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The Veeda Newsletter

DECEMBER 2021: ISSUE 12

May the New Year bring you happiness,
peace and prosperity

HAPPY NEW YEAR

Partners in Creating

a healthier tomorrow

Veeda News
Update about our latest training and a new joinee

Regulatory
FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention

Financial
Indian Pharmaceutical Sector: A Catalyst for Investment Opportunities

Clinical Research
Can we live forever? New anti-ageing vaccine could bring immortality one step closer

Merger and Acquisition
Thermo Fisher Scientific Completes PPD Acquisition

Indian Pharma
Indian Pharma Market registers 6.6% growth in November 2021

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Training on Multiply your Growth with Business Skills Mastery by Mr. Bhavin Shah

We conducted an exclusive training held for the Project Management, Sales and Marketing team of Veeda Clinical Research on Effective Client Communication

Welcome Dr. Suresh Kankanwadi

We are delighted to welcome Dr. Suresh Kankanwadi who has joined us as President. Dr. Kankanwadi has more than 25 years of experience including in academia and industry.

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FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention

Today, the U.S. Food and Drug Administration approved Apretude (cabotegravir extended-release injectable suspension) for use in at-risk adults and adolescents weighing at least 35 kilograms (77 pounds) for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV. Apretude is given first as two initiation injections administered one month apart, and then every two months thereafter. Patients can either start their treatment with Apretude or take oral cabotegravir (Vocabria) for four weeks to assess how well they tolerate the drug.

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Euro Roundup: Commission acts to stop Brexit from disrupting supply of medicines

The European Commission has set out how it plans to stop Brexit from disrupting the supply of drugs in certain markets, most notably Northern Ireland. The plan builds on the proposal the Commission made in October as part of the multiple rounds of negotiations with the United Kingdom. Under parts of the Brexit agreement designed to avoid a hard border on Ireland, Northern Ireland, which is part of the UK, is subject to European Union regulations.

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FDA clears second at-home Covid treatment, from Merck

The Food and Drug Administration on Thursday authorized Merck's antiviral pill to treat Covid-19 for emergency use, adding another tool in the nation's arsenal to combat the virus. The FDA's move comes a day after it authorized another antiviral drug, from Pfizer. Merck's treatment, known as molnupiravir and developed in partnership with Ridgeback Biotherapeutics, is cleared for use in adults with mild to moderate Covid who are at risk for severe disease, the agency said in a statement. Pfizer's pill was authorized for people as young as 12.

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DCGI seeks more data from SII over its application for Covovax

The Drugs Controller General of India (DCGI) has raised queries and sought more data from Serum Institute of India over its application seeking emergency authorisation for Covid vaccine Covovax, official sources said on Thursday. Serum Institute of India (SII) had sent an application to the DCGI in October for the grant of market authorisation of Covovax for restricted use in emergency situations.

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EMA launches the Regulatory Science Research Needs initiative

For the first time, EMA has issued a list of regulatory science topics that need further research to close gaps and improve medicine development and evaluation to enable access to innovative medicines for patients. EMA has identified around one hundred specific topics in the Regulatory Science Research Needs list. These topics, and the initiative itself, emerged from the stakeholder consultations which underpinned the development of the Regulatory Science Strategy to 2025. EMA carried out interviews with chairs of its scientific committees and working parties, and also with external experts and opinion leaders from the principal stakeholder groups.

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Indian Pharmaceutical Sector: A Catalyst for Investment Opportunities

The Indian pharmaceutical sector has certain characteristics that ensure its standing in the global market. India is considered as the “Pharmacy of the world”. The reason for such a title caters to the ability of the nation to manufacture bulk quantities of low-cost generic medicines, which is steadily growing with a strong network of 3,000 drug companies and 10,500 manufacturing units, ranking in the third position for pharmaceutical production by volume and 14th by value globally.

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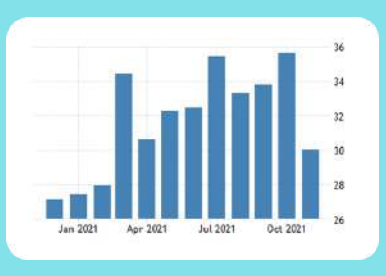
India exports $2.47 billion worth of APIs in April to October, 2021

India has exported active pharmaceutical ingredients (APIs) including bulk drugs and drug intermediates worth $2.47 billion during the first seven months of the current fiscal year, which is around 57 per cent of the total API exports from the country in the previous year. The API exports over the three years from 2018-19 has reported a growth of 13.1 per cent. According to the data from the Ministry of Commerce and Industry, India has exported APIs worth $2.47 billion during the period from April to October, 2021. This is almost 57 per cent of the $4.40 billion export registered during the 12 month period from April 2020 to March, 2021.



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Biogen’s decision to halve price of Alzheimer’s drug is ‘a day late and a dollar short,’ says Raymond James

Biogen Inc.’s decision to cut the price of its Alzheimer’s drug Aduhelm in half starting Jan. 1 is “a day late and a dollar short,” according to Raymond James, which is not expecting the move to change the trajectory of the drug launch or restore Biogen’s battered reputation. “If price represented the only barrier to adoption, we think there would have been some measurable out-of-pocket demand at this point,” analysts led by Danielle Brill wrote in a note to clients.

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India's cumulative COVID-19 vaccination coverage exceeds 135.25 cr

With the administration of 60,12,425 vaccine doses in the last 24 hours, India's COVID-19 vaccination coverage has exceeded 135.25 crore mark, the Union Health Ministry informed on Thursday. As per the ministry's press release, 1,35,25,36,986 COVID-19 vaccines doses have been administered in India as per provisional reports till 7 am today. "This has been achieved through 1,41,93,269 sessions," the ministry said.

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Govt panel weighing risks and benefits of Merck's Covid drug

Antiviral Covid-19 pill Molnupiravir, which received emergency use authorisation (EUA) from the US FDA on Thursday, is likely to be narrowly endorsed in India, people in the know told ET. The Subject Expert Committee (SEC) under the drug regulator of India has asked manufacturers in India to specify the category of Covid patients that are likely to receive the greatest benefit of the treatment from the drug be indicated.

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Can we live forever? New anti-ageing vaccine could bring immortality one step closer

What if you could live forever? It's a question long pondered by fictional supervillains and Silicon Valley billionaires alike. Now researchers in Japan say they may have taken a step toward boosting human longevity with successful trials of a vaccine against the cells that contribute to the ageing process. In laboratory trials, a drug targeting a protein contained in senescent cells - those which have naturally stopped reproducing themselves - slowed the progression of frailty in older mice, the researchers from Tokyo's Juntendo University said.

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Medanta brand owner, Veeda Clinical get Sebi's nod to float IPOs

Global Health Ltd, which operates and manages hospitals under the Medanta brand, and clinical research organisation Veeda Clinical Research has received markets regulator Sebi's go-ahead to raise funds through an initial public offering (IPO). These companies, which filed their preliminary IPO with Sebi in September, obtained its observations on December 21, an update with the regulator showed on Monday. In Sebi parlance, the issuance of observations letter implies its go-ahead for the IPO.

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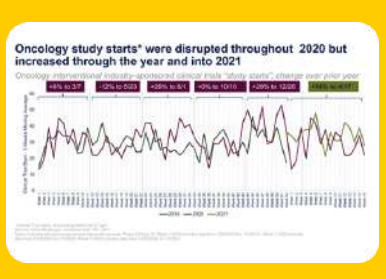
The impact of COVID-19 on cancer care and oncology clinical research: an experts' perspective

The coronavirus disease-19 (COVID-19) pandemic promises to have lasting impacts on cancer clinical trials that could lead to faster patient access to new treatments. In this article, an international panel of oncology experts discusses the lasting impacts of the pandemic on oncology clinical trials and proposes solutions for clinical trial stakeholders, with the support of recent data on worldwide clinical trials collected by IQVIA.



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Representation in Oncology Drug Trials Impacts Patient Health

In clinical trials evaluating the effects of cancer drugs on patient populations, there has been a long-standing, consistent lack of diversity that is representative of the US patient populations likely to receive the treatment.1-3 Additionally, landmark oncology trials frequently fail to report the racial diversity of their patient populations, with one study finding that only 33% of the trials reviewed over a 14-year period reported on ethnicity,1 and a second finding that trials leading to FDA oncology drug approvals reported race only 63% of the time between 2008 and 2018.

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Making clinical trials more successful

The statistics around drug development, especially clinical trials are sobering. A study conducted by the Institute for Safe Medication Practices (ISMP) found that the median cost of pivotal phase III trials was US$48? Million. In addition to overall cost, the study also looked at cost drivers and found that the largest single cost driver was the number of patients required for the study (average estimated cost per patient: US$41,413) followed by the number of trial clinic visits (estimated median cost of each patient visit to the study clinic: US$3,685).

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Thermo Fisher Scientific Completes PPD Acquisition

Thermo Fisher Scientific Inc. has completed its acquisition of PPD, Inc., a global provider of clinical research services to the biopharma and biotech industry, for $17.4 billion. "We are very excited to officially welcome our PPD colleagues to Thermo Fisher Scientific," said Marc N. Casper, chairman, president and chief executive officer of Thermo Fisher Scientific. "Expanding our value proposition for our biotech and pharmaceutical customers with the addition of PPD's leading clinical research services advances our work in bringing life-changing therapies to market, benefitting patients around the world."

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Sanofi Acquires Amunix Pharmaceuticals for $1 Billion

Sanofi announced on Dec. 21, 2021, that it agreed to acquire Amunix Pharmaceuticals, an immuno-oncology company, for approximately $1 billion, with an additional payment of $225 million contingent on various developmental milestones. Amunix's portfolio includes conditionally-activated biologics in the field of immuno-oncology. Amunix's lead candidate is AMX-818, a masked human epidermal growth factor receptor 2-directed T-cell engager (TCE).

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Natco Pharma proposes to acquire Dash Pharmaceuticals

Natco Pharma Limited through its affiliates is proposing to enter into an agreement to acquire Dash Pharmaceuticals LLC subject to satisfactory completion of due diligence, execution of definitive agreements and compliance with statutory requirements. According to a press release issued by the Hyderabad-based drug maker, Dash is a front-end pharmaceutical sales, marketing and distribution entity based in New Jersey, USA which is expected to have approximate net sales of USD 15 million for the year ending December 2021.

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Cipla to acquire 33 per cent stake in Clean Max Auriga Power

Cipla yesterday said it has inked a pact to acquire 33 per cent stake in renewable energy firm Clean Max Auriga Power LLP for up to Rs six crores. In line with the commitment to enhance the share of renewable power source in its operation and to comply with regulatory requirement for being a captive user under electricity laws, the company has entered into agreements to acquire up to 33 per cent partnership interest in Clean Max Auriga Power LLP, the drug maker said in a regulatory filing.

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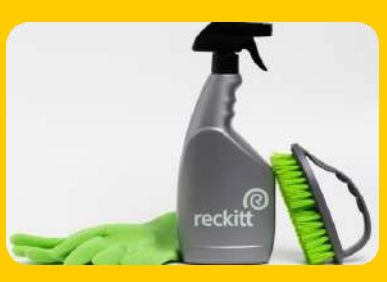
Karo Pharma enters into an agreement for the potential acquisition of the E45® brand from Reckitt

Karo Pharma Aktiebolag ("Karo") has today entered into a put option agreement pursuant to which it may acquire the dermatology brand E45® from Reckitt for total consideration of GBP 200m (the "Transaction"). Subject to the execution of the put option by Reckitt, the acquisition of the E45® brand will be effected through the put option agreement. Completion of the Transaction will additionally be subject to customary conditions including the completion by Reckitt of information and consultation processes with its French works councils.



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Indian Pharma Market registers 6.6% growth in November 2021

The Indian Pharmaceutical Market (IPM) has registered a growth of 6.6 per cent for the month of November 2021, after registering a growth of 5 per cent for the month of October 2021. According to AIOCD AWACS report, moving annual total (MAT) has seen a growth of 15.2 per cent over the corresponding period of last year. Among the top therapies, gastro, respiratory, pain analgesics and gynaec segment continue to show a robust growth for the month of November 21.

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Indian Pharma Industry's response to the pandemic and outlook for the new year

The pandemic continues to be a challenging humanitarian crisis globally with the Omicron variant sparking new fears. With the population facing a risk to their lives and livelihood, an estimated 300 million lives have been impacted and over 5 million casualties around the world by COVID-19. With over 34.7 million cases in the country, and 0.4 million people dead, there is hardly a family to have left unscathed by the virus. The challenges have been equally tough for the healthcare and pharma industry, which have been at the forefront of the pandemic's demands.

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Discerning the next frontier for quality excellence in Indian pharma industry

As the COVID-19 pandemic forced pharma companies and regulators to think out of the box, industry leaders today have advanced tools powered by AI and ML tools to help them comply with quality norms. However, experts also realised that without the "why", employees might not truly understand, and imbibe, the relevance of concepts like quality excellence, data integrity etc. Making these concepts part of the mindset of every employee, not just the quality department, is therefore mission-critical to increase compliance levels and achieve quality excellence.

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Lack of awareness about generic drugs leading to rising healthcare costs among public: Experts

Lack of awareness about the availability of generic medicines at the medical shops and pharmacies is forcing common public to spend more on branded medicines, because of which people are facing the brunt of increasing healthcare costs, opined pharmacy experts from Hyderabad. Most of the experts from the pharmacy profession observed that in India there are thousands of pharma companies which are manufacturing different varieties of generic medicines for various diseases and therapeutic uses and exporting low cost high quality medicines to the world.

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The Future of Pharma: Are CDMOs shaping up a more holistic industry

The Indian pharma industry has witnessed a tremendous growth in the last two decades driven by its strength in the global generics space. Globally, the country is among the largest producers and exporters of active pharmaceutical ingredient (API), generics: supplying 57% of APIs used by the World Health Organization (WHO); meeting 40% of US generic demand and 25% of all drugs in the UK. India occupies 20% export share by volume in the supply of generic medicines worldwide and within the country almost 97% of marketed products are generic.

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