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The Veeda Newsletter

NOV 2020: ISSUE 11

May your blessings be multiplied this year and throughout your life.
Happy Thanksgiving wishes to you!

Veeda Webinar

In the month of November, we conducted webinar on India's Resurgence as a Clinical Trial Destination.

Regulatory

FDA Authorizes Monoclonal Antibodies for Treatment of COVID-19

Financial

Indian Pharma Market registers 9.6% growth in October 2020

Clinical Research

'First of its kind' clinical trial to help lung cancer patients

Merger and Acquisition

Pfizer's Upjohn spinoff completes merger with Mylan to form new generics giant Viatris

Indian Pharma

Govt to provide industrial park facilities to grow API, pharma & nutraceutical industry

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Missed attending our webinars?

As drug development cost and complexity spiral, sponsors continue to face mounting pressures from regulatory agencies, the medical community and the public to reduce costs while improving development time, improving drug quality and safety. India, accounting for nearly 18% of the global population, is an increasingly attractive location for clinical trials, given its large urban population of over 1.3 billion, improving infrastructure and greater focus by governments in supporting medical research.

We conducted a webinar on India's Resurgence as a Clinical Trial Destination on 05th November to discuss this in detail.

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

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FDA Authorizes Monoclonal Antibodies for Treatment of COVID-19

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for casirivimab and imdevimab to be administered together for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age or older weighing at least 40 kilograms [about 88 pounds]) with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progressing to severe COVID-19.

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FDA Authorizes First COVID-19 Test for Self-Testing at Home

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the first COVID-19 diagnostic test for self-testing at home and that provides rapid results. The Lucira COVID-19 All-In-One Test Kit is a molecular (real-time loop mediated amplification reaction) single use test that is intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19.

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Advice for developers of COVID-19 vaccines

Sponsors and researchers developing COVID-19 vaccines are invited to contact the MHRA to discuss their regulatory strategy and plans for filing regulatory submissions in the UK. To support companies' development plans for COVID-19 vaccines the MHRA provides expert scientific and regulatory advice, including on rolling reviews of quality, non-clinical and clinical data, preparation of risk management plans and advice on Good Manufacturing Practice.

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WHO HTS Info app

The first WHO guidelines app from the Department of HIV and Hepatitis provides on-the-go access to WHO's current HIV Testing Services (HTS) guidelines and information. "WHO HTS Info" makes it easy to view WHO guidance on HIV testing on your smartphone or tablet, whether you're online or offline.

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US FDA issues final guidance on execution of clinical trials

The US Food and Drug Administration (FDA) has issued final guidance on designing and executing clinical trials of drugs and biologics to enhance diversity. The guidance 'Enhancing the Diversity of Clinical Trial Populations–Eligibility Criteria, Enrollment Practices, and Trial Designs' has been issued with the agency's recommendations on executing the trials of drugs that include people with different demographic and non-demographic characteristics.

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Indian Pharma Market registers 9.6% growth in October 2020

The Indian Pharmaceutical Market (IPM) has registered a growth of 9.6 per cent for the month of October 2020, after growing at 4.5 per cent in September. According to AIOCD AWACS report, the IPM has recorded sales of Rs. 1,43,999 crore for moving annual total (MAT) basis during October 2020. Amongst the top 10 corporates, Mankind exhibited the highest growth of 8.6 per cent, followed by Torrent Pharma at 7.9 per cent.

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Govt approves Rs 15,000 cr to pharma sector to encourage local manufacturing of drugs

In an endeavour to encourage local manufacturing of drug, the government recently approved Rs 15,000 crore financial outlays over five-year period to the Department of Pharmaceuticals. The decision was undertaken in a Cabinet meeting held recently.

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New $100M Program Aims to Improve Diversity in Clinical Trials

A new $100-million program aims to improve the diversity of participants in U.S. clinical trials with the ultimate goal of achieving better health outcomes and parity in care for underserved patient populations. The initiative seeks to extend the reach of clinical studies to underserved populations in the nation's urban and rural communities, and promote treatment development for all patient groups, the Bristol Myers Squibb Foundation and National Medical Fellowships announced in a press release.

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Why investors need to be overweight on pharma

Investors need to be overweight on pharma as there is a structural story developing there. Overall, the competitive intensity has reduced globally and in the largest US generic market and Indian pharma companies have gained a lot of expertise in managing the regulatory environment.

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To boost pharma investments, Modi Govt sets up panel to revamp policies & draw up action plan

The Modi government has formed an expert committee to identify the bottlenecks in the pharmaceutical industry and design an action plan to attract investments, ThePrint has learnt. In an office memorandum issued 2 November by the Department of Pharmaceuticals (DoP), six representatives were chosen by the government to revamp the pharma policies in India. Of them, five are members from the pharma industry and one is a government official.

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Health dept. to conduct clinical trials of BCG in collaboration with ICMR

The state Health department in collaboration with the Indian Council of Medical Research (ICMR) is set to conduct the clinical trial of BCG vaccine against Covid in December. This is for the first time when a state government department is tieing up with a Centre owned organisation to carry out a trial in the city to check the efficacy of BCG vaccine against Covid. Earlier, the ICMR had carried out a similar trial with the NICED in Kolkata.

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‘First of its kind’ clinical trial to help lung cancer patients

Lung cancer is the third most common cancer in the UK, with around 47,800 people diagnosed each year. Around 80 – 85% of lung cancers in the UK are non-small cell lung cancer (NSCLC), which start in the mucus making gland cells in the lining of the airways. Approximately 25% of NSCLC lung cancer patients are diagnosed with stage 3 disease, meaning that the cancer has spread from where it started to nearby tissue or lymph nodes.

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What COVID-19 has taught us about clinical trials

With the United States firmly in the grip of a COVID-19 surge, the race to prevent and treat infections is more important than ever? At the heart of this effort are drug and vaccine clinical trials that are being planned, developed and executed at an accelerated rate. To this end, the Food and Drug Administration has approved an emergency program that provides rapid reviews for COVID-19 clinical trials.

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Sex differences and women’s representation in clinical trials

In 1993, the US National Institutes of Health (NIH) introduced its Revitalization Act, which mandates that Phase 3 clinical trials funded by the NIH must actively include women and minority group subjects, where this is appropriate to the research.

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Eye on joint clinical trials, India training nations in South Asia

As India prepares to administer a vaccine against the novel coronavirus infection to its population early next year, it is working with countries in its neighbourhood on possible collaborative clinical trials of vaccine candidates in the future. A specialist team of scientists and researchers from the Indian Council of Medical Research and the Department of Biotechnology under the Union Ministry of Science and Technology, has imparted training to doctors and regulators in at least seven countries.

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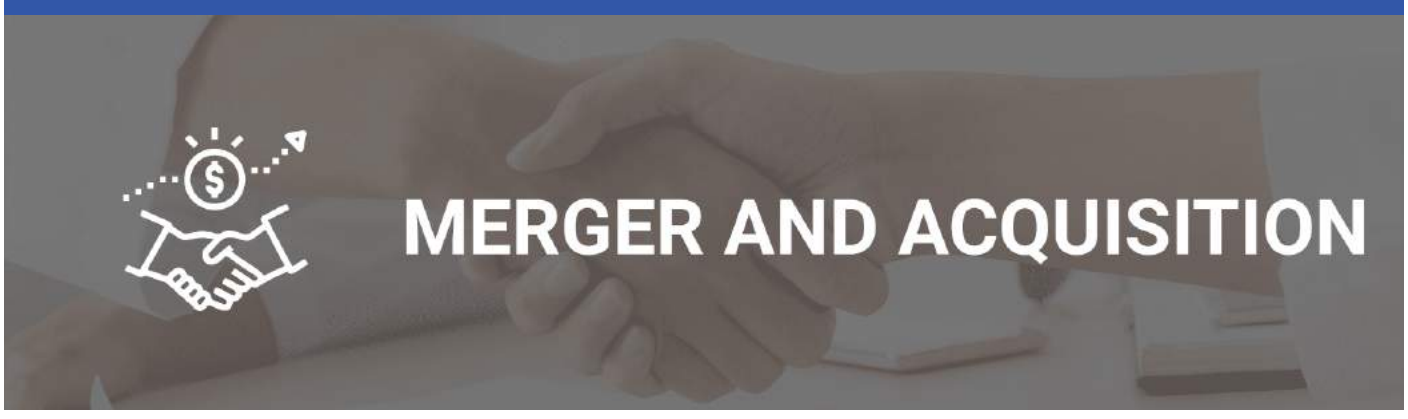

Merck acquires VelosBio: exploring the promise of ROR1 in cancer

Pharma giant Merck has entered into a definitive agreement to acquire oncology biotech VelosBio for $2.75bn in cash. The acquisition remains subject to certain customary adjustments and conditions; the deal is expected to be closed by the end of 2020. Pharma giant Merck has entered into a definitive agreement to acquire oncology biotech VelosBio for $2.75bn in cash.

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Pfizer's Upjohn spinoff completes merger with Mylan to form new generics giant Viatris

Viatris, a new global healthcare company launched through the merger of Mylan and Upjohn – the legacy division of Pfizer, started trading on Tuesday. The newly merged entity is forecast to have a market capitalisation of about $24 billion and will include in its portfolio blockbuster products like Pfizer's Viagra and Mylan's EpiPen.

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CCL acquires Strathealth Pharma

CCL Pharmaceuticals is a leading regional multinational company with over 50 years of experience in the pursuit of health and wellbeing, a statement said on Wednesday. With operations in over 16 countries across South Asia, South East Asia, Central Asia and Africa, offering a vast range of over 200 products in major therapeutic categories, it added..

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Novo Nordisk set to acquire Emisphere Technology for $1.8bn

Danish pharma company Novo Nordisk has announced an agreement to acquire drug delivery specialist Emisphere Technologies for $1.8bn. Following the acquisition deal completion, Novo will pick up Emisphere's drug delivery technology – Eligen SNAC – which it uses in its oral diabetes drug Rybelsus (oral semaglutide).

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Aurobindo Pharma Ltd completes acquisition of 100% ownership of Eugia Pharma Specialities

Aurobindo Pharma Ltd had earlier announced about entering into a share purchase agreement to acquire 100% equity share capital of MViyeS Pharma Ventures Private Limited (MViyeS). The aforesaid acquisition has been completed on November 6, 2020.

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Govt to provide industrial park facilities to grow API, pharma & nutraceutical industry

The government is proactively looking to provide industrial park facilities to grow active pharmaceutical ingredient (API), pharmaceutical and nutraceutical industry, Chemicals and Fertilizers Minister D V Sadananda Gowda has said. Indian pharma industry will continue to play a prominent role as the pharmacy of the world, the Chemicals and Fertilizers Ministry said in a statement.

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Gujarat FDCA asks DCGI and ICMR to encourage use of CP therapy in COVID-19 patients

The Gujarat Food and Drug Control Administration (FDCA) has asked the Drugs Controller General of India (DCGI) and Indian Council of Medical Research (ICMR) to encourage use of convalescent plasma (CP) therapy in COVID-19 patients. This is the following evidence based advisory of ICMR issued to the stakeholders to address inappropriate use of convalescent plasma in COVID-19 patients.

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Indian Cabinet approves MoU with UK over medical product regulation

The Indian Cabinet has given its approval for signing a memorandum of understanding (MoU) between the Central Drugs Standard Control Organisation (CDSCO) and the United Kingdom Medicines and Healthcare Products Regulatory Agency for cooperation in medical products regulation, according to an official statement.

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Twin challenges for Indian pharma-boosting drug discovery and localizing API production

India is often referred to as the ‘pharmacy of the world’; not without reason. The third largest pharmaceutical market in the world by volume, India supplies a bulk of generic drugs globally not just to under-developed countries but also to the US and UK.

Read More

DoP issues revised guidelines for procurement of Make in India medical device

Department of Pharmaceuticals
Ministry of Chemicals and Fertilizers
Government of India

The Department of Pharmaceuticals (DoP) has issued revised guidelines for implementing the provisions of public procurement (preference to Make in India) Order (PPO)- 2017 DPITT guidelines for procurement of Make in India medical devices. The Department for Promotion of Industry and Internal Trade (DPIIT), pursuant to Rule 153 (iii) of the general financial rules 2017, had issued PPO - 2017 dated June 15, 2017 which was partially modified on May 28, 2018, May 29, 2019 and September 16, 2020.

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