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The Veeda Newsletter

JULY 2021: ISSUE 07

Our Expertise in **Pazopanib Clinical Trials**

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16 YEARS OF DELIVERING EXCELLENCE

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Veeda acquires majority stake in Bioneeds

After acquiring a minority stake in Bioneeds in March, Veeda has now acquired a controlling 50.1% stake in Bioneeds.

This news comes in after our latest funding round where we raised USD 16 million (~118 cr) in a round led by the private equity fund, Sabre Partners.

This will help us further align our capabilities, systems, processes and people to capitalize on the full potential of our combination of Veeda, Ingenuity and Bioneeds.

Veeda Clinical Research acquires majority stake in Bioneeds preclinical

Veeda has completed several regulatory inspections and is approved by USFDA, UK MHRA, ANVISA (Brazil), and WHO **(Bloomberg)**

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FDA Approves First Intravenous Immunoglobulin for Adult Dermatomyositis

The U.S. Food and Drug Administration (FDA) has approved Octagam® 10% [Immune Globulin Intravenous (Human)], the first and only intravenous immunoglobulin (IVIg) for the treatment of adult dermatomyositis. Dermatomyositis is a rare immune-mediated inflammatory disease. It is an autoimmune disorder of unknown cause affecting approximately 10 out of every million U.S. residents.

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USFDA approves new use of transplant drug based on real-world evidence

The US Food and Drug Administration approved a new use for Prograf (tacrolimus) based on a non-interventional (observational) study providing real-world evidence (RWE) of effectiveness. The agency approved Prograf for use in combination with other immunosuppressant drugs to prevent organ rejection in adult and paediatric patients receiving lung transplantation.

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WHO releases first guidelines on hepatitis C virus self-testing

New guidelines from WHO strongly recommend offering self-testing for hepatitis C virus (HCV) as an additional approach to HCV testing services. WHO releases the new guidelines – it's first on HCV self-testing during the International AIDS Society Conference 2021. WHO set a goal to eliminate HCV as a public health problem by 2030 in its Global health sector strategy on viral hepatitis (2016–2021), with targets to diagnose 90% of those with HCV and to treat 80% of those diagnosed.

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EMA and ECDC update on COVID-19

Complete vaccination courses vital for maximum protection. Vaccination remains one of the best protective measures against COVID-19. Recommendations for vaccination are in place in all Member States and roll-out of vaccination is ongoing. The European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) urge EU citizens to get vaccinated and to adhere to the recommended number of doses.

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Asia-Pacific Roundup: Malaysia publishes guidance on manufacturing cell and gene therapies

Malaysia's National Pharmaceutical Regulatory Agency (NPRA) has released guidance about cell and gene therapy manufacturing facilities. The guidance describes the process for setting up a facility in Malaysia and the local and international regulations and guidelines that cover the production of cell and gene therapies.

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NPPA releases revised price list of 631 products under five medical devices

The National Pharmaceutical Pricing Authority (NPPA) has released price listing of 631 medical devices, which falls under the five medical devices it capped trade margins at 70 per cent at the Price to Distributor (PTD) level earlier this month. The NPPA, in an office memorandum on July 14, 2021, had directed manufacturers and importers of pulse oximeter, blood pressure monitoring machine, nebuliser, digital thermometer and glucometer, to submit the revised MRPs of their products following the rationalisation of trade margin it imposed.

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Indian Pharma Market growth slips to 14.1% in June 2021

The Indian Pharmaceutical Market (IPM) has registered a growth of 14.1 per cent for the month of June 2021, after registering a growth of 47.8 per cent for the month of May 2021. According to AIOCD AWACS report, the IPM has recorded a robust growth of 11.7 per cent value growth for moving annual total (MAT) basis during June 2021. IPM Value trend indicates a gradual normalisation of the sales trend.

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NPPA seeks PTR & MAT value for 29 formulations from drug manufacturers & marketers to fix ceiling prices

The National Pharmaceutical Pricing Authority (NPPA) has asked drug manufacturers and marketers to furnish the information relating to price to retailer (PTR) and moving annual turnover (MAT) in value term for about 29 NLEM formulations for the month of March 2021. The information will be used by NPPA for fixing ceiling price of the formulations under provisions of DPCO, 2013.

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Pharma industry expected to clock in 12-15% growth this year: B R Sikri

Shrugging off the Covid-19 challenges in its second wave through prudent planning and execution of manufacturing and distribution, the pharmaceutical industry in the country is expected to grow by 12-15 per cent this year, according to an industry expert. The availability and pricing of raw materials are also stabilising, thanks to the normalising supplies from China.

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Centre working with Moderna to see how its COVID-19 vaccine can be brought to India: Dr VK Paul

The government said on Friday that it is working actively with COVID-19 vaccine manufacturer Moderna to see how its vaccine can be imported and made available in the country. Moderna's COVID-19 vaccine was granted emergency use authorisation last month. Responding to a question at a press briefing, NITI Aayog member (Health) Dr V K Paul said, "Moderna vaccine is under emergency use authorisation.

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Patient Perspective in Clinical Trials

The patient perspective is at the heart of what we do. Since Fight CRC's inception, we've recognized the need to put the patient voice in all things research, ensuring that science has the community's best interests in mind. The RATS program does just that. It trains advocates on the research so they can work alongside scientists and make sure that their perspectives are being heard and taken seriously. Julie Krause, a stage IV colorectal cancer (CRC) survivor joined the RATS program in 2015, and ever since has been a fierce advocate for clinical trials.

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Digital transformation: Pharma's pivot for post-pandemic success

Digital evolution has led to a fundamental shift in the way pharmaceutical organisations conduct business with a focus on patient experience across all the stages of value chain. India's pharmaceutical industry is estimated to reach $65 billion by 2024, according to the Indian Economic Survey 2021. With the increase in demand for prescription medicines, vaccines and medical devices, this sector has struggled with attending overwhelmingly large patients and identifying therapeutic interventions for COVID-19.

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A year of clinical research change, challenge, and champions: Your questions answered

COVID-19 has brought many challenges to clinical research, with investigator sites having to adapt their operations to ensure they successfully meet the safety concerns for both research staff and study participants. In this on-demand select Science webinar, Ellie Robertson, managing director, and Dr. Kirstin Taylor, clinical research physician at Intelligent Clinical.

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Data Sharing and Integrations: Transformative Forces in Clinical Trials

O2020 created an entirely different clinical research landscape, with the rise of precision medicine and remote-enabled research at the forefront. This shifting landscape also points to a crucial element: data. This greater reliance on data and technology integrations in research means that clinical research sites can support more intensive patient recruitment, discover candidates who live outside of their immediate area and run studies more efficiently.

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Medidata explains how technology is changing clinical trials

Reece Armstrong speaks to Paul O'Donohoe, scientific lead, eCOA and Mobile Health at Medidata about how digital technologies are affecting clinical trials throughout the pharmaceutical industry.

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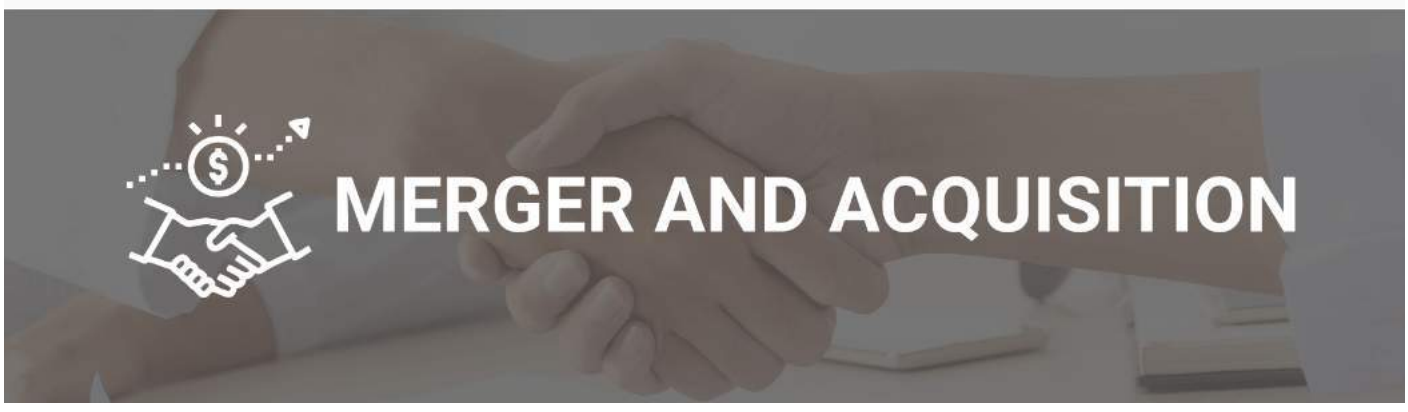

Veeda Clinical Research acquires majority stake in Bioneeds preclinical

Veeda Clinical Research Ltd, a full-service clinical research organisation (CRO), on Friday said that it has acquired a controlling 50.1% stake in Bioneeds India Pvt Ltd, after acquiring a significant minority stake earlier in March. Earlier in June this year, Veeda had also received an equity investment of $16 million led by private equity fund, Sabre Partners and HNIs like Pranabh Mody (of JB Chemicals), Havells family office, Nikhil Vora (founder of Sixth Sense Ventures), Arjun Bhartia (of Jubilant), amongst others.

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Partners Group to acquire Pharmathen from BC Partners for $1.9bn

Private equity firm Partners Group has agreed to acquire Pharmathen from an international investment firm BC Partners in a deal valued about $1.88bn (€1.6bn). Private equity firm Partners Group has agreed to acquire Pharmathen from an international investment firm BC Partners in a deal valued about $1.88bn (€1.6bn).

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Envision Pharma Group Company Two Labs Acquires Riparian | Ohio

Two Labs, an industry-leading pharmaceutical services company and part of the Envision Pharma Group, is today a pharmaceutical consulting and SaaS Company that helps manufacturers navigate pricing, reporting, strategy, and program operations. Announced that it has acquired Riparian.

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AstraZeneca deal for Alexion to close soon as UK regulator clears acquisition

With the purchase of Alexion, AstraZeneca is gaining a major foothold in an increasingly lucrative market for rare disease drugs. Alexion currently sells five medicines for seven different conditions and brought in more than $6 billion in revenue last year. Sales of its blockbuster Soliris, a monoclonal antibody approved to treat four rare diseases, topped $4 billion.

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Wave of acquisitions hits pharma industry this week

The past several days have seen a relatively large number of industry acquisitions, with Lilly, Phillip Morris, WCG, CTI and others making notable buys. This year has already seen its shares of interesting acquisitions—ICON purchasing PRA for a reported $12b USD and Thermo Fisher Scientific buying PPDfor about $17.4b USD are among the noteworthy deals. However, this week has seen more acquisition activity than most.

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Indian pharma industry to touch USD 130 bn by 2030: Reddy

The Indian pharmaceutical industry is expected to grow almost by three times to about 130 billion US dollars by 2030, Chairman of Dr Reddy's Laboratories, K Satish Reddy said on Saturday. "If you see, currently its (pharmaceutical industry) about 42 billion dollars, half between the domestic sales, half between the exports. We expect that it will grow almost by three times in the coming decade, reaching almost 120 to 130 billion dollars by 2030.

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ICMR is making 'questionable decisions' on Covid in India

For a century, the Indian Council of Medical Research was a little known government body quietly studying illnesses in New Delhi. But during the pandemic, it's taken on a role akin to Anthony Fauci's National Institute of Allergy and Infectious Diseases in the US a powerful position that's made it a controversial face of India's struggles with Covid-19. As the ICMR has acted as a key medical adviser to Prime Minister Narendra Modi and his health ministry.

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India Needs To Up RnD Spends, Diversify Pharma Raw Material Imports: RBI Paper

The Covid-19 pandemic has been a "stress test" for the Indian pharma industry, and exposed its high dependence on imported raw materials and "surprisingly low" research and development efforts, a paper in RBI's July bulletin said on Thursday."The high import dependency and surprisingly low R&D intensity of exports in the Indian pharmaceutical sector call for timely diversification.

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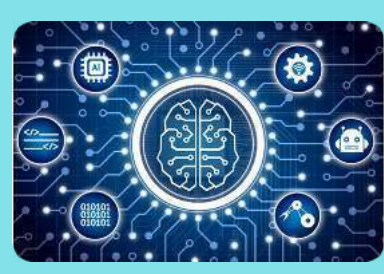
Pharma companies take the digital pathway with AI algorithms and Big Data to speed up drug discovery

Pharma companies are seen to tread the digital pathway during the ongoing pandemic phase with the implementation of artificial intelligence (AI) and Big Data to speed up drug discovery and focus on operational cost-effectiveness. According to Shashank Kumar, senior consultant, Cloud Engineering Studio, Brillio, technology disruption is helping pharma companies to innovate and improve drug development, upgrade production plants and rebuild the business model to ensure operational cost effectiveness.



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ICMR and University of Oxford to conduct India-UK RECOVERY trial of baricitinib for Covid-19

The Indian Council of Medical Research (ICMR) along with University of Oxford is proposing to conduct a multi-centre, adaptive platform trial in Covid-19 patients, titled 'India-UK RECOVERY (Randomised Evaluation of Covid-19 Therapy) trial. The Indian Council of Medical Research (ICMR) along with University of Oxford is proposing to conduct a multi-centre, adaptive platform trial in Covid-19 patients, titled 'India-UK RECOVERY (Randomised Evaluation of Covid-19 Therapy) trial.

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