veeda clinical research

The Veeda Newsletter

ISSUE 09: SEP 2020

KEEPING CLINICAL TRIALS
MOVING BEYOND THE PANDEMIC

Our First to File Study

We are proud to have executed the entire Clinical Process of a First to File Study for a leading U.S. based pharmaceutical company

Regulatory

US FDA is setting a higher bar for emergency Covid vaccine approvals

Financial

Indian pharma has potential to be $100bn pharma factory of world: Deloitte

Clinical Research

EMA finalizes pediatric trial preparedness framework

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Indian Pharma

Indian pharma calls for guidance document on disposal of expiry dated drugs

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Coronavirus has a disruptive effect on health systems and healthcare delivery worldwide. Clinical research practice is no exception. Since the onset of the pandemic, social distancing measures and restricted travel decreased patient mobility and investigator and site availability - disrupting clinical trials and drug programmes.

While the Clinical Research Industry was going through this difficult time, we are proud to have executed the entire Clinical Process of a First to File Study for a leading U.S. based pharmaceutical company that specializes in development, manufacturing, and distribution of niche generic products.

Here's a video on how we delivered Quality Results in just 12 day

With over 15 years of experience, we offer an end to end clinical trial support through our robust technology, extensive drug testing environment and unparalleled customer experience.

Know more about us!

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FDA Publishes Comparative Performance Data for COVID-19 Molecular Diagnostic Tests

Today, the U.S. Food and Drug Administration published comparative performance data for some authorized COVID-19 molecular diagnostic tests. The tables show the Limit of Detection (LoD) of more than 55 authorized molecular diagnostic COVID-19 tests against a standardized sample panel provided by the FDA.

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US FDA is setting a higher bar for emergency Covid vaccine approvals

Drug makers seeking an emergency authorization for a Covid-19 vaccine will have to meet a higher standard of efficacy than normally would be required for such a clearance, the head of the U.S. Food and Drug Administration's office that handles vaccines said. Typically, an emergency use authorization, or EUA, would require a company to show their product may be effective.

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DCGI instructs industry to follow defined pathways for application submission of rational FDCs

The Central Drugs Standard Control Organisation (CDSCO) has given the six months' time to existing as well as new manufacturers to submit their applications for obtaining the manufacturing and marketing approval for a total of 86 fixed-dose combinations (FDCs) declared as rational by the DTAB committee.

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MTaI welcomes CDSCO notice on ease of doing business for medical device sector

Medical Technology Association of India (MTaI) has welcomed two CDSCO notices which address operational and regulatory challenges faced by the medical device industry. As per a release, MTaI had apprised the Central Drugs Standard Control Organisation (CDSCO) regarding the issues faced in the SUGAM portal in the post approval change (PAC) submission in changing the name or address of the authorized agent.

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US FDA releases guidance to detect and prevent nitrosamines in drugs

The US Food and Drug Administration (US FDA) has published guidance 'Control of Nitrosamine Impurities in Human Drugs' for immediate implementation. This guidance recommends steps, including a comprehensive risk assessment strategy and other actions that manufacturers can take to reduce or prevent the presence of nitrosamine impurities in their drugs.

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Indian pharma has potential to be $100bn pharma factory of world: Deloitte

India's Pharmaceutical sector is estimated to be at USD 40 billion with USD 32 billion coming from formulation & USD 8 billion coming from API (Active Pharmaceutical Ingredient). Deloitte in its discussion paper says 'Indian Pharmaceutical industry has 'potential to be a USD 100 billion pharma factory of the world'.

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India's pharma firms see strong growth

As the country battles the Covid-19 pandemic, India's pharmaceutical industry and health care services have been in the spotlight. In that scenario, pharma has been one of the few sectors to have expanded during the lockdown and even after the restarting of the economy.

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India's native COVID injections can enhance its own pharma market

India is actually called "the drug store of the planet," and also the label is actually just. The second-most populated nation is actually a medication production goliath. One in 3 supplements eaten in the U.S. is actually helped make in India. Its own manufacturing facilities produce majority the entire world's complete injection source and also make additional common medications than anywhere else.

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Pharma sector to remain a market favourite due to earnings visibility, say analysts

The healthcare index hit a record high on Friday led by a rally in sector majors Lupin, Dr Reddy's Laboratories and Cipla on the back of positive news flow. The sector will remain a market favourite due to earnings visibility, which does not exist for most sectors currently because of the pandemic. Analysts said there is potential for earnings to double in the next five years.

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China hikes prices of key drug ingredients

China has increased prices of key starting materials (KSMs), which are used for making medicines, by 10-20%, leaving those of basic raw materials — or active pharmaceutical ingredients (APIs) — largely unchanged. Both KSMs and APIs are imported in India for making life-saving antibiotics, steroids and other medicines.

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Can Virtual Trials Maintain Their Momentum After COVID?

A conversation with Monica Chmielewski and Kyle Faget, Foley & Lardner LLP, and Laurie Halloran, Halloran Consulting Group. Prior to COVID-19, there were many discussions about how it might be possible to conduct clinical trials in a virtual setting, using technology and innovative measures. While that technology was arguably available long before COVID-19, it really had not been embraced or utilized in a widespread manner. Now that has all changed.

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How to Expedite Drug Development by Waiving Certain Clinical Trials

The COVID-19 pandemic has caused numerous obstacles for clinical research across the world. Widespread movement restrictions, a diversion of healthcare personnel to the frontline and a compromised ability to ensure participant safety are examples of the many challenges faced by the pharmaceutical industry.

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How will clinical trials change in light of COVID-19?

COVID-19 has impacted almost every aspect of society and the scientific R&D industry is no exception. With clinical trial disruptions, cancellations and delays, many studies have not gone to their original plan. However, now that restrictions are being eased globally, some clinical studies can resume, albeit with a few differences.

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AI Bridges Multiple Sclerosis Patients to Relevant Clinical Trials

Clinical trials are a significant milestone in the development of innovative drugs and therapies for people diagnosed with different medical conditions including multiple sclerosis (MS). Many clinical trials are taking place around the world to find and improve treatments and symptom management.

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EMA finalizes pediatric trial preparedness framework

The European Medicines Agency (EMA) has released the final version of a framework for pediatric clinical trial preparedness. The final document aims to “increase the likelihood of a smooth and timely course of a paediatric clinical trial, integrating information from multiple stakeholders on what is possible within individual studies and therefore also for the overall drug development plan within which a trial is embedded,” according to EMA.

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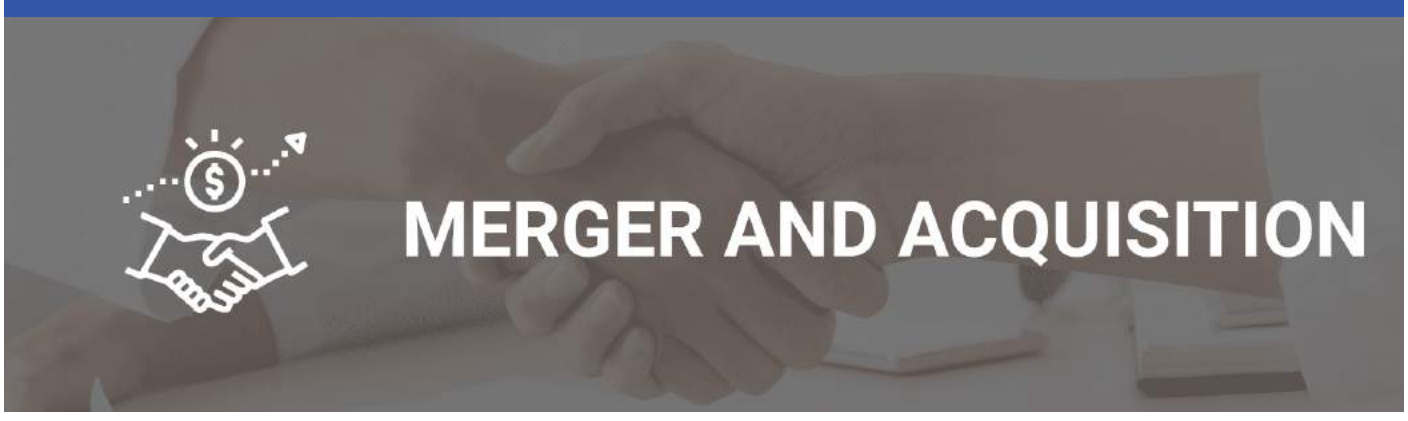

CCI Approves Acquisition Of 20 Percent Stake In Piramal Pharma By Carlyle Group

The Competition Commission of India (CCI) on Friday said it has approved acquisition of 20 percent stake in Piramal Pharma by US-based global investment firm Carlyle Group Inc. Piramal Enterprises, in a regulatory filing, in June had said Carlyle Group Inc will buy 20 percent stake in Piramal Pharma for around USD 490 million (over Rs 3,700 crore).

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Mylan to acquire thrombosis business in Europe from Aspen Pharmacare for EUR 641.9 mn

Mylan announced an agreement to acquire the related intellectual property and commercialisation rights of Aspen Pharmacare Holdings' thrombosis business in Europe for EUR 641.9 million, subject to customary closing conditions and European regulatory clearances.

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Acquisitions and collaborations: September round up

Given that most of the summer months were in lockdown, August and September were surprisingly busy months for acquisitions and collaborations. Here, NutraIngredients rounds up the best of them. At the end of last month, Nestlé Health Science (NHSc) revealed plans to acquire US-based biopharmaceutical firm Aimmune Therapeutics, in a €2.2bn deal that extends its food allergy portfolio.

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Nestlé to acquire BioPharma Company, Aimmune Therapeutics

Nestlé and Aimmune Therapeutics, a BioPharma company developing and commercializing treatments for potentially life-threatening food allergies, have entered into a definitive agreement pursuant to which Nestlé Health Science (NHSc) would acquire Aimmune. Aimmune's Palforzia is the first and only FDA-approved treatment to help reduce the frequency and severity of allergic reaction to peanuts, including anaphylaxis, in children aged 4 through 17. The acquisition is an extension of NHSc's food allergy portfolio.

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Ionis acquires all outstanding shares of akcea

Shares of Akcea Therapeutics were up more than 58% in premarket trading after its majority owner Ionis Pharmaceuticals announced it will acquire all outstanding shares of the company, which amounts to about 24% of available stock for $18.50 per share. With the announcement, shares of Akcea have soared from Friday's closing price of $1138 to $18.10 in early trading. Ionis' acquisition of the remaining shares amounts to a total transaction value of approximately $500 million.

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Why COVID-19 presents a golden opportunity to Indian pharma firms

India is among the leaders in the global pharma industry, being the third-largest producer in terms of volume and at the 10th position in terms of value. A significant raw material base and availability of a skilled workforce have enabled India to emerge as an international manufacturing hub. It is one of the top manufacturers of generic medicines worldwide, with 20 per cent share in their global supply.

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3 vaccines at clinical trial stage in India, SII to begin Phase 3 trial soon: ICMR

The Indian Council of Medical Research (ICMR) said on Tuesday three vaccine candidates against the coronavirus disease (Covid-19) are in the clinical stage of trials in India and one of them will soon begin Phase 3 trials after getting clearances.

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Future of Pharmaceutical industry in India

COVID-19 pandemic is not only a global health catastrophe, it is also a hard-hitting economic crisis for several economies. This period has been a trying time for the manufacturing industries in general, and highlighted the urgency for India to become self-reliant. Though the 'Atmanirbhar Bharat' rhetoric anticipated growth after a brief pause, the continuing pandemic has affected the "self-reliant" discourse quickly.

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Indian pharma calls for guidance document on disposal of expiry dated drugs

The Union government will need to formulate a guidance document on disposal of unused and expiry dated drugs as there is a pressing need for a system of collection, segregation and disposal of pharmaceutical products at the domestic as well as specific stages, said Atul Nasa, Deputy Drugs Controller, Controlling Authority& Licensing Authority, Delhi Drugs Control Department.

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India scaling up production of active pharmaceutical ingredients

India, a global hub for generic drugs, has launched a new scheme to boost production of active pharmaceutical ingredients that are greatly dependent on the Chinese supply chain, according to NITI Aayog CEO Amitabh Kant. Speaking at the 14th Annual BioPharma and Healthcare Summit, he said India is now gearing up for innovation in its pharmaceutical ecosystem focusing on speedy and scaled up delivery of new vaccines and personalised medicines.

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