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Veeda Group at the Biopharma Conclave

Veeda Group recently attended the Biopharma Conclave on 29th and 30th September in Hyderabad.

This comprehensive 2-day conclave had parallel sessions on Biologics, Biosimilars, Cell & Gene Therapy and Vaccines.

Our experts Mr Rajkumar Agarwal, Dr Ravi Krovidi, Dr Mallikarjun Dixit and Mr Yashwant Kurnool were present at our physical booth to share how we can support your end to end drug development programs, right from drug discovery to post-marketing surveillance.

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FDA Takes Steps Aimed at Improving Quality, Safety and Efficacy of Sunscreens

The U.S. Food and Drug Administration today took steps aimed at improving the quality, safety, and efficacy of sunscreens as part of its implementation of new authorities for certain over-the-counter (OTC) drugs. In the short term, these new authorities essentially preserve status quo marketing conditions for these sunscreens. However, the agency today proposed revisions and updates to those requirements related to maximum sun protection factor (SPF) values, active ingredients, broad spectrum requirements, and product labeling, among other provisions. “Sun safety is important for everyone, regardless of your skin tone.

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U.S. authorises Pfizer booster for the elderly and high-risk

The U.S. moved a step closer Wednesday to offering booster doses of Pfizer’s COVID-19 vaccine to senior citizens and others at high risk from the virus as the Food and Drug Administration signed off on the targeted use of extra shots. The FDA authorized booster doses for Americans who are 65 and older, younger adults with underlying health conditions and those in jobs that put them at high risk for COVID-19.

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FDA Issues Draft Guidance on Donor Eligibility and Manufacturing of Cellular Therapies for Animals

Today, the U.S Food and Drug Administration issued for public comment two draft guidance documents that, if finalized, will help manufacturers of animal cells, tissues, and cell- and tissue-based products (ACTPs) understand current good manufacturing practice requirements (CGMPs) for new animal drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act). CGMPs help prevent contamination and help ensure ACTP quality.

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U.S. FDA approves first biosimilar rival to Roche’s blockbuster eye drug

The U.S. Food and Drug Administration on Monday approved South Korean drugmaker Samsung Bioepis Co Ltd and Biogen Inc’s biosimilar rival to Roche Holding AG’s blockbuster eye drug, Lucentis. Biosimilars are cheaper versions of biologic drugs made from living organisms. Lucentis, which already faces competition from Novartis AG’s Beovu, is approved to treat eye diseases such as wet age-related macular degeneration and brought in sales of CHF 1.4 billion ($1.50 billion) in 2020.

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WHO calls on world leaders at the UN General Assembly to focus on vaccine equity, pandemic preparedness, and getting the SDGs back on track.

WHO is urging leaders attending the 76th session of the United Nations General Assembly (UNGA) to guarantee equitable access to COVID-19 vaccines and other life-saving tools; ensure the world is better prepared to respond to future pandemics; and renew efforts to achieve the Sustainable Development Goals (SDGs). The COVID-19 pandemic has already claimed the lives of nearly 5 million people around the globe, and the virus continues to circulate actively in all regions of the world.

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AstraZeneca invests in Imperial's self-amplifying RNA technology with eye on future drugs

AstraZeneca Plc on Thursday struck a deal with the firm behind Imperial College London's experimental COVID-19 vaccine to develop and sell drugs based on its self-amplifying RNA technology platform in other disease areas. Under the deal, VaxEquity, a startup founded by Imperial vaccinologist Robin Shattock, could receive up to $195 million if certain milestones are met, in addition to royalties on approved drugs and equity investment from AstraZeneca and life sciences investor Morningside Ventures.

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Serum Institute to invest $68 million in UK vaccine maker Oxford Biomedica

Vaccine maker Serum Institute of India (SII) will invest 50 million pounds ($68 million) in Oxford Biomedica to help fund the development of a plant that manufactures COVID-19 shots, the British company said on Wednesday. Serum - the world's largest vaccine manufacturer by volume - and Oxford Biomedica both produce AstraZeneca's COVID-19 vaccine.

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Kiran Mazumdar-Shaw & Adar Poonawalla spell out the road map for Biocon-Serum alliance

Kiran Mazumdar-Shaw and Adar Poonawalla talk about their new alliance in an interview to ET Now. . Edited excerpts: Tamanna Inamdar: How do you think your partnership with Serum would help solve the issue of vaccine inequity? Kiran Mazumdar-Shaw: Adar Poonawalla has talked about building a large capacity and also about leveraging our capacities. We will look at all the requirements globally in terms of how we can scale up supply in whichever way possible. There is a huge amount of vaccine inequity. There is a huge unmet demand in the world for vaccines. Together we will explore what is possible.

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Dr Reddy's inks pact with Citius Pharma to sell all rights to anti-cancer agent E7777

Dr Reddy's Laboratories on Saturday said it has inked a pact with US-based Citius Pharmaceuticals to sell its rights to an anti-cancer agent. The drug firm said it has entered into a definitive agreement with Citius to sell all of its rights to E7777 (an engineered IL-2-diphtheria toxin fusion protein) and certain related assets.

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U.S. to pay $2.9 billion for an additional 1.4 million doses of Regeneron's COVID-19 therapy

Shares of Regeneron Pharmaceuticals Inc. REGN, -3.10% gained 2.1% in premarket trading on Wednesday, the day after the company said the U.S. government had purchased an additional 1.4 million doses of its monoclonal antibody treatment for COVID-19 for $2.9 billion. The treatment, which costs $2,100 per dose, is free to Americans at high risk of hospitalization and death who have tested positive or have been exposed to the virus. Most of the doses are expected to be delivered in the final three months of 2021.

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The right tech can add real-world context to clinical trials: Sharecare

According to a leader from the health engagement solutions firm, intelligent use of technology tools can add patient-centricity and realism to a study. Traditionally, researchers seek to isolate their studies and the subjects from any variables and intrusions. However, removing research from the 'real world' completely can create a number of unexpected issues and prevent a study from yielding the best, most accurate results possible. Francesca Rinaldo, senior vice president of clinical product and innovation with Sharecare.

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Device regulating oxygen in premature infants goes to clinical trials

An MU researcher has created a device that could help premature babies get the oxygen they need in the critical first few weeks of life. After birth, many premature newborns are sent to the Neonatal Intensive Care Unit. Here, care is provided around-the-clock with equipment to help monitor the infants. Such care includes regulating oxygen levels, a task that involves numerous adjustments to dial in just how much oxygen the infant needs. For a premature infant, saturated oxygen levels must remain between 88% and 95%.

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Clinical Trial Trends: 18 Months of Faster Tech Adoption, Real World Data, Increased Collaboration

Namita Limaye, Research VP at IDC, gave a broad overview of IDC's survey findings over the past 18 months at this week's Bio-IT World Conference and Expo held in Boston and online. She highlighted trends in the life sciences and clinical trials industries that included increased collaboration, speedier adoption of technologies, reliance on real world data, and more. After the unprecedented disruption of the COVID-19 pandemic, companies in the life sciences industry returned with a focus on digital resiliency—seeking to recover and grow in the new times.

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Rare Diseases 2021: maintaining the human element in decentralised trials

Finding the right patients to recruit into clinical trials is one of the most challenging aspects of clinical research. With rare diseases, this is greatly exacerbated due to patient populations that are few and far between, as well as gaps in diagnosis and a lack of experts in the disease areas. The move to decentralisation in recent years has been a boon in many areas of clinical research, including in the rare disease space, but as Florida-headquartered biotech AGTC's director of patient enrollment, Halley Losecamp outlined in her presentation.

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No clinical trial of COVID-19 jab on transgenders, fear and mistrust keep majority of them away

Kolkata, Sept 18 (PTI) A sizeable number of transgenders in West Bengal are yet to get the COVID-19 jab, the primary reasons being fear and mistrust among them about its impact owing to lack of clinical trial on them till date, experts said on Saturday. Kolkata, Sept 18 (PTI) A sizeable number of transgenders in West Bengal are yet to get the COVID-19 jab, the primary reasons being fear and mistrust among them about its impact owing to lack of clinical trial on them till date, experts said on Saturday.

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Elligo Health acquires clinical services firm ClinEdge for $135m

Elligo Health Research has acquired research practice management and clinical services firm ClinEdge in a $135m transaction. The deal was financed via new co-lead investors Morgan Stanley Expansion Capital and Ally Bridge. Norwest Venture Partners and current investors also joined the funding round. ClinEdge caters to clinical research sites, pharmaceutical companies and clinical research organisations. It offers site conduct and patient access solutions with trial expediting strategies.

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Irish clinical trials company Icon gets €4m in State funding

Nasdaq-listed clinical trials group Icon has been awarded €4 million in R&D supports by the Irish Government. The Dublin-founded company, which employs more than 1,000 people in the Republic, is to use the funding to expand patient access to clinical research through the use of technology. The R&D support will help in the development of tech-enabled systems that provide greater flexibility and reduce the burden felt by clinical trial participants, Icon said.

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Merck in advanced talks to buy Acceleron Pharma - WSJ

Merck & Co is in advanced talks to acquire drugmaker Acceleron Pharma Inc, the Wall Street Journal reported https://www.wsj.com/articles/merck-nears-deal-to-acquire-acceleron-pharma-11632778405?mod=latest_headlines on Monday, citing people familiar with the matter.

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Hikma Pharma acquires Custopharm for $375m

Hikma Pharmaceuticals, one of the largest suppliers of generic injectable medicines in the US, announced on Monday that it is acquiring Custopharm from Water Street Healthcare Partners, for an initial $375m (£273m, €320m). Hikma said it will pay the initial cash consideration on a debt and cash-free basis, with a further $50m in contingent consideration, payable upon the achievement of set commercial milestones.

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Syneos Health Acquires Clinical Trial Recruitment and Retention Company StudyKIK

Syneos Health, a fully integrated biopharmaceutical solutions organization, has acquired StudyKIK, a technology-enabled clinical trial recruitment and retention company. Accelerating product development by better connecting patients, sites and communities, the acquisition boosts Syneos Health's ability to deliver technology-enabled, insight-powered solutions. Customer benefits include accelerated patient enrollment and retention, extensive patient population-based insights, improved site, sponsor and physician experiences and reduced patient burden.

Syneos Health STUDYKIK

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Registration of medical devices will benefit industry: DCGI

The national drug regulator has assured the medical devices industry that the registration of medical devices will be beneficial for the industry itself and will help the regulator to pull out details of products if there are complaints registered by the users or hospitals. The transition of the medical devices regulation, from classification of the devices to licensing, would be smooth and the regulator will hand hold the industry in the initial stages.

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IPC releases guidance document on Quality Management System in testing laboratory

The Indian Pharmacopoeia Commission (IPC) has released a guidance document on Quality Management System (QMS) in testing laboratory. QMS consists of documentation of the laboratory policy and objectives, system procedures and instructions for assuring the quality of its results to meet safety and regulatory requirements and to satisfy the needs of the customers.

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Pharma market shows a healthy momentum in August

Domestic pharmaceutical market delivered a robust growth of nearly 18% in August, buoyed by sales of acute therapies. The acute medication grew around 17% yoy in August on a low base, while chronic therapies rose about 12.5% yoy, India Ratings and Research (Ind-Ra) said. Post normalisation of the high growth months of April (51.5%) and May (47.8%) led by the lockdown related lower base last year and higher volume growth, the average IPM (Indian pharma market) growth from June to August 2021 stood at 15.2% yoy.

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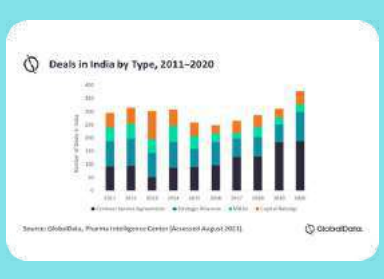
Covid-19 shapes Indian pharma deals landscape, says global data

India has a rapidly growing pharmaceutical market that, being the third largest pharmaceutical industry in the world by volume, holds a prominent place in global health. Over the last decade, the Indian pharmaceutical market has seen increasing domestic and foreign investment. While the overall number of deals fluctuated only slightly between 2011 and 2019, a considerable increase was confirmed for deals struck in 2020. Between 2019 and 2020, the deal number increased by 22%, likely triggered by the COVID-19 pandemic, reveals GlobalData, a leading data and analytics company.



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India's vaccines industry can grow from $2 bn up to $5 bn by 2026: Report

As new Indian and global pharmaceutical companies include vaccines as a key part of their portfolios, India's vaccines industry can grow from $2 billion to $4 billion or even $5 billion, said a report released by global consulting firm Kearney, in collaboration with the Confederation of Indian Industry (CII) on Monday. The report titled "Taking India's life science to the global stage: Make in India to fuel 4x growth in biosimilars and vaccines by 2026", said that vaccines have become the top-most item on the agenda for governments and investors because of the pandemic.

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