The Veeda Newsletter

JANUARY 2022: ISSUE 01

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VEEDA NEWS

Our Managing Director, Mr Ajay Tandon's conversation with BioSpectrum India

'STRENGTHENING CAPABILITIES TO FULLY SERVICE BIOSIMILARS SEGMENT'

"We continue to see significant growth potential in generics with the long pipeline of products scheduled to go off-patent in the near to medium term. There is a significant development pipeline in biosimilars as well given scheduled patent expiries and we have been strengthening our capabilities to fully service this segment. We also see increasing potential for conducting late phase clinical trials in India across a spectrum of drug products and therapeutic areas, and have been investing in our team, processes and technology to support our global clientele in these."

- AJAY TANDON,
Managing Director,
Veeda Clinical Research, Ahmedabad

Glimpse of Veeda's 17th Annual Function Celebration

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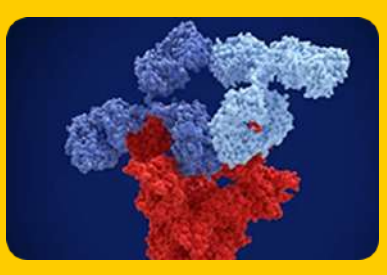
FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant

As we have throughout the COVID-19 pandemic, the U.S. Food and Drug Administration has used the best available science as the virus has evolved to make informed decisions with the health and safety of the American public in mind. Ensuring that healthcare providers on the frontlines have the best tools available to treat patients is a top priority for the agency.



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Regulatory harmonisation of clinical trials in the EU: Clinical Trials Regulation to enter into application and new Clinical Trials Information System to be launched

On 31 January 2022, the Clinical Trials Regulation (CTR) will come into application harmonising the submission, assessment and supervision processes for clinical trials in the European Union (EU). The backbone of the changes brought about by the CTR is the new Clinical Trials Information System (CTIS). CTIS is a single entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data which includes a public searchable database for healthcare professionals, patients and the general public.

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Accelerating Clinical Trials in the EU (ACT EU): for better clinical trials that address patients' needs

Today, the European Commission (EC), the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) have launched an initiative to transform how clinical trials are initiated, designed and run, referred to as Accelerating Clinical Trials in the EU (ACT EU). The aim is to further develop the EU as a focal point for clinical research, further promote the development of high quality, safe and effective medicines, and to better integrate clinical research in the European health system.

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ICMRA and WHO map out flexibilities used by regulators to respond to the COVID-19 pandemic

The International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO) have reviewed some of the practices applied by regulatory authorities worldwide to respond to the challenges faced during the COVID-19 pandemic. In the context of COVID-19, regulatory authorities have adapted some of their regulatory frameworks and streamlined their procedures.

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FDA issues trio of guidances aimed at boosting generic competition, reducing review cycles

The US Food and Drug Administration (FDA) on Wednesday issued three guidances – two final and one revised draft aimed at clarifying aspects of generic drug submissions and labeling updates. "These guidances are part of our continued efforts to bring greater efficiency and transparency to the generic drug review process, which helps spur competition and improves consumer access to the medicines they need at affordable prices.

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India needs to invest in affordable innovation, support innovative start-ups for growth: Expert

India needs to invest in affordable innovation and embrace entrepreneurship as an economic model of growth and backing innovative start-ups as a model to create economic and employment growth, says Upadhyayula Suryanarayana Murty, director, National Institute of Pharmaceutical Education & Research (NIPER)-Guwahati.

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Topography Health Emerges from Stealth with $21.5 Million to Help Patients Access Life-Saving Clinical Trials

After getting to know one another, Topography Health's co-founders realized that they had all witnessed family members try—sometimes unsuccessfully—to access clinical trials for emerging drugs addressing treatment-resistant medical issues. That proved the genesis of Topography Health, a Los Angeles- and New York-based clinical trials startup that came out of stealth Wednesday with $21.5 million in Series A funding led by Bain Capital Ventures.

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Dr Reddy's launches molnupiravir at Rs 35 per pill, matching Mankind's price

Dr. Reddy's on Tuesday said it will launch its COVID-19 antiviral molnupiravir capsules under its brand name Molflu across India at matching the price of Mankind Pharma. Dr. Reddy's Molflu will be priced at Rs. 35 per capsule with 10 capsules contained per strip, and the total course of 40 capsules over 5 days costing Rs. 1,400 making it among the most affordable treatment options available to patients.

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Pharma, healthcare industry looks to sustain momentum in 2022

Having proved its prowess to the world during the challenging times of the pandemic by supplying 60 per cent of the global COVID-19 vaccine requirements, the Indian pharma and healthcare industry is looking to build on the experience of the last two years, strengthen the partnership with the government and sustain the momentum in 2022. Organisation of Pharmaceutical Producers of India (OPPI) Director-General K G Ananthakrishnan told PTI that it is crucial for the industry to further build momentum towards the gains secured over the course of the pandemic which will help it carve a niche in the global pharma value chain.

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Government to curb pharma imports from China

The government plans to tighten the regulatory noose around pharmaceuticals imports from China through stricter scrutiny of active pharmaceutical ingredients (APIs), key starting materials (KSMs) for medicines and medical equipments. Higher duties on Chinese products may also be on the cards, official sources said. These moves gathered pace in the wake of the military face-off between India and China in east Ladakh and the continuing diplomatic tension since then, prompting the government to explore all options to reduce import dependence on China.

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Clinical trial diversity: It's time to quit talking and start doing

Clinical trial diversity, specifically concerning race and ethnicity, has emerged as the latest buzzword in pharma over the last few years, with several companies pledging their commitment to diversify studies. The reticence of minority populations to enroll in trials is often cited as a major cause for the lack of diversity in trials. However, experts say that it is in fact trial-related costs and protocols that require significant time from participants, which often keep them from participating. Moreover, institutional and systemic biases prevent minority populations from even being offered clinical trials.

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Revealed: the pharma companies best equipped with AI

The pharmaceutical industry is not only starting to take notice of artificial intelligence (AI), but many companies have started to future-proof their approaches to keep their competitive edge. Using GlobalData's Thematic Research ecosystem, we look at which companies are leading the field in AI. First, some background: one feature of the ecosystem is the Thematic Scorecard, which evaluates companies on how equipped they are in a certain theme, such as AI, over the next two-to-three years. This is based on their current AI activity and investment.

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Changing Clinical Trials

Thousands of clinical trials all across the world were disrupted, delayed or stopped while countries struggled to curb the pandemic and research resources were redeployed. The long-term impacts of the turmoil caused by the COVID crisis have yet to be completely understood, but it's already clear that the increased focus on participant needs' and on the logistical challenges of current models are not likely to go away soon. This disruption is opening ways for revisiting traditional approaches to clinical trial conduct.

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Decentralised trials: beyond the pandemic

The adoption of decentralised activities was a major factor in allowing clinical trials to continue during the early stages of the pandemic. Ben Hargreaves examines whether this adoption looks set to become a permanent feature of clinical trials moving into the future, rather than just supplying the tools to a temporary need. Decentralised clinical trials (DCTs) have become a major talking point due to their ability to ensure that drug development can continue efficiently through the current pandemic.

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Which Asia-Pacific country sees most growth for data analytics roles in clinical trials?

The fastest growing country in terms of data analytics roles in the clinical trials industry between September and November was India, which saw 4.2% of all data analytics job adverts. There is an increase to 6.1% in the three months ending November this year. That was followed by China (up 0.9 percentage points), Canada (up 0.9), and the United Kingdom (up 0.5).

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The top 10 biopharma M&A deals in 2021

Biopharma merger and acquisition (M&A) activity was subdued in 2021, and it would have approached a record low for recent years but for a flurry of deals in the last quarter. The top 10 biopharma M&A deals last year reached a combined value of just under $53 billion, well down from the $97 billion tally in 2020 and a fraction of the $207 billion spent on the 10 largest transactions in 2019.

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Hikma Acquires Teligent Sterile Injectable Assets for $45.75M

Hikma Pharmaceuticals PLC (Hikma), a multinational pharmaceutical company, has agreed to acquire the Canadian assets of Teligent Inc. for $45.75 million. The transaction is expected to be completed before the end of 1Q22. The acquisition marks Hikma's expansion into Canada and includes a portfolio of 25 sterile injectable products, three in-licenced ophthalmic products and a pipeline of seven additional products, four of which are approved by Health Canada.

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India sees record M&A volume in 2021, first-time buyers lead

India witnessed mergers and acquisitions (M&A) at an all-time high in 2021, led by more first-time buyers accounting for more than 80 per cent of the deals closed in 2020 and 2021 – an increase from less than 70 per cent through 2017 to 2019, a new report showed on Tuesday. The nature of deals was broad-based, including more mid-sized deals ranging from $500 million-$1 billion, compared to the mega $5 billion deals that drove activity in 2017-19, according to a Bain & Company report.

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CSL Nabs Vifor in $11.7 Billion Deal

CSL closed out the year with one of the most expensive acquisitions. In December, the Australia-based company acquired Vifor Pharma for $11.7 billion. Although the deal has yet to be finalized, when it is completed, CSL will gain Vifor's pipeline of drugs aimed at treating iron deficiency, kidney and cardio-renal diseases.

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Aceto strengthens focus on pharma & biopharma with acquisitions and facility investments

Over the last 18 months, Aceto has made a series of manufacturing acquisitions, allowing it to better serve customers in biopharmaceutical, vaccine and pharmaceutical industries. It is now investing in several of its newly-acquired North American facilities: while keeping an eye out for further acquisition opportunities. Aceto is a global manufacturer and supplier of differentiated specialty ingredients: offering over 3,000 chemical compounds for the pharmaceutical, nutraceutical, agricultural and specialty chemical industries.

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Indian pharma industry estimated to grow 9-11% in 2021-22: ICRA

The Indian pharma industry is estimated to grow at 9-11 per cent in 2021-22 and in the next few quarters, it will be driven by domestic and emerging markets, according to ratings agency ICRA. In a sample of 21 Indian pharmaceutical companies, ICRA said revenue growth was moderate at 6.4 per cent in the second quarter of FY22, down from 16 per cent in the first quarter of 2021-22.

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Pharma & healthcare expect govt to boost R&D with incentives to spur drug discovery

Pharma and healthcare see the need for government to boost R&D with incentives to spur drug discovery and disease prevention. With the Union Budget 2022-23 on February 1, the industry is hoping that considerable focus will be given to measures to fight the pandemic. There is need for novel drugs that are affordable and the government needs to announce investments in healthcare to accelerate economic growth.

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Indian Pharma Company inks deal with Chinese business on generic medicines

India's Lupin Limited has entered into partnership with China's Shenzhen Foncoo Pharmaceutical Co. Ltd to take generic medicines to patients in China, the Indian company said in its filing with the Bombay Stock Exchange, Wednesday. "Lupin is committed to serving the healthcare needs of the Chinese population by providing high quality generic and complex generic products," said Fabrice Egros, President of Growth Markets at Lupin.

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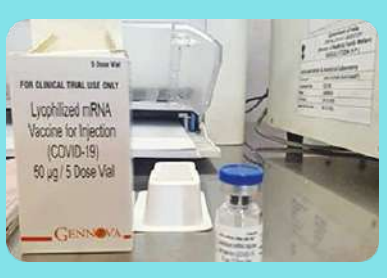
India’s 1st homegrown mRNA vax to be tested amid Omicron spike

Pune-based Genova Biopharmaceuticals has submitted Phase 2 data for mRNA vaccine and has also completed recruitment of Phase 3 data. Official sources said the Subject Expert Committee (SEC) of the Drug Controller General of India (DCGI) is likely to review the data soon. Earlier in the month of September 2021, Genova issued a press statement and updated about the vaccine trials, “The Drug Controller General of India has approved the Phase II and Phase III study protocols for HGCO19, which is India’s first clinical trial.”



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Health ministry amends Drug Rules to include liquid antiseptic under Schedule K

The Union health ministry has issued a final amendment to include liquid antiseptics for household use under the Schedule K of Drugs Rules, 1945 exempting the product category from the requirement of sale license. Through the notification, liquid antiseptics for household use have been added as the 39th entry in Schedule K under the Drugs Rules, 1945. The exemption is from the provisions mandating sale licenses in Form 20 or Form 20A, which is expected to make the use of liquid antiseptics more accessible to the consumer.

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