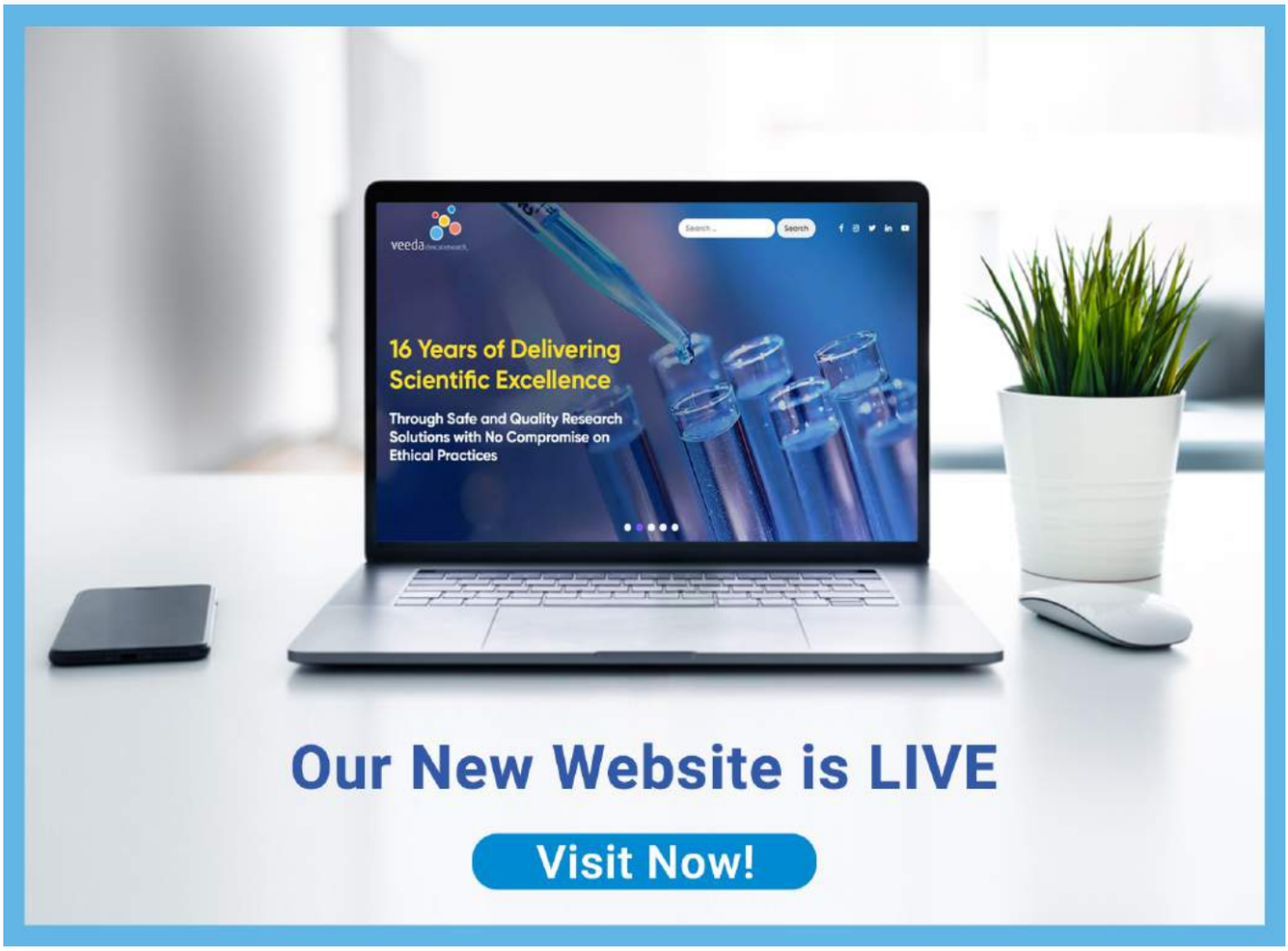
The Veeda Newsletter

MAY 2021: ISSUE 05



16 YEARS OF DELIVERING EXCELLENCE

Veeda News
Webinar on Stereo-isomeric drugs & Bioanalysis

Regulatory
FDA Authorizes Additional Mono-clonal Antibody for Treatment of COVID-19

Financial
Indian Pharma Market registers 51.5% growth in April 2021

Clinical Research
FDA leader discusses breaking barriers in clinical care

Merger and Acquisition
AstraZeneca's $39 billion takeover of U.S.-based Alexion Pharmaceuticals examined by U.K. regulator

Indian Pharma
India, UK decide to enhance partnership on vaccines

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Missed attending our webinar?

We conducted a webinar on Stereo-isomeric drugs & Bioanalysis on 13th May, 2021.The webinar covered the importance of chirality in drug development, regulatory requirements for chiral drugs during the drug development phase, a historical view of the chiral drug in bio-analysis and briefly discussing case studies of few chiral drugs.

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

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FDA Authorizes Additional Monoclonal Antibody for Treatment of COVID-19

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the investigational monoclonal antibody therapy sotrovimab for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and 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 progression to severe COVID-19, including hospitalization or death.

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Medical Device Regulation comes into application

Regulation (EU) 2017/745 on medical devices becomes applicable in the European Union today, 26 May 2021. The Medical Device Regulation (MDR), which was adopted in April 2017, changes the European legal framework for medical devices and introduces new principal and supportive responsibilities for EMA and for national competent authorities in the assessment of certain categories of products.

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EMA issues advice on use of sotrovimab (VIR-7831) for treating COVID-19

EMA's human medicines committee (CHMP) has completed its review on the use of the monoclonal antibody sotrovimab (also known as VIR-7831 and GSK4182136) to treat patients with COVID-19. This review was undertaken to provide a harmonised scientific opinion at EU level to support national decision-making on the possible use of the antibody prior to marketing authorisation.

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FDA updates guidance on covariate treatment in clinical trials

In a revised draft guidance, the US Food and Drug Administration (FDA) has clarified how drug developers should adjust for covariates in certain clinical trials. The revision provides "more detailed recommendations for the use of linear models for covariate adjustment and also includes recommendations for covariate adjustment using nonlinear models," according to FDA's Federal Register notice of the newly revised draft.

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WHO and UNICEF launch new tools for the promotion of adolescent mental health

The Helping Adolescents Thrive Toolkit, launched today, provides programmatic guidance for people working in the health, social services, education and justice sectors on how to implement strategies for adolescent mental health promotion and protection. The Toolkit covers the legal foundations required for such programmes to succeed.

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veeda clinical research

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Indian Pharma Market registers 51.5% growth in April 2021

The Indian Pharmaceutical Market (IPM) has registered a growth of 51.5 per cent for the month of April 2021, as against a growth of 10.3per cent for the month of March 2021. According to AIOCD AWACS report, the IPM has recorded sales of Rs. 1, 52,826 crore for moving annual total (MAT) basis during April 2021. Amongst the top 10 corporates, Cipla exhibited the highest growth of 13.6 per cent, followed by Intas at 8.2 per cent.

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Indian Market May Recover on Better Visibility of COVID Vaccinations (1st Dose)

India’s benchmark stock index Nifty (NSEI) closed around 14677.40 Friday; closed almost flat after recovering from a deep plunge on positive global cues and improving the visibility of India’s COVID vaccinations. On Thursday, while the Indian market was closed for a holiday, global cues were negative on higher bond yield amid hotter than expected core inflation in the U.S. On the early U.S. session, Thursday.

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Dr Reddy's to make, sell Eli Lilly's COVID-19 drug Baricitinib in India; 5th drugmaker to do so

Dr Reddy's Laboratories has entered into a royalty-free, non-exclusive voluntary licencing agreement with US-based pharma major Eli Lilly and Company for the manufacture and sale of the drug, Baricitinib. Baricitinib has received 'restricted emergency use approval' from the health ministry's central drugs standard control Organisation for use in combination with Remdesivir for treatment of suspected or confirmed COVID-19 patients.

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Serum Institute of India to make £240 mn investments in UK

The Serum Institute of India (SII) will invest GBP 240 million in the UK to expand its vaccine business and set up a new sales office creating a large number of jobs, Downing Street has announced as part of plans for a GBP 1 billion India-UK Enhanced Trade Partnership creating around 6,500 jobs in Britain. The Pune-based vaccine manufacturer is among a list of nearly 20 Indian companies.

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Support to countries’ equitable and resilient recovery from the pandemic towards the health SDGs

Geneva, 20 May 2021 – WHO and 12 other signatory agencies to the Global Action Plan for Healthy Lives and Well-being for All (SDG3 GAP) have released their second progress report, Stronger collaboration for an equitable and resilient recovery towards the health-related SDGs. This report presents progress achieved, especially at country level, where SDG3 GAP is being implemented in 37 countries.

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FDA leader discusses breaking barriers in clinical care

Acting FDA commissioner Janet Woodcock explains how government, researchers, doctors and patients can contribute to improving the clinical research system. With more than three decades of experience at the US Food and Drug Administration (FDA), acting commissioner Janet Woodcock has an informed perspective of the government's contributions to pharmaceutical development, drug safety, and clinical research.

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What You Must Know About APAC before Deploying Your Next Clinical Trial

Right now, no place in the world is a hotter spot to conduct clinical trials that the Asian-Pacific region (APAC). This popularity of the region is not new. In 2018 China was one of the hottest topics of conversation I heard at the DIA Annual Meeting. Shortly thereafter I wrote an article that featured the insights of three experts on that region.

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Looking ahead: the future of clinical research

At the end of March 2021, the Department of Health published a paper on the future of clinical research in the UK (available here). The paper, which received input from the NHS, regulators, medical research charities and the life sciences industry, sets out the government's UK-wide vision for a more patient-centred, pro-innovation and digitally-enabled clinical research environment.

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Accelerating patient care through digital transformation and decentralized clinical trials

The adoption of digital health technologies (DHTs) in the industry continues to pave the way to enable decentralized clinical trials (DCTs). Participants' needs and convenience are main drivers behind these technologies, and electronic clinical outcome assessments (eCOAs), along with digital endpoints, are becoming more commonplace.

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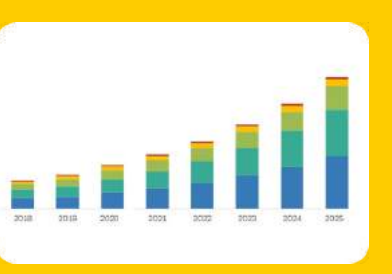
Oncology Biosimilar Market Is Growing

More biosimilars continue to be prescribed, and price competition is improving. Although the United States is behind Europe in terms of biosimilars approved and launched, the FDA is adding more approvals each year—29 since 2014—and 73 additional biosimilar candidates are in clinical trials and/or under FDA review. In the hospital community, financial incentives are heavily weighted in favour of biologic reference products, which means that biosimilars in many cases are not even considered, said Ted Okon, MBA, executive director of the Community Oncology Alliance.



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AstraZeneca's $39 billion takeover of U.S.-based Alexion Pharmaceuticals examined by U.K. regulator

The U.K.'s Competition and Markets Authority said on Tuesday it was opening a consultation on the $39 billion planned takeover of U.S. drug company Alexion Pharmaceuticals, to determine whether it would adversely affect competition. The watchdog is trying to assess whether the merger "may be expected to result in a substantial lessening of competition within any market or markets in the United Kingdom for goods or services."

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Acasti Pharma Inc.'s Acquisition of Grace Therapeutics

On May 7, 2021, Acasti Pharma announced the entering into of a definitive agreement to acquire Grace Therapeutics, a biopharmaceutical company that develops innovative drug delivery technologies for rare and orphan diseases. Upon completion of the acquisition, Acasti will acquire Grace's pipeline of drug candidates addressing critical unfulfilled medical needs, and the potential to deliver significant value to patients and providers.

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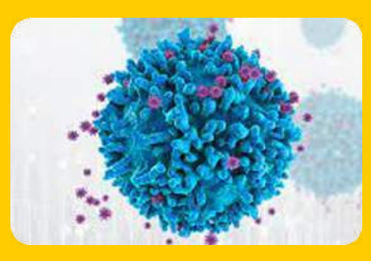
Premier Research Acquires Camargo Pharmaceutical Services

Premier Research announced today that it has acquired Camargo Pharmaceutical Services based in Cincinnati. Premier Research is a leading provider of strategic and regulatory advisory services as well as clinical development services to the biotechnology, specialty pharma, and medical device industry.



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Aceto Expands Life Science Manufacturing with Acquisition of Finar Limited

Aceto, a leading global provider of specialty materials for life sciences and advanced technology end markets, announced today the acquisition of a majority stake in Finar Limited. Finar is a leading manufacturer, supplier, and distributor of pharmaceutical excipients, lab chemicals, aquaculture inputs, and food grade additives.

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WCG acquires Avoca to enhance trial quality management

WCG has acquired life-sciences consulting firm, The Avoca Group, to expand its portfolio of solutions for enhancing clinical trial quality management and compliance transformation. Focused on advancing efficiency, boosting process quality and alleviating risk in clinical trials, Avoca supports biopharma, biotech, CRO and clinical service providers.

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Five pharmaceutical companies get approval to make black fungus drug

The Drugs Controller General of India (DCGI) has cleared applications from five pharmaceutical companies to manufacture anti-fungal drug Amphotericin B, used to treat mucormycosis or black fungus. The subject expert committee (SEC) of the health ministry on Wednesday had given its nod to proposals from drug makers to boost the availability of Amphotericin B.

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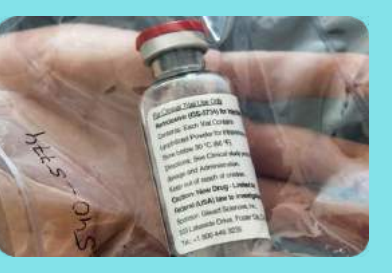
India increases the production capacity of Remdesivir to nearly 119 lakh vials per month

With the sudden increase of cases during the second wave of the pandemic, the government has taken swift actions to enhance the availability of an anti-viral drug Remdesivir across the country. Presently, nearly 119 lakh vials of Remdesivir are being produced per month, the Department of Pharmaceuticals informed on Monday.



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Experts at IPC, CDSCO meet to outline plan for designing PV as per regional needs for setting up PV cell

Experts at Indian Pharmacopoeia Commission (IPC) and Central Drugs Standard Control Organisation (CDSCO) recently met to outline a plan towards designing Pharmacovigilance (PV) as per the regional needs for addressing challenges in setting up PV cells in pharmaceutical companies in the country..

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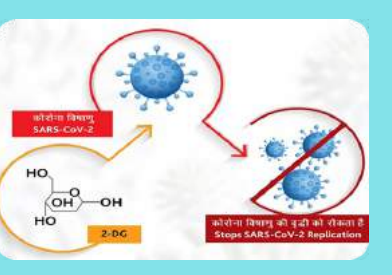
India's DRDO with Dr Reddy Develop Anti-Covid19 Drugs For Faster Recovery

Amid the exploding Covid19 cases in India, a joint efforts by Defence Research and Development Organisation (DRDO) and Dr Reddy's Laboratories have succeeded in developing an Anti- Covid19 drug. An anti-COVID-19 therapeutic application of the drug 2-deoxy-D-glucose (2-DG) has been developed by Institute of Nuclear Medicine and Allied Sciences (INMAS), a lab of Defence Research and Development Organisation (DRDO), in collaboration with Dr Reddy's Laboratories (DRL), Hyderabad.



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India, UK decide to enhance partnership on vaccines

India and the UK on Tuesday pledged to expand on their cooperation in health to help guarantee an equitable global supply of vaccine by April 2022. This was one of the highlights of the India-UK Summit that was addressed by Indian Prime Minister Narendra Modi and his UK counterpart Boris Johnson virtually due to the spike in the number of covid-19 cases in India.

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

ADDRESS:

VEEDA CLINICAL RESEARCH® PVT. LTD.
Block 6, Magnet Corporate Park 100 ft.
Thaltej - Hebatpur Road, Nr.Sola Bridge,
Off. S.G. Highway, Thaltej, Ahmedabad
380054

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