veeda clinical research

The Veeda Newsletter

OCT 2020: ISSUE 10

DELIVERING EXCELLENCE IN
CLINICAL STUDIES AND DRUG DEVELOPMENT

Veeda Webinars
In the month of October, we conducted two webinars.

Regulatory
FDA Approves First Treatment for COVID-19.

Financial
Indian Pharma Market registers 4.5% growth in September 2020

Clinical Research
NIH begins large clinical trial to test immune modulators for treatment of COVID-19

Merger and Acquisition
PAG-led consortium to acquire API maker Anjan Drug

Indian Pharma
Six Indian drug companies to set up a large pharma cluster in Mexico

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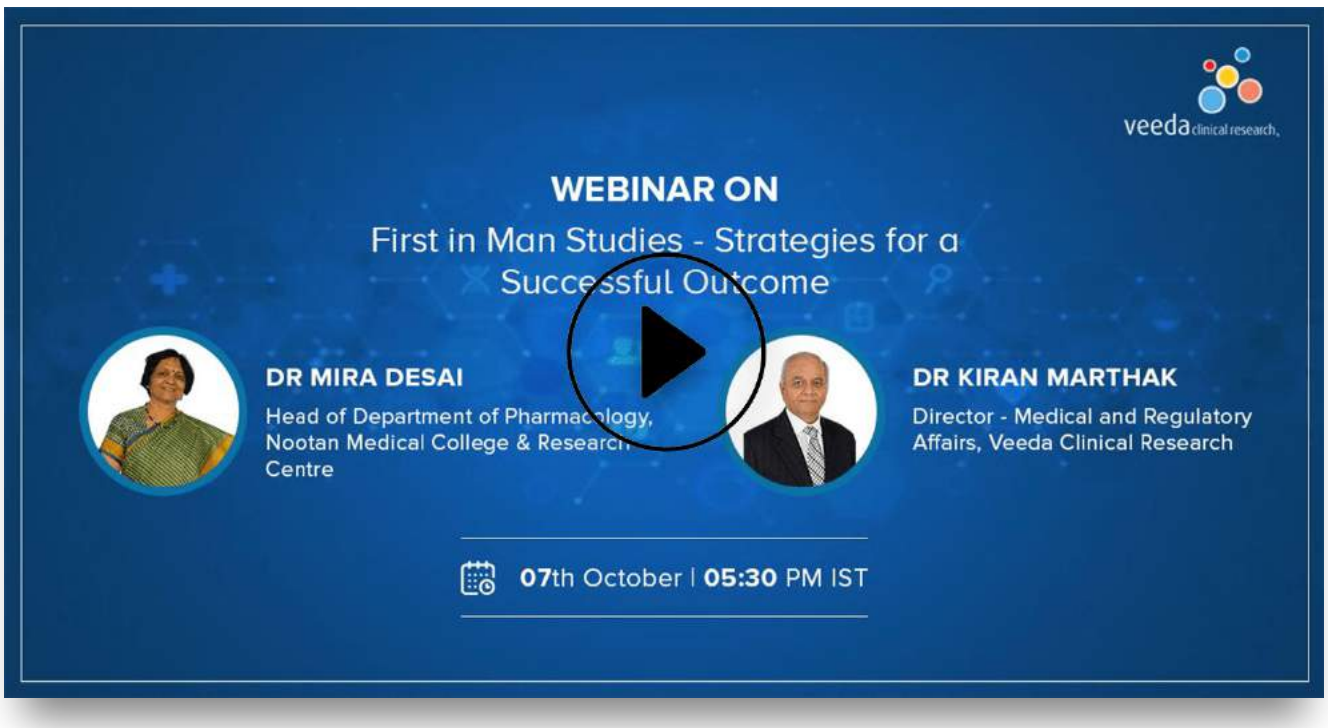
Missed attending our webinars?

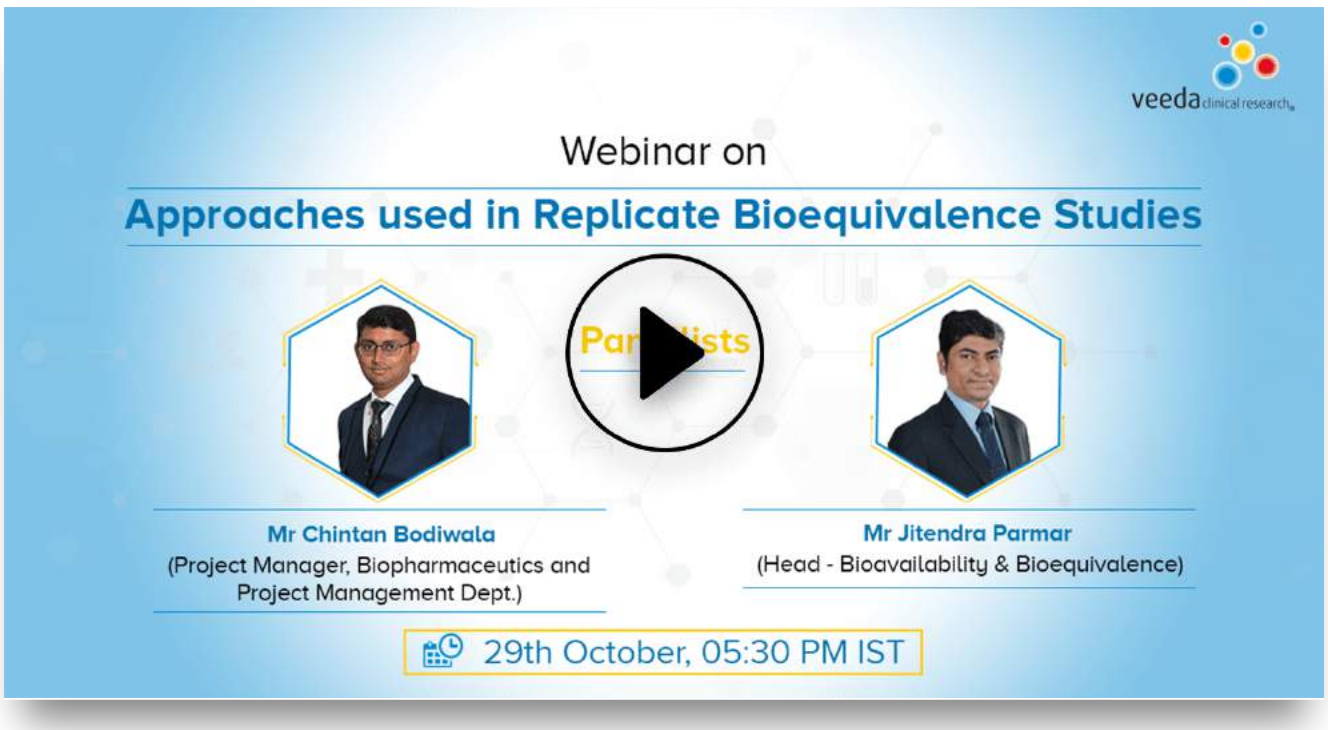
October was full of learning for us. We conducted two webinars, First in Man Studies – Strategies for a Successful Outcome on 07th October and Approaches used in Replicate Bioequivalence Studies on 29th October.

If you missed attending the webinars, below are the link to access the complete recording.

Webinar 01: First in Man Studies – Strategies for a Successful Outcome



Webinar 02: Approaches used in Replicate Bioequivalence Studies



Know more about us!

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FDA Approves First Treatment for COVID-19.

Today, the U.S. Food and Drug Administration approved the antiviral drug Veklury (remdesivir) for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalization. Veklury should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

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CDSCO panel recommends granting permission to conduct phase 3 clinical trials of Covid-19 vaccine

An expert panel at the Central Drugs Standard Control Organisation (CDSCO) has recommended granting permission for conducting phase 3 clinical trials of its indigenously developed Covid-19 vaccine with certain conditions. The recommendation was given after assessing the safety and immunogenicity data of phase 1 and 2 clinical trials and have been sent to the Drugs Controller General of India (DCGI) for final approval.

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Medical devices given exceptional use authorizations during the COVID-19 pandemic

List of manufacturers and their medical devices which have been granted an exemption by the MHRA. The list also includes manufacturers whose exemption expired or was cancelled. This information will be listed for 2 months after expiry or cancellation. To ensure transparency around the supply of medical devices in the UK, we are now providing a list of manufacturers and devices granted an exceptional use application.

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First CAR-T cell medicine for mantle cell lymphoma

EMA has recommended granting a conditional marketing authorisation in the European Union (EU) for Tecartus (autologous anti-CD19-transduced CD3+ cells) for the treatment of adult patients with a rare cancer of white blood cells called mantle cell lymphoma (MCL) when the symptoms or the disease come back (relapse) or when they are not responding (refractory) after two or more lines of systemic therapy.

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FDA Approves First Treatment for Ebola Virus

Today, the U.S. Food and Drug Administration approved Inmazeb (atoltivimab, maftivimab, and odesivimab-ebgn), a mixture of three monoclonal antibodies, as the first FDA-approved treatment for Zaire ebolavirus (Ebola virus) infection in adult and pediatric patients. “Today’s action demonstrates the FDA’s ongoing commitment to responding to public health threats—both domestically and abroad—on the basis of science and data,” said FDA Commissioner Stephen M. Hahn, M.D.

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Minister says Indian pharma sector can grow to 65 bln USD by 2024

Indian minister for chemicals and fertilizers D. V. Sadananda Gowda Thursday said the country was one of the largest manufacturers and exporters of generic medicines across the world. "Indian pharma sector can grow to 65 billion U.S. dollars industry by 2024," Gowda said. "We have recently launched schemes for the development of seven mega parks-three bulk drug parks and four medical device parks across the country."

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Indian Pharma Market registers 4.5% growth in September 2020

The Indian Pharmaceutical Market (IPM) has registered a growth of 4.5% for the month of September 2020, after five months of COVID-19 crisis. According to AIOCD AWACS report, the IPM has recorded sales of Rs. 1,42,868 crore for moving annual total (MAT) basis during September 2020. Amongst the top 10 corporates, Mankind exhibited the highest growth of 8.4 per cent, followed by Torrent Pharma at 7.1 per cent. Amongst the 11 to 25 ranked corporates, Aristo exhibited highest growth of 13 per cent followed by Glenmark Pharmaceuticals at 15.4 per cent.

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These are the stocks to short when a COVID vaccine is ready, says JPMorgan

Executives at drugmakers Pfizer PFE, -0.68% and Moderna MRNA, -0.41% say their COVID-19 vaccine candidates could be ready, at least for limited use, by the end of the year. It will be good — make that, great news for the economy if the vaccines are effective enough that face-to-face interactions can once again resume without much fear of spreading, or contracting, the new coronavirus.

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How Much Will You Pay for a COVID-19 Vaccine? Here's What We Know

All data and statistics are based on publicly available data at the time of publication. Some information may be out of date. Visit our coronavirus hub and follow our live updates page for the most recent information on the COVID-19 outbreak.

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Despite volume lag, drug firms hike price

Domestic pharma sales bounced back in September, but what's interesting is that this rise was led by pricing growth. During the pandemic when people are avoiding hospitals and clinics and fresh prescription growth has slowed down the volume growth in the domestic market has also fallen. However, a deeper look at the data shows that the volume decline too has been slowing it fell 4 per cent year-onyear in September against 9.2 per cent decline in August.

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India ran 122 medicine trials for Covid in first 4 months of pandemic, 67 of them were AYUSH

India undertook more than 100 clinical trials in the first four months after the Covid-19 pandemic hit the country, a review article published in the Indian Journal of Medical Research (IJMR) has said. The analysis, conducted by researchers at the Indian Council for Medical Research (ICMR), the apex body in the field, found that of the 122 trials registered in India.

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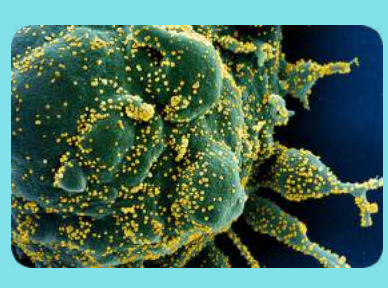
NIH begins large clinical trial to test immune modulators for treatment of COVID-19



The National Institutes of Health has launched an adaptive Phase 3 clinical trial to evaluate the safety and efficacy of three immune modulator drugs in hospitalized adults with COVID-19. Some COVID-19 patients experience an immune response in which the immune system unleashes excessive amounts of proteins that trigger inflammation called a “cytokine storm”.

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Why technology holds the key to a revolution in clinical trials

Clinical trials, particularly those involved in finding a Covid-19 vaccine, have never been so crucial in getting society back onto some sort of even keel. Yet they’ve also never been in such a state of transformation. Scientists and pharmaceutical companies are racing to get coronavirus drugs into the hands of those who need them most.

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There is value to patients when independent sites offer clinical trials

The COVID-19 pandemic suddenly changed the clinical trials environment with impacts on all stakeholders that at first are negative, but could be positive in the long term. There is talk of transformation that could last well beyond the crisis. Optimistic views include speculation that there could be wider adoption of practices that have languished in concept or startup mode until now.

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Clinical technology firm takes a human approach to trials

Clinical researchers often site improved patient recruitment, engagement and inclusion as a goal in their work. A new clinical trial solutions firm aims to help hit those targets with technology designed to better bring in the patient thought process and include their voice. Outsourcing-Pharma (OSP) spoke with April Lewis (AL), Hū’s executive vice president and general manager of clinical trial solutions.

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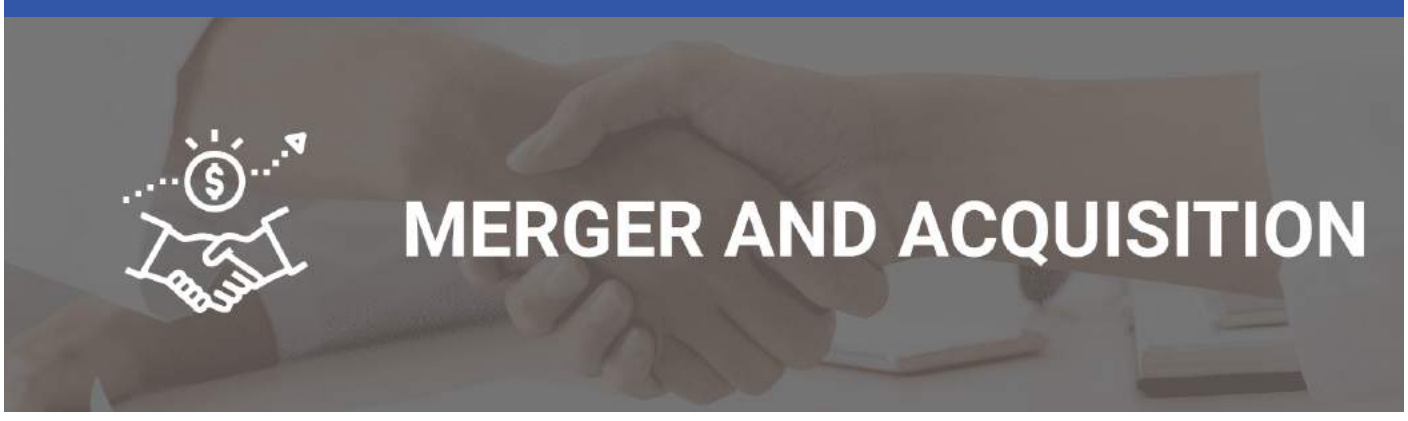

Pharma giant Eli Lilly acquires Washington University-founded startup Disarm Therapeutics for $135M

Pharmaceutical giant Eli Lilly & Co. has acquired a startup created by a pair of Washington University School of Medicine Scientists that is developing treatments for degenerative diseases such as Parkinson's, ALS and multiple sclerosis.

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Aurobindo Pharma acquires 100 per cent share of Eugia Pharma Specialities

Aurobindo Pharma has entered into a share purchase agreement today to acquire 100 per cent equity share capital of MViyeS Pharma Ventures. MViyeS holds 32.18 per cent shareholding in Eugia Pharma Specialities, a JV company engaged in developing, manufacturing and marketing hormonal and oncology generic formulations.

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UCB acquires new campus to support UK operations

Belgian pharma company UCB has agreed to acquire a new campus to further support its operations in the UK. The acquisition of the site in Windlesham, Surrey is expected to be completed in November 2020, and reflects UCB's commitment to retain the UK as one of its three global hubs for research and development alongside Belgium and the US.

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Astellas to Acquire iota Biosciences

Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") and iota Biosciences, Inc. (Co-founders and Co-CEOs: Michel Maharbiz, Ph.D. and Jose Carmena, Ph.D., "iota") announced today that Astellas through a U.S. subsidiary, and iota have entered into a Merger Agreement pursuant to which Astellas will acquire iota.

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PAG-led consortium to acquire API maker Anjan Drug

PAG, a leading Asia-focused private equity firm, announced that along with consortium partners CX Partners and Samara Capital, it had reached an agreement to acquire a controlling stake in Anjan Drug Pvt. Ltd., a Chennai-based manufacturer of active pharmaceutical ingredients (API).

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India, UAE explore healthcare collaboration

'UAE-India Healthcare Conference 2020', was recently organized jointly by Embassy of India, Abu Dhabi and Consulate General of India, Dubai, FICCI and Invest India, to explore ways and means for promoting collaboration and partnerships in the fields of healthcare, pharmaceuticals, medical devices and alternative medicines.

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India Emerges as Hot Spot for Manufacturing COVID-19 Vaccines

India is fast emerging as the most sought-after destination for manufacturing COVID-19 vaccines even as hundreds of institutions around the world are hotly chasing potential vaccine candidates to stall the pandemic. As the unprecedented scenario hastens the front-runners to breakneck speed, the task of the global distribution of the vaccine doses remains a formidable challenge.

Read More

A New Prescription: How COVID-19 Has Changed Indian Pharma

In the bonfire of disruptions across India Inc, triggered by the pandemic, the lattice of the pharmaceutical industry can hardly escape the embers. The business of medicine-making has for long remained immune to the ups and downs of business cycles, priding itself as a defensive sector that is firmly anchored on the premise that as long as people are sick medicines will be in demand.

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Six Indian drug companies to set up a large pharma cluster in Mexico

Six generic drug makers, Dr Reddy’s Laboratories, Zydus Cadila, Glenmark Pharmaceuticals NSE 3.49 %, Torrent Pharmaceuticals, Hetero Drugs and Ackerman Pharma have signed a deal with Hidalgo State of Mexico to set up a large pharmaceutical cluster for production and logistics.

Read More

Indian pharma explores virtual inspections post COVID-19

Extraordinary times call for extraordinary measures. In keeping with this dictum, in mid-April this year, the Indian pharmaceutical industry called on the USFDA to consider conducting virtual inspections of their plants and facilities. With Covid-19-enforced imperative to protect its personnel, the FDA had suspended physical inspections in March and indicated towards late July that it was looking to restart domestic inspections.

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