapies space, buoyed by the growth it has witnessed in this segment. Moving beyond a wide portfolio of Covid drugs and diagnostic kits, the Mumbai-based company — with revenues of nearly Rs 20,000 crore — now plans to partner foreign companies for large-scale fill-and-finish services for coronavirus vaccines. Cipla, which witnessed robust year-on-year (YoY) growth of nearly 74% in May on the back of Covid drugs (Tocilizumab, Remdesivir & Azithromycin) has sought clarity from the government on the vaccine ecosystem, even as it weighs options.



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Cadila, Bayer extend JV partnership for three years

Cadila Healthcare and Bayer NSE -0.41 % (South East Asia) have decided to extend the operations of their joint venture by three years with effect from June, the companies said in a joint statement on Monday. The companies had entered into an agreement on January 28, 2011, to set up the joint venture Bayer Zydus Pharma for the sales and marketing of pharmaceutical products in India, with headquarters in Mumbai.

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NPPA directs manufacturers, marketing cos to pass on benefit of reduced GST to customers

The National Pharmaceutical Pricing Authority (NPPA) has directed all producers and marketing firms of medicine, formulations and medical units to scale back costs of merchandise already out there on which items and companies tax has been lowered, in order to guarantee compliance and pass on the benefit to finish shoppers. "All manufacturers and marketing companies are required to revise the maximum retail prices of drugs/formulations on which tax/GST rates have been reduced taking into effect the revised rates of Tax/GST," the authority stated.

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FDA issues draft guidance encouraging rational expanded patient eligibility for oncology clinical trials

Today, the FDA issued a draft guidance encouraging industry to include patients with incurable cancers (when there is no potential for cure or for prolonged/near normal survival) in cancer clinical trials, regardless of whether they have received existing alternative treatment options. Historically, many clinical trials have required that participating patients previously received multiple therapies.

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Veeda Clinical Research raises $16 million

Veeda Clinical Research has announced that it has raised $16 million in a round led by private equity fund, Sabre Partners. This round also saw participation from HNIs such as Pranab Mody (of JB Chemicals), Havells India family office, Nikhil Vora (fFounder of Sixth Sense Ventures) and Arjun Bhartia (of Jubilant). Ajay Tandon, MD, Veeda said, “We will continue to invest in developing our delivery capabilities, to be increasingly relevant to our client’s objectives.”

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UK releases implementation plan for developing clinical research delivery

The UK Government has released an implementation plan for its initiative to enable the UK clinical research sector to tackle health inequalities, bolster economic recovery and improve the lives of people across the country. In March 2021, the government published saving and Improving Lives: The Future of UK Clinical Research Delivery, which set out the government’s plans to unleash the full potential of UK clinical research delivery.

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Virtual clinical trials change the face of the clinical research industry

Obviohealth discuss how their platform for virtual clinical trials is set to change the face of the clinical research industry for the better. Within a clinical trial environment remote monitoring is the ability to not have to visit the site in order to transfer and review trial data. With remote monitoring comes the ability for virtual data review. The use of digital technology allows for the relevant people within the trial to access the data wherever they are whenever they want.

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How big data has made clinical trials faster, better and cheaper

Technological developments have boosted the healthcare community to improve their research. Over the past few years, clinical research has witnessed a significant growth. Researchers and healthcare specialists are implementing big data tools and technologies to accelerate the research procedure and get a cost-effective measure for accurate results. The need for faster results is mainly due to the increasing demand for a deeper understanding of various diseases and viruses and to find out the perfect treatment for these ailments.

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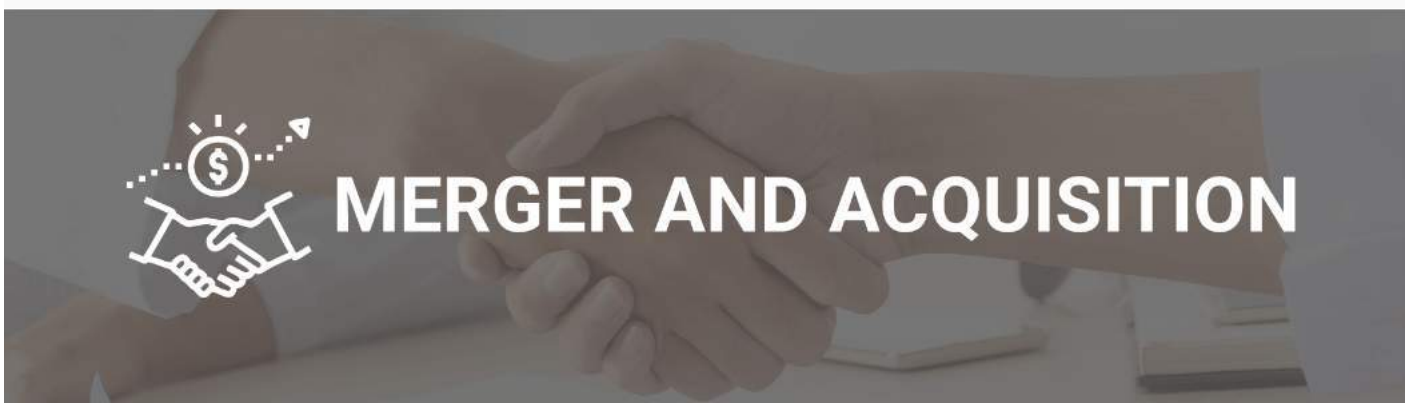

RAMM Pharma Completes Acquisition of Canapar Corp.

Further to its news releases dated May 12 and June 14, 2021, RAMM Pharma Corp. (including its wholly owned subsidiaries, the “Company” or "RAMM") (CSE: RAMM), a leader in plant-derived cannabinoid pharmaceutical and other cannabis-based products, is pleased to announce that the Company has completed its previously announced acquisition of Canapar Corp. (“Canapar”).

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Icon to raise $2bn to help fund major clinical research merger

Earlier this year, Icon announced its intention to acquire clinical research rival PRA Health Sciences in a $12bn deal. Now, the Dublin-headquartered pharma group has said it plans to raise more than $2bn through a private offering of senior secured notes to partially fund the deal. Icon intends to offer $500m of senior secured notes due 2026 and $1.51bn of senior secured notes due 2028. Founded in Dublin in 1990 by Dr John Climax and Dr Ronan Lambe, Icon has become a major clinical research player on the world stage.

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Health Union acquires Wego Health in play for social scale

Health Union acquired Wego Health, fusing its sizable platform of chronic-condition communities with the latter’s vast network of patient leaders. The privately held firms told clients of the news Monday afternoon and were expected to announce it publicly Tuesday morning. The deal, terms of which were not disclosed, brought together two social platforms for patients living with chronic illness, both of which also make revenue by connecting those patients with pharma brands.

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MorphoSys to Acquire Constellation Pharmaceuticals

MorphoSys AG (FSE: MOR; NASDAQ: MOR) (“MorphoSys”), and Constellation Pharmaceuticals, Inc., (NASDAQ: CNST) (“Constellation”) today announced that they have entered into a definitive agreement whereby MorphoSys will acquire Constellation for $34.00 per share in cash, which represents a total equity value of $1.7 billion.

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Nordic Capital acquires Advanz Pharma for $846m

Private equity investor Nordic Capital has acquired speciality pharmaceutical company Advanz Pharma in a deal worth $846 million (£596m). The deal is expected to bring significant investment and expertise to help fuel Advanz Pharma’s growth, with the potential to bring further cost-savings to the NHS and wider European healthcare systems while enhancing choice and access to critical medicines globally.

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Indian pharma market: Emerging medico-legal issues in COVID era

The increasing spread of COVID-19 has led to the emergence of various controversial medico-legal issues. While some of these issues are related to medical responsibility and malpractice, others are related to medical ethics and the relationship between physician and patient. Further, India has been fighting the pandemic without any prominent public health law in place.

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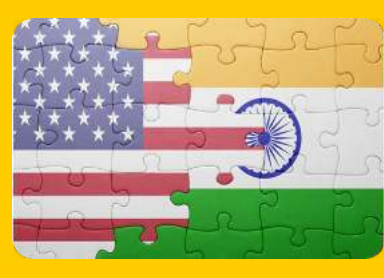
Indian envoy holds meetings with CEOs of top US companies on Covid crisis

The Indian envoy in the US is having an intense engagement with the CEOs of top American companies, particularly from the pharma sector, to help India get the necessary medical equipment and drugs to successfully combat the COVID-19 pandemic. Spoke today afternoon with Medtronic CEO Geoff Martha on their support in India's fight against the pandemic including through supply of ventilators along with other partners," India's Ambassador to the US, Taranjit Singh Sandhu tweeted after the meeting on Wednesday.



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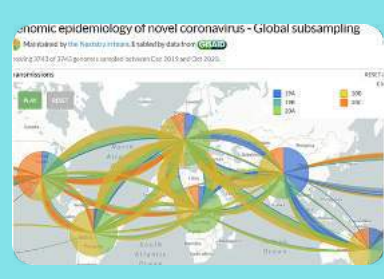
India needs real time mapping of genomic surveillance to enable robust public health response

India needs real time mapping of genomic surveillance that will enable a robust public health response. The chances of emergence of new variants of Covid-19 are a cause of concern due to widespread infections and taking into consideration our population. Only if the country keeps a high level of genomic vigilante, it will be able to pick up new mutants quickly and effectively mount a public health response with test, treat, trace and isolation. This is a genuine cause of worry.



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India to set up multi-product warehouse cum distribution centre in Guatemala

India is exploring the possibility of starting a multi-product warehouse cum distribution centre in Guatemala, which is considered the largest pharma market in the Central American region. It will scale up pharma exports in the region. The initiative is being taken by the Federation of Indian Export Organizations (FIEO) along with the Union ministry of commerce and industry and embassy of India in Guatemala. It will address a major concern of time taken for containers to reach from India to Central America.

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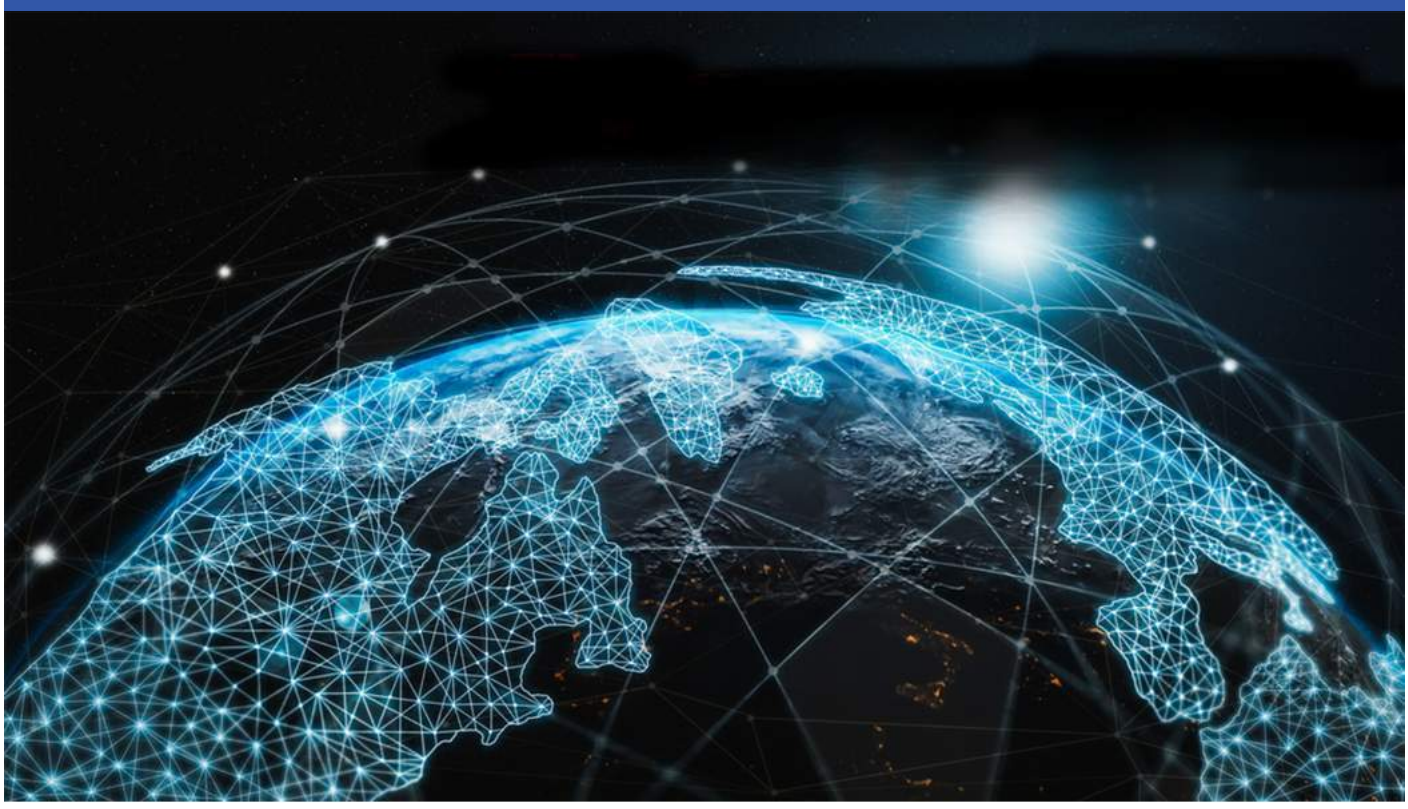

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