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The Veeda Newsletter

MARCH 2021: ISSUE 03

Veeda Clinical Research acquires stake in preclinical CRO, Bioneeds

16 YEARS OF DELIVERING EXCELLENCE

Veeda News
Glimpse of our inaugural event for Ingenuity BioSciences

Regulatory
FDA Authorizes First Machine Learning-Based Screening Device to Identify Certain Biomarkers That May Indicate COVID-19 Infection

Financial
Australia to support clinical trials for mental illness treatments

Clinical Research
Clinical trials are adapting with new tech in the COVID era

Merger and Acquisition
FTC launches pharma merger analysis group

Indian Pharma
Indian Pharma Market growth slips to 1.1% in February 2021

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The Veeda Newsletter

MARCH 2021: ISSUE 03

Glimpse of the International Women's Day celebration at Veeda. We invited two prolific guests to speak on Women Empowerment and the importance of Healthy Nutrition for Working Women.

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The Veeda Newsletter

MARCH 2021: ISSUE 03

FDA Authorizes First Machine Learning-Based Screening Device to Identify Certain Biomarkers That May Indicate COVID-19 Infection

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the first machine learning-based Coronavirus Disease 2019 (COVID-19) non-diagnostic screening device that identifies certain biomarkers that are indicative of some types of conditions, such as hyper coagulation (a condition causing blood to clot more easily than normal).

FDA U.S. FOOD & DRUG ADMINISTRATION

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Is U.S. FDA getting tougher under Biden?

Although U.S. President Joe Biden has yet to nominate his choice to lead the FDA, his nomination of Xavier Becerra as the next Health and Human Services (HHS) secretary – and Becerra's Senate confirmation March 18 could signal a shift to a more conservative approach at the FDA.

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WHO publishes new clinical and service delivery recommendations for HIV prevention, treatment and care

These guidelines provide new and updated recommendations on the use of point-of-care testing in children under 18 months of age and point-of-care tests to monitor treatment in people living with HIV; the treatment monitoring algorithm; and timing of antiretroviral therapy (ART) among people living with HIV who are being treated for tuberculosis.

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FDA Issues Authorization for First Molecular Non-Prescription, At-Home Test

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the Cue COVID-19 Test for Home and Over the Counter (OTC) Use. The product is a molecular nucleic acid amplification test (NAAT) that is intended to detect genetic material from SARS-CoV-2 virus present in the nostrils.

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EMA issues advice on use of antibody combination (bamlanivimab / etesevimab)

EMA's human medicines committee (CHMP) has completed its review on the use of the monoclonal antibodies bamlanivimab and etesevimab to treat patients with COVID-19. This review was undertaken to provide a harmonized scientific opinion at EU level to support national decision making on the possible use of the antibodies prior to marketing authorization.

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The Veeda Newsletter

MARCH 2021: ISSUE 03

Australia to support clinical trials for mental illness treatments

The Australian Government is launching a competitive grant round of $11.6m (A$15m) to kick-start clinical trials to develop treatments for mental illness. The A$15m Innovative Therapies for Mental Illness Grant Opportunity under the Medical Research Future Fund (MRFF) will be used to explore the use of combination therapies to treat debilitating mental illnesses, such as anxiety disorders, depression, and substance abuse disorders.

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NPPA devices cos to submit price related info for price monitoring exercise extends deadline till April 15 for medical

The National Pharmaceutical Pricing Authority (NPPA) has extended deadline till April 15, 2021 for medical devices manufacturers of all non-scheduled medical devices covering 24 categories to submit price related information for price monitoring exercise from the earlier deadline of March 11, 2021. NPPA on Februray 16, 2021 had issued an office memorandum (OM) wherein it was directed to submit price related information in the prescribed format for 24 categories of non-scheduled medical devices.

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NPPA makes price revision on pharma products based on commerce ministry's annual change in WPI

The National Pharmaceutical Pricing Authority (NPPA) has made price revision on pharma products based on Union commerce ministry's annual change in WPI at 0.53638% during the calendar year 2020 over the corresponding period in 2019. The WPI data is available on the website of the office of the economic advisor, Department for Promotion of Industry and Internal Trade (DIPP).

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European stocks move higher despite anxieties around rollout of COVID-19 vaccines

European stocks opened higher on Tuesday, chasing Monday's momentum from Wall Street as concerns continue over the rollout of COVID-19 vaccines across the continent. The pan-European Stoxx 600 SXXP, +0.19% rose near 0.9%, while London's FTSE 100 UKX, +0.26% was 0.7% higher. The CAC 40 PX1, -0.49% in Paris was up 0.4% and Frankfurt's DAX DAX, +0.25% lifted 0.9%.

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Govt places new purchase order with SII for 10 crore doses of Covishield vaccine

The Centre has placed a new purchase order with the Serum Institute of India (SII) for the supply of 10 crore doses of the Oxford-AstraZeneca COVID-19 vaccine, Covishield, each costing Rs 157.50, including GST, according to official sources. The HLL Lifecare Limited, a public sector undertaking, has issued the supply order on behalf of the Union health ministry on March 12.

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The Veeda Newsletter

MARCH 2021: ISSUE 03

Clinical trials are adapting with new tech in the COVID era

As the COVID-19 pandemic rages on, clinical trial conduct is being reimagined in ways few thought possible. As all stakeholders rethink how to develop protocols, consent patients, ensure compliance, and gather quality clinical trial data when patients and staff are remote, patient centricity has stepped to the forefront.

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Automating Clinical Trials: Why it's Essential for Success

Many companies in the life sciences industry are slow to adopt new technologies due to complex regulatory requirements. However, there's been a lot of advancement in new and emerging technologies in recent years. The US FDA has recognized the benefits and is supportive of their use. Running clinical trials costs a lot of money! Despite that, there's no guarantee of success.

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How Remote Patient Monitoring and Biomarkers Are Changing in Clinical Research

Biomarkers, or biological markers, are objective measurements indicative of a specific biological state, often measured to evaluate a particular condition or process. At its most basic form, a biomarker can be a single data point such as temperature, or it can be a more complex combination of data points that together indicate the presence, imminence or severity of a physiological situation.

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Globalization of Cancer Clinical Trials Widened Racial Disparity Gap for Black Enrollees

The globalization of cancer clinical trials resulted in fewer Black patients being enrolled, further widening the racial gap in cancer clinical trials, a study suggests. "There have been a number of studies investigating factors such as access to healthcare, physician biases, and socioeconomic status that may lead to underrepresentation of Black patients," said Serena Tharakan, BS, of the Icahn School of Medicine at Mount Sinai in New York City, in a press release.

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Bringing clinical trials to the people

Traditional clinical trials are costly, inefficient and logistically demanding. Recruiting volunteers and patients, and then being able to retain them has long been a problem. With the world expected to see more infectious disease outbreaks in future, traditional trial models and practices are no longer sustainable. The pharmaceutical industry needs a new and innovative approach to clinical trials – one that will ensure patients have access to lifesaving treatments.

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FTC launches pharma merger analysis group

The Federal Trade Commission (FTC) is launching a new international working group in an "imperative" move to better analyse the impact of pharmaceutical mergers. Among the working group's goals, it aims to develop understanding of the impact big pharma mergers have on innovation in the market.

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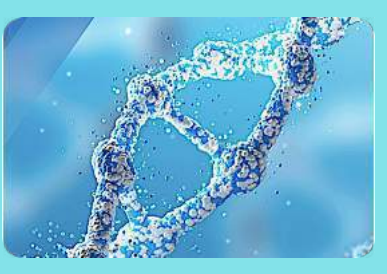
WuXi Biologics to Acquire CMAB Biopharma Group

WuXi Biologics entered into a purchase agreement with CBC Group, a healthcare-dedicated investment firm, and other companies including Ming Bioventures under which WuXi Bio will acquire over 90% interest of CMAB Biopharma Group.



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Romaco Acquires STE Tecpharm

Romaco Holding GmbH has acquired STE Tecpharm, S. L., a Spanish manufacturer of processing technology, which will operate under the name Romaco Tecpharm, S. L. Romaco has initially acquired 75 percent of the share capital of STE Tecpharm, S. L., which was previously owner-managed. The remaining 25 percent will be transferred subsequently.

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Creso Pharma expanding into psychedelics with planned acquisition

Creso Pharma (ASX: CPH) is looking to tap into the emerging psychedelics medicine market with the proposed acquisition of Canadian company Halucenex worth more than $7 million. If successful, the deal would give Creso a foothold in the growing global medical market for psychedelics like LSD, psilocybin and MDMA estimated to be worth up to US$100 billion.

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Sun Pharma subsidiary to acquire 12.5% stake in WRS Bioproducts

Sun Pharmaceutical Industries, an international, integrated, speciality pharmaceutical company, announced that one of its wholly-owned subsidiaries has agreed to acquire 428,571 ordinary shares (equivalent to 12.5% stake) in WRS Bioproducts, Australia. WRS Bioproducts, an early stage company based in Australia, developing novel technologies to produce and commercialize supplements and nutraceutical ingredients from diverse algae species.

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The Veeda Newsletter

MARCH 2021: ISSUE 03

India working to develop patient-centric medication management and patient safety culture: Expert

India is now working to develop a patient-centric medication management and patient safety culture. This is where the increasing importance of pharmacists at every outlet is mandated to enable safe prescription practices and prevent unsafe use of medicines. Efforts are now on by India to further strengthen its pharmacovigilance Programme.

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India pushes for continued growth in the Pharma Sector

India's pharmaceutical and life sciences industry plays a pivotal role on the world stage, fulfilling over 50% of the global demand for vaccines, 40% of demand for generic drugs in the USA and 25% of all medicines in the UK. India continues to be the world's largest supplier of cost-effective generic drugs. The Indian pharmaceutical industry has performed strongly over the past two (2) decades attracting foreign investments of over INR878.14 billion (approx. US$11.90 billion) from April 2000 to March 2020.

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Indian Pharma Market growth slips to 1.1% in February 2021

The Indian Pharmaceutical Market (IPM) has registered a growth of 1.1% for the month of February 2021, after registering a growth of 4.5% for the month of January 2021. According to AIOCD AWACS report, the IPM has recorded sales of Rs. 1, 46,104 crore for moving annual total (MAT) basis during February 2021. Amongst the top 10 corporates, Cipla exhibited the highest growth of 7.3 per cent, followed by Torrent Pharma at 5.5 per cent.

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Launch of generic brands for expensive oncology drugs improves treatment affordability and access in India

The Central Drugs Standard Control Organization (CDSCO) has recently approved several generic versions of sunitinib to treat kidney cancer. Against this backdrop, the approval of generic brands of expensive oncology drugs will not only help in reducing the cost of these life-saving drugs, but also improve access and adherence to treatment in the future, says Global Data.

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India's pharma industry revaluating reliance on China APIs

Significant disruptions to supplies of active pharmaceutical ingredients (APIs) from China caused by the COVID-19 pandemic have led India to fundamentally rethink its supply chains and the structure of its pharmaceutical industry, according to industry executives and consultants.

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The Veeda Newsletter

MARCH 2021: ISSUE 03

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