The Veeda Newsletter

DEC 2020: ISSUE 12

DELIVERING EXCELLENCE IN
CLINICAL STUDIES AND DRUG DEVELOPMENT

Veeda News
Here are the latest news from Veeda Headquarters for the month of December

Regulatory
FDA Takes Additional Action in Fight against COVID-19 by Issuing Emergency Use Authorization for Second COVID-19 Vaccine

Financial
API price normalization: Indian manufacturers well placed to reap long-term growth benefits

Clinical Research
Alliance forms to accelerate adoption of decentralized clinical trials

Merger and Acquisition
The top 5 pharma M&A deals of 2020

Indian Pharma
India and UK to accelerate collaboration on vaccines to prevent future pandemics

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We are delighted to announce that we have been awarded with the BioSpectrum Excellence Awards 2020 (India).

Missed attending our webinar?

Regulatory guidance & detailed evaluation of the new information generated through Pharmacovigilance activities is of paramount importance for all products to ensure their safe use.

We conducted a webinar on Regulatory & Pharmacovigilance Considerations for NCEs on 17th December to discuss this in detail.

If you missed attending it, below is the link to access the complete recording.

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NPRA Updates on Reports of Kidney-Related and Liver-Related Adverse Reactions after Consumption of Ganoderma (Lingzhi / Reishi) Products

Ganoderma lucidum, an oriental fungus, is a large, dark mushroom with a glossy exterior and a woody texture. In China, G. Lucidum is commonly known as lingzhi, and in Japan, reishi or mannentake. It has a long history of use for promoting health and longevity in China, Japan, and other Asian countries.

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MINISTRY OF HEALTH MALAYSIA

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FDA Takes Additional Action in Fight against COVID-19 by Issuing Emergency Use Authorization for Second COVID-19 Vaccine

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the second vaccine for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The emergency use authorization allows the Moderna COVID-19 Vaccine to be distributed in the U.S. for use in individuals 18 years of age and older.

FDA

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FDA Approves First Oral Hormone Therapy for Treating Advanced Prostate Cancer

Today, the U.S. Food and Drug Administration approved Orgovyx (relugolix) for the treatment of adult patients with advanced prostate cancer. The American Cancer Society estimates that in 2020, there will have been more than 190,000 cases of prostate cancer in the U.S.

FDA APPROVED

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India, UK Drug Regulators Agree To Enhance Corporation, Share Information under New Deal

India and the United Kingdom announced a new memorandum of understanding between India's Central Drugs Standard Control Organisation (CDSCO) and the United Kingdom Medicines and Healthcare Products Regulatory Agency (UK MHRA) on Wednesday, December 16.

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FDA Authorizes Antigen Test as First Over-the-Counter Fully At-Home Diagnostic Test for COVID-19

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the first over-the-counter (OTC) fully at-home diagnostic test for COVID-19. The Ellume COVID-19 Home Test is a rapid, lateral flow antigen test, a type of test that runs a liquid sample along a surface with reactive molecules.

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API price normalization: Indian manufacturers well placed to reap long-term growth benefits

Indian API (Active Pharmaceutical Ingredient) manufacturers have remained in focus ever since the start of the pandemic. China's supply disruption earlier and rising API prices thereafter have benefitted Indian manufacturers during the past few quarters.

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Pfizer may price Covid-19 vaccine lower in India than in UK, US.

India may get access to cheaper Pfizer-BioNTech's Covid-19 vaccines as compared to the UK and US, as the nation races to get its hands on effective vaccines after several foreign countries grant approval. Pfizer's vaccine, at $37 per dose, was not one of the major vaccine candidates for the country due to its steep pricing and possible issues with cold storage.

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Australia invests AUSD 4 mn for research with India on COVID-19

The Australian government has invested AUSD 4 million for a joint study, along with Indian researchers, into the long-term health effects of COVID-19 and its early detection, the Australian Industry, Science and Technology minister announced. The Australia-India Strategic Research Fund (AISRF) is financing six new projects, ranging from farming technology to coronavirus detection.

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NPPA fixes price of off patent diabetic drug vildagliptin without consulting industry stakeholders and DoP

The National Pharmaceutical Pricing Authority (NPPA) has fixed price of off patent diabetic fixed dose combination (FDC) drug vildagliptin 50 mg plus metformin hydrochloride 500/850/1000 mg in public interest without consulting Department of Pharmaceuticals (DoP) and industry stakeholders. “By doing so the NPPA clearly went overboard on Drug Prices Control Order-2013 (DPCO 2013) provisions.

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A $69 million India quant fund trounces Sensex in pandemic year

A $69 million Indian quant fund has delivered more than double the returns of the nation’s benchmark stock index this year by avoiding volatile shares and focusing on sector diversification.

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49% of clinical trial disruption due to slow enrollment: Global Data

As of November 30, 2020, the top reason for disrupted clinical trials is slow enrollment, which is causing delays in 49 per cent of trials. The other main reasons for disruptions are enrollment suspension at 35 per cent, and delayed initiation at 16 per cent, as per a statement from Global Data.

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Alliance forms to accelerate adoption of decentralized clinical trials

The Decentralized Trials and Research Alliance (DTRA) recently launched to accelerate the broad adoption of patient-focused decentralized clinical trials and research. It plans to unite stakeholders across the health spectrum to further policies, research practices and technology innovation for decentralized clinical trials.

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Advancing Digital Endpoints in Clinical Trials

With the adoption of digital health technologies, sponsors, CROs, and other stakeholders are discovering how technologies such as wearable devices can enable patient-centric measurement of health markers and that frequent and continuous monitoring beyond the clinic can offer more precise and accurate assessments than traditional observational models.

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How to Overcome Major Pitfalls When Planning Clinical Studies

When clinical investigators and study coordinators start planning a new study design in the new normal, speed and efficiency are paramount. Running a clinical study takes careful planning. Whether this is your 1st clinical study or your 21st, the last thing you probably want to do is waste resources on delays caused by easily-preventable hurdles in data collection.

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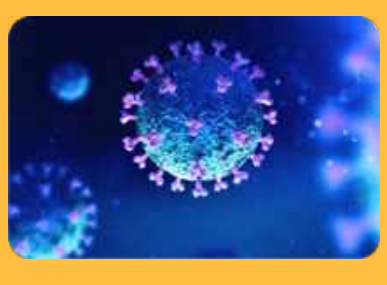
COVID-19 could change clinical trials for the better



In the race to find effective COVID-19 treatments, scientists are setting up clinical trials that test multiple drugs simultaneously, in the hopes of quickly determining which ones work best. These "platform" trials have already led to important breakthroughs. One, sponsored by the University of Oxford, tested multiple treatments, including the antimalarial hydroxychloroquine, HIV protease inhibitors lopinavir and ritonavir, and steroid dexamethasone.

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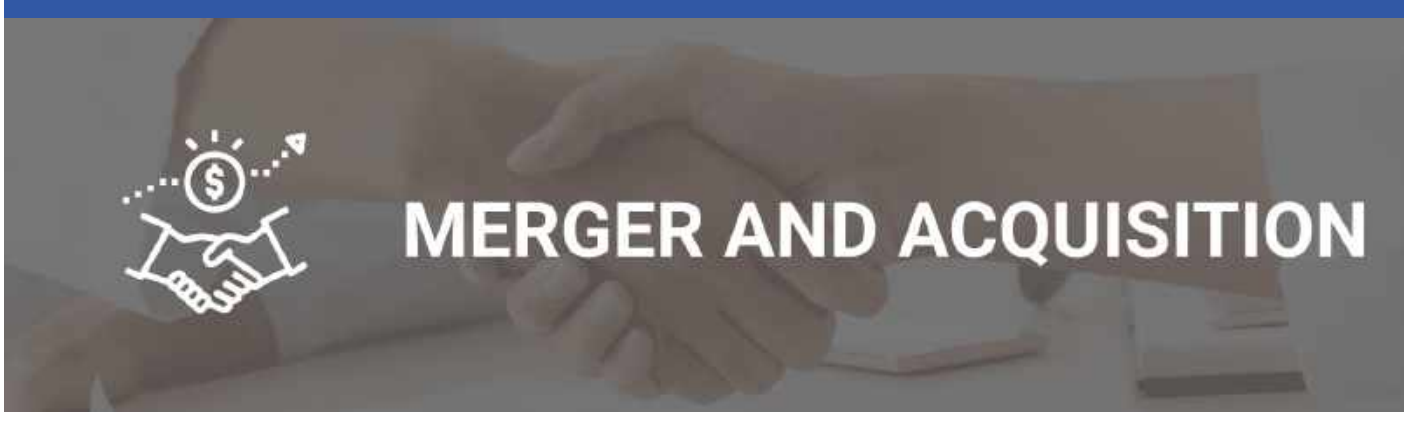

The top 5 pharma M&A deals of 2020

2020's M&A activity hasn't quite reached the heights of last year's, where two pharma mega-mergers – BMS' buyout of Celegne and AbbVie's acquisition of Allergan – accounted for almost 40% of total M&A deal values. That said, there were still some interesting moves indicating new directions of travel for big pharma players – with most deals focused on specific drugs from biotechs, particularly in cancer (though we did get rumours of an AstraZeneca-Gilead merger.

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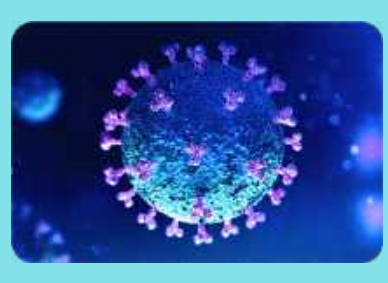
M&A activity remains high despite Covid-19, with mega-deals boosting deal value



Billions of dollars are being spent on mergers & acquisitions (M&A) by Bio/Pharma companies, with average deal value increasing significantly over 2018 and 2019. This year despite the Covid-19 pandemic, M&A activity was boosted by the closing of the $85B acquisition of Allergan by AbbVie in May 2020 to an aggregate deal value almost twice that of 2017, which had the lowest deal value over the last five years.

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Novartis to acquire Cadent Therapeutics for $770 mn

Cadent Therapeutics and Novartis have signed a definitive agreement under which Novartis will acquire all of the outstanding capital stock of Cadent Therapeutics. Upon the closing of the agreement, Cadent will receive a $210 million upfront payment and will be eligible for up to $560 million in milestone payments, for a total potential consideration of $770 million. Cadent Therapeutics launched in 2017 through the merger of Luc Therapeutics and Ataxion Therapeutics, has a focus on small molecules targeting neuronal ion channels.

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Lilly to Acquire Prevail Therapeutics in $1B Deal

Eli Lilly and Co. has entered a definitive agreement to acquire Prevail Therapeutics Inc. for a total consideration of up to $1.04 billion, payable subject to certain terms and conditions. Prevail is a biotechnology company developing potentially disease-modifying AAV9-based gene therapies for neurodegenerative diseases.

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AstraZeneca Acquires US Drug Developer Alexion in Massive $39 Billion Deal

UK-based Pharmaceutical firm AstraZeneca announced signing a $39 billion deal to acquire the US drug developer Alexion on Saturday, December 12. The Boston-based Alexion Pharmaceuticals Inc. and AstraZeneca have entered into a definitive agreement wherein Alexion shareholders will receive $60 in cash and 2.1243 AstraZeneca American Depositary Shares for the acquisition.

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Increasing US demand to benefit Indian Pharma Companies

India Ratings and Research (Ind-Ra) has said Indian pharma companies are expected to benefit from improving demand in the US market. According to the ratings agency, the Indian pharma companies have garnered 45 per cent of all new Abbreviated New Drug Application (ANDA) approvals over the past nine months. Ind-Ra expects the regulatory environment to remain stringent.

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India and UK to accelerate collaboration on vaccines to prevent future pandemics

Experts from India and the UK will join forces through a new virtual hub to deliver vaccines for coronavirus and other deadly viruses, the UK Foreign Secretary Dominic Raab announced in India today (Wednesday 16 December). The Foreign Secretary met Prime Minister Modi to discuss the UK and India working together as a force for good and launching the pioneering new vaccines hub which will share best practice for regulation and clinical trials, and foster innovation.

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India set to deliver 600 million COVID-19 vaccine shots over 6-8 months

Over the next six to eight months, India will attempt to deliver 600 million doses of COVID-19 vaccines using its expansive election machinery. As part of this move, the most vulnerable groups will be given the vaccine, which will be stored in cold chain systems. VK Paul, the head of experts on vaccines told Reuters that cold storage facilities between 2- 8 degree Celsius can be maintained.

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Indian Pharma Industry Touch Millions of Lives through Social Initiatives

Indian Pharmaceutical Alliance (IPA) member companies, through their CSR and social activities, reached to more than 15 million Indians across demographics and geographies during the FY 2018-19 as per IPA Samhita report titled, "Beyond Business: Contributions to Social Initiatives."The report is researched and compiled by IPA in collaboration with Samhita Social Ventures.

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Indian Pharma Firms Vaccine Plans

Several Indian pharmaceutical companies are working to develop or manufacture at least eight anti-Covid-19 formulations as the world's largest producer of vaccines prepares for a massive response to the coronavirus pandemic. India, which has itself been badly hit by the pandemic with nearly 10 million infections.

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