The Veeda Newsletter

JAN 2021: ISSUE 01

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Veeda News
Awarded as the Best Quality Clinical Research Services in India

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FDA Approves First Extended-Release, Injectable Drug Regimen for Adults Living with HIV

Financial
Indian Pharma Market registers 8.5% growth in December 2020

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Lilly Completes $1B Acquisition of Prevail

Indian Pharma
India begins Covid-19 vaccine exports to Brazil, Saudi Arabia

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We are delighted to announce that we have been awarded as the Best Quality Clinical Research Services in India by Praxis Media Private Limited.

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Anvisa's guidelines for vaccination services

Which provides for recommendations for vaccination services during the pandemic period, is now available for consultation. The document aims to help state health departments, municipal and Federal District and local health surveillance in planning immunization activities, as well as guidance services for the vaccination campaign against the Covid-19.

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FDA Approves First Extended-Release, Injectable Drug Regimen for Adults Living with HIV

The U.S. Food and Drug Administration today approved Cabenuva (cabotegravir and rilpivirine, injectable formulation) as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults to replace a current antiretroviral regimen in those who are virologically suppressed on a stable antiretroviral regimen.

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Global regulators highlight key role of healthcare professionals in fostering confidence in COVID-19 vaccines

EMA has endorsed a joint statement published today by the International Coalition of Medicines Regulatory Authorities (ICMRA) to inform and help healthcare professionals answer questions about the evaluation, approval and monitoring of safe, effective and high-quality COVID-19 vaccines.

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FDA Releases Artificial Intelligence/Machine Learning Action Plan

Today, the U.S. Food and Drug Administration released the agency's first Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan. This action plan describes a multi-pronged approach to advance the Agency's oversight of AI/ML-based medical software.

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UNICEF, WHO, IFRC and MSF announce the establishment of a global Ebola vaccine stockpile

The four leading international health and humanitarian organizations announced today the establishment of a global Ebola vaccine stockpile to ensure outbreak response. The effort to establish the stockpile was led by the International Coordinating Group (ICG) on Vaccine Provision, which includes the WHO, UNICEF, IFRC, and (MSF), with financial support from Gavi, the Vaccine Alliance.

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SII receives purchase order from Government of India for 11 million doses of Covishield

The government placed a purchase order with Serum Institute of India (SII) for 11 million doses of Oxford COVID-19 vaccine, Covishield, each dose costing Rs 210 including GST, official sources said. Dispatch of the vaccine is likely to start by late Monday evening, they said.

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Margin improvement, volume-led growth to return in India for pharma companies

The Indian pharmaceutical companies are expected to see a rise in their operating margins on improved product mixes and cost control along with normalization in volume growth during the quarter ending December 2020, analysts said.

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Indian Pharma Market registers 8.5% growth in December 2020

The Indian Pharmaceutical Market (IPM) has registered a growth of 8.5 per cent for the month of December 2020, as against growth of one per cent in November 2020. According to AIOCD AWACS report, the IPM has recorded sales of Rs. 1,45,354 crore for moving annual total (MAT) basis during December 2020.

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NPPA Calls for Tighter Control on FDC Drugs

Calling for tighter controls on Fixed Dose Combinations (FDC) drugs and their rationality, the National Pharmaceutical Pricing Authority (NPPA) is now going to take up the matter with the Union Health Ministry.This came after the Authority noted that most of the retail price applications of new drugs mainly consist of Fixed Dose Combinations (FDCs) of two or more drugs following which the National Pharmaceutical Pricing Authority (NPPA) has decided to raise concerns on drug cocktails before the Ministry of Health and Family Welfare (MoHFW).

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BioNTech, Pfizer to sell 40 million doses to lower-income countries

BioNTech SE BNTX, +2.85% and Pfizer Inc. PFE, +0.19% said Friday that they plan to sell 40 million doses of their COVID-19 vaccine this year to Covax, a group that aims to ensure 92 lower-income countries have access to coronavirus vaccines. BioNTech's stock gained 1.2% in trading on Friday, while shares of Pfizer were up 0.3%.

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Clinical research of advanced regenerative medicine to be put under state control

The government has named stem cells and gene therapy as "K-regenerative medicine" and established a basic plan to advance regenerative medicine over the next five years. Under the plan, the government will review all advanced regenerative medicine clinical research and link the area to state health insurance to accelerate the regenerative medicine field and national benefits.

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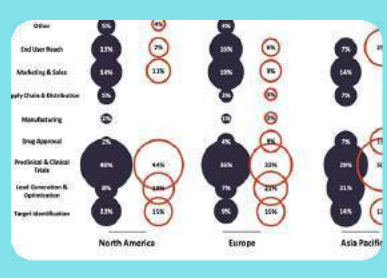
Pre-clinical and clinical trial processes likely to benefit most from digital transformation: Survey

Declining profit margins and increasing costs have prompted the pharmaceutical industry to expedite digital transformation to adopt to the changing business environment. GlobalData has conducted surveys in 2019 and 2020 across North America, Asia Pacific and Europe to assess which processes within the life science sector are expected to benefit the most from this digital transformation.



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Digitisation of clinical trials surged over the last decade

The use of digital technologies in clinical trials in the last decade has increased exponentially, according to data from GlobalData's pharmaceutical, medical devices and clinical trials databases. The advent of smartphones and other wearable devices have transformed the way clinical trials are being conducted across the world.

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The Changing Clinical Trials Landscape

Clinical trials are becoming more and more precise. We've learned that both the biology of a patient's tumor and their genetic makeup can impact treatment options that may work best for them. Results from PanCAN's Know Your Tumor® precision medicine service showed that patients who were able to go on treatment that aligned with their tumor biology lived an average of one year longer than patients who weren't able to get matched treatment.

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Pandemic Accelerates the Evolution of Clinical Trials

How much has the COVID-19 pandemic accelerated the evolution of clinical trials? A new report from Oracle Health Sciences and Informa Pharma Intelligence attempts to answer that question. The companies surveyed 252 professionals around the world who are involved in clinical trials at biopharmaceutical and med device companies as well as CROs. The goal was to determine how the pandemic was changing clinical trial operations and identify the key challenges and opportunities surrounding those changes.

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Lilly Completes $1B Acquisition of Prevail

Eli Lilly and Company has successfully completed its $1.04 billion acquisition of Prevail Therapeutics Inc., adding a new modality for drug discovery and development at Lilly, and extending research efforts through the creation of a gene therapy program that will be anchored by Prevail's portfolio of clinical-stage and preclinical neuroscience assets.

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Nexelis acquires the GSK vaccines clinical bioanalytical laboratory located in Marburg - Germany and enters into a 5-year strategic agreement with GSK

Nexelis, a portfolio company of Ampersand Capital Partners, and a leading provider of advanced assay development and laboratory testing services in the infectious, oncologic, and metabolic diseases fields, has signed an asset purchase agreement with GSK to acquire its GCLP-certified clinical bioanalytical laboratory located in Marburg, Germany.

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Beximco Pharma to acquire majority stake in Sanofi Bangladesh

It has not disclosed the amount of proposed transaction but said it has signed an agreement to acquire the majority shares of Sanofi Bangladesh, Beximco said in a press release. Sanofi Group currently holds 54.6 percent shares in the paid-up capital of Sanofi Bangladesh. Industries ministry holds nearly 25.36 percent and Bangladesh Chemical Industries Corporations holds around 19.96 percent shares of Sanofi Bangladesh.

BEXIMCO PHARMA here's to life

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Radiant Pharma acquires Julphar for Tk 140cr

Radiant Pharmaceuticals has acquired Julphar Bangladesh, a subsidiary of United Arab Emirates-based multinational Julphar Gulf Pharmaceutical Industries, for around Tk 140 crore. It is the latest development in a series of what seems to be an exodus of multinationals selling off their local ventures such as Pfizer of the US, Hoechst of Germany and Organon Pharmaceuticals of the Netherlands.

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Sanofi to acquire clinical-stage biopharma firm Kymab for $1.45bn

Sanofi has signed an agreement to acquire clinical-stage biopharmaceutical company Kymab for an upfront payment of about $1.1bn in cash. The deal also includes payment of up to $350m on achieving particular milestones.

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India begins Covid-19 vaccine exports to Brazil, Saudi Arabia

India will begin commercial shipments of Covid-19 vaccines to Brazil and Morocco Friday, followed by Saudi Arabia and South Africa, as Prime Minister Narendra Modi attempts to burnish his credentials as a key global leader. ”There’s huge international demand for our vaccines,” foreign secretary Harsh Shringla told Bloomberg TV in an interview.

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India to gift two million doses of Covishield COVID-19 vaccine to Bangladesh

India will gift Bangladesh two million doses of Covishield Indian vaccine produced by Serum Institute of India on January 20. Covishield is an Oxford-AstraZeneca vaccine and the gifted consignment will arrive at Hazrat Shahjalal International Airport Dhaka. This is in the final planning stages even certain preparations have started in Dhaka.

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Indian pharma industry has risen to occasion during the pandemic

The Indian pharma industry has risen to the occasion and has made efforts to ensure that medicines and vaccines reach people during the pandemic, Dr Reddy's Laboratories Chairman Satish Reddy said on Friday. Speaking at the 25th Wharton India Economic Forum, he said the Indian pharma industry ensured the continuity of supplies.

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India’s Pharma industry and challenges from China

India and China are the two most consequential countries in the world. China is the largest populated country in the world, closely followed by India that is projected to overtake China in the near future.

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Health ministry to strengthen role of AMCs for AEFI surveillance system

Even as the country is bracing up for the vaccination for coronavirus, the Union health ministry is in the process of outlining a plan to strengthen the role of 311 adverse drug reaction (ADR) monitoring centers (AMCs) under the Pharmacovigilance Programme of India (PvPI) for the adverse events following immunization (AEFI) surveillance system.

Ministry of Health & Family Welf
Government of India

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For any further information or Business enquiry contact us at info@veedacr.com

ADDRESS:

VEEDA CLINICAL RESEARCH® PVT. LTD.
Veeda House, Beside YMCA club S.G. Highway, Vejalpur, Ahmedabad- 380015, Gujarat, India

ADDRESS:

Registered Office

- Shivalik Plaza-A, Near IIM Ambawadi, Ahmedabad- 380015, Gujarat, India. CIN No. U73100GJ2004PTC044023
- Insignia, Besides Auda Garden, Opp. Zenobia Residency, Sindhu Bhavan Road, Off. S. G. Highway, Bodakdev, Ahmedabad- 380059, Gujarat, India
- Radhe Palladium, Floor 1st (Shop No 9, 10 & 11), 2nd & 3rd Floor Panchot, Nr. Panchot Bypass Circle, N. H. No. 6, Mehsana, Gujarat – 384002