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The Veeda Newsletter

APRIL 2022: ISSUE 04

Our Latest Case Study on Dermatology Phase I Trial

Partners in Creating

a healthier tomorrow

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VEEDA NEWS

Veeda's team would be attending 13th Annual Clinical Trials Conference 2022 on 19th May at Kohinoor Continental Hotel, Mumbai

13th Annual Clinical TRIALS 2022

A panel discussion on

veeda clinical research®

Key changes and visible trends in clinical trials

Dr. Rakesh Patel
Associate Vice President – Clinical Operations
Veeda Clinical Research Limited

Ensuring the patient safety and centricity in clinical trials

Dr. Kiran Marthak
Non-executive Director
Veeda Clinical Research Limited

19th May, 2022

Kohinoor Continental Hotel, Mumbai, India

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FDA finalizes guidance for drugs and biologics containing nanomaterials

The US Food and Drug Administration (FDA) has released its final guidance for industry on human drug and biological products that contain nanomaterials. Initial draft guidance for industry, released in December 2017, noted that FDA doesn't distinguish between whether a drug or biologic with nanomaterials are benign or harmful, but products containing nanomaterials "may merit particular examination" regarding intrinsic and extrinsic factors to assess risks and benefits.

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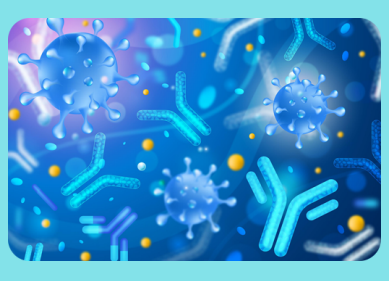
EMA's committee recommends conditional marketing approval for Roche's bispecific antibody mosunetuzumab to treat r/r follicular lymphoma

Roche announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended approval under conditional marketing authorisation for mosunetuzumab for the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL), who have received at least two prior systemic therapies. Based on this positive CHMP opinion, a final decision regarding the conditional approval of mosunetuzumab is expected from the European Commission in the near future. Follicular lymphoma is the second most common form of lymphoma globally, accounting for 20% of all non-Hodgkin lymphomas (NHL) diagnosed worldwide.



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CDC Launches New Center for Forecasting and Outbreak Analytics

The Centers for Disease Control and Prevention (CDC) announced the launch of the Center for Forecasting and Outbreak Analytics (CFA). CFA seeks to enhance the nation's ability to use data, models, and analytics to enable timely, effective decision-making in response to public health threats for CDC and its public health partners. CFA's goals are to improve outbreak response using infectious disease modeling and analytics and to provide support to leaders at the federal, state, and local levels.

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WHO to start a new chapter in global traditional medical systems

WHO's GCTM will be a global home for the likes of Kerala's Ayurveda, Japanese Kampo medicines or African herbal medicines Be it Kerala's traditional Ayurveda, or Indian yogic practices from the North India, or the ancient Japanese Kampo medicines or African herbal medicines, there is soon going to be a global hub in Gujarat's Jamnagar for all traditional alternative healing systems, with an endorsement from the World Health Organization (WHO).

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DCGI claims India on course to become global drugs hub

Claiming that India is on course to become a 'global hub for medicines', Dr VG Somani, Drug Controller General of India (DCGI), said that there has been a fourfold increase in applications of the investigational new drugs in the country. Speaking at the Indian Drug Manufacturers' Association (IDMA) Annual Conclave, Somani said, "We are getting the applications of the investigational new drugs. Earlier, there used to be hardly 5-10 applications.

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NPPA to examine whether price reduction of 50% on drugs going off-patent could be on case-to-case basis

NPPA to examine whether price reduction of 50% on drugs going off-patent could be on case-to-case basis Gireesh Babu, New Delhi Monday, April 18, 2022, 08:00 Hrs [IST] At a time when drugs worth around $240 billion are expected to go off-patent in the next few years till 2026, the drug pricing authority of the country may examine whether the price reduction on such drugs at a benchmark of 50% of the patented compound could be on a case-to-case basis. The matter comes after the National Pharmaceutical Pricing Authority (NPPA) last month fixed the prices of generic fixed dose combinations (FDCs) of sitagliptin and linagliptin, the diabetes drugs going off patent soon, with a 50 per cent reduction on the patented component.

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Catalent snaps up NJ cell therapy plant for $44.5M days after revealing big biologics expansion

Days after throwing down $350 million to beef up biologics manufacturing in Indiana, high-flying CDMO Catalent is buying a cell therapy plant on the East Coast. Catalent has paid $44.5 million for Erytech Pharma's commercial cell therapy factory in Princeton, New Jersey, the company said Monday. As part of the deal, Catalent will chip in on long-term supply of Erytech's lead product candidate eryaspase—also known as Graspa—in development for acute lymphoblastic leukemia.

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NPPA grants exemption to SII's indigenously developed pneumococcal vaccine from price control for five years

The drug price watchdog in the country, the National Pharmaceutical Pricing Authority (NPPA) has approved exemption to Serum Institute of India's (SII) indigenously developed pneumococcal polysaccharide conjugate vaccine against pneumonia from fixing the prices for a period of five years, under the provisions of the Drugs (Prices Control) Order, 2013. It is the first indigenously developed vaccine against pneumonia. The exemption has been granted for SII's formulation Pneumococcal Polysaccharide Conjugate Vaccine (Absorbed) IP (10 valent) in single dose 0.5 ml vial, five dose 2.5 ml vial and pre-filled syringes 0.5 ml single dose, following the company's application.

NPPA
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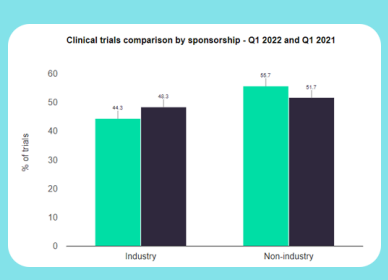
Global clinical trials activity decreased 9.4% YoY in Q1 2022

Global clinical trials activity decreased by 9.4% in Q1 2022, when compared with the same quarter in 2021, according to GlobalData. Industry sponsored trials accounted for a 48.3% share of overall activity in Q1 2022, an increase of 4.0% when compared with Q1 2021. Non-industry sponsored trials accounted for a 51.7% share of all clinical trials in Q1 2022, marking a decrease of 4.0% when compared with the same period in 2021.



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NPPA notifies revised ceiling price for 872 dosage forms and strengths of scheduled formulations based on WPI

The National Pharmaceutical Pricing Authority (NPPA) has notified the revised ceiling price for 872 dosage forms and strength of scheduled formulations effecting the annual change of 10.77 per cent in Wholesale Price Index (WPI) for the calendar year 2021 as against 2020. The increased ceiling prices are applicable with effect from April 1, 2022 and exclusive of goods and services tax (GST), said the Authority. In respect of formulation where pack wise ceiling price is notified, for any other pack size manufactured, the manufacturer shall approach NPPA under para 11(3) of DPCO, 2013 for specific price approval for its formulations.

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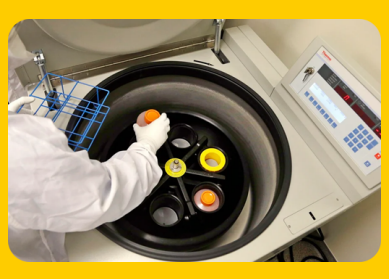
First AI-designed Antibody Enters Clinical Trials

Aulos Biosciences is now recruiting cancer patients in Australian medical centers for a trial of the world's first antibody drug designed by a computer. The computationally designed antibody, known as AU-007, was planned by the artificial intelligence platform of Israeli biotech company Biolojic Design from Rehovot, in a way that would target a protein in the human body known as interleukin-2 (IL-2).



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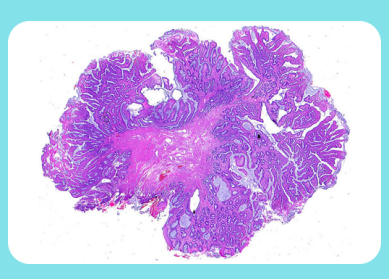
FSHD Society to enhance trial design with AI technology deployment

The FSHD Society is set to improve clinical trial design for facioscapulohumeral muscular dystrophy (FSHD) by deploying Artificial Intelligence (AI) technology. It has announced the launch of a partnership with the FSHD Clinical Trial Research Network (CTRN) and BullFrogAI for analysing the natural history dataset obtained from FSHD patients. The debilitating, genetic disease FSHD causes life-long, progressive muscle weakness.



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The decentralization of clinical trials is a key catalyst for innovation in artificial intelligence

The lines between healthcare, drug discovery, clinical research and commercialisation are blurring, as the patient becomes a key partner and focus. We are seeing a rapid expansion in the use of mobile and patient-centric devices, exponential growth in the volume and diversity of life sciences data and acceleration in the use of data-dependent computation to gain insight and automate – loosely called artificial intelligence (AI).

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United Kingdom: Legislative changes for clinical trials on the horizon

The Medicines & Healthcare products Regulatory Agency (MHRA) launched a consultation in early 2022 as part of its post-Brexit efforts to develop a world-class and flexible regulatory environment for clinical trials The consultation closed in March 2022, but continues to offer insights into what the future holds for the UK regime for clinical trials. It deals with improving the speed and efficiency of approvals of medicinal products, supporting innovation, enhancing transparency, encouraging greater risk proportionality, and promoting patient and public involvement in clinical trials.

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Glenmark to Conduct Clinical Trials of Its Molecule On Cancer Patients

Glenmark Pharmaceuticals on Monday said its unit has received approval from the Drug Controller General of India (DCGI) to conduct phase 1 clinical trials of its novel molecule on patients with advanced solid tumours. Glenmark Specialty SA has received approval from the DCGI to conduct a Phase 1 clinical trial of its novel small molecule, GRC 54276, a hematopoietic progenitor kinase 1 (HPK1) inhibitor. GRC 54276 is one of the many novel molecules from Glenmark's Innovative Medicines Group specialising in the development of novel molecular entities for critical unmet medical needs.

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Hikma acquires US company Custopharm for $425m

Hikma Pharmaceuticals has acquired US-based generic sterile injectables company Custopharm from Water Street Healthcare Partners in a deal valued at $425m. The move comes after the US Federal Trade Commission granted conditional approval to conclude the acquisition.

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Consegna buys Fathom to expand long-acting injectable pipeline

Consegna Pharma is stepping up its bid to use long-acting injectables (LAIs) to combat the opioid crisis, striking a deal to acquire Fathom Pharma and its lead treatment for chronic pain in terminally ill patients. Pittsburgh-based Consegna is deploying computational technologies to create delivery systems for LAIs. Using the systems, the company is building a pipeline of candidates in therapeutic areas in which LAIs can make a difference, for example by addressing non-adherence. The pipeline features a formulation of naloxone, a drug used to treat opioid overdoses.

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Samsung Biologics acquires Samsung Bioepis joint venture for $2.3bn

Samsung Biologics has concluded the acquisition of Biogen's stake in the Samsung Bioepis joint venture in a deal valued at $2.3bn. In January this year, Samsung Biologics signed an agreement for the stake acquisition. As per the terms of the deal, Samsung Biologics made the initial payment of $1bn in cash and completely acquired Samsung Bioepis as its fully owned subsidiary.

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Wallaby hops to €500M acquisition of fellow stroke devicemaker Phenox

Like a young joey carried safely in a marsupial's pouch, so too will devicemaker Phenox be tucked into its new parent company, the aptly named Wallaby Medical. Both companies have developed lines of neurovascular devices meant for use in interventional stroke treatments. Wallaby's include a neuro-embolic coil system to treat aneurysms and a handful of stroke-focused catheters—while Phenox has put out ranges of flow diverters and stent retrievers, plus coating technologies for those implants.

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Natus Medical to go private in $1.2B private equity acquisition deal

Two decades after hitting the Nasdaq as a publicly traded company in 2001, Natus Medical is saying goodbye to all that. The devicemaker has agreed to be acquired by healthcare-focused private equity firm ArchiMed in a deal that would value it at about $1.2 billion and remove it from public trading, Natus said Monday. The company's board of directors has already unanimously approved the agreement and is recommending shareholders follow suit. Pending shareholder approval and other regulatory requirements, the acquisition is expected to be finalized sometime in the third quarter of this year.

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After India-Aus FTA, Indian pharma industry sees global opportunities

After the Comprehensive Economic Cooperation Agreement (CECA) signed between India and Australia for increasing bilateral merchandise trade, the domestic pharmaceutical industry is seeing a plethora of opportunities for international trade. The Indian Pharmaceutical Alliance has said that the development will further cement the already deep, close and strategic relations between the two countries.

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Indian Pharma Sector – Transforming through Disruption

The Covid-19 pandemic has fetched an accelerated adaptation in the Indian Pharmaceutical sector. With technology engulfing the entire gamut of the pharma universe, the wide-ranging transformations have unlocked new prospects. With the government categorizing Pharmaceuticals as a Sunrise sector in Budget 2022, new vistas of support have opened up. Unraveling the road forward for the Indian Pharma sector, Elets Technomedia along with eHealth Magazine announces the 4th Elets Pharma Leadership Summit 2022 on the theme 'Transformation through Disruption' on 11th May 2022.

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Mauritius looking for Indian pharma & biotech industry's robust support to become pharma hub of Africa

In a bid to position the country as the pharmaceutical hub of Africa, Mauritius is looking for Indian pharmaceutical and biotechnology industry's support to create a flourishing pharmaceutical and vaccine manufacturing sector. Speaking at Global Ayush Investment & Innovation Summit in Gandhinagar on April 20, Mauritius Prime Minister Pravind Kumar Jugnauth said "India is hailed as pharmacy of the world. We are encouraging pharma and vaccine manufacturing units in Mauritius with an aim to position the country as the pharmaceutical hub of Africa.

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NGT directs Environment Ministry to finalise norms for releasing pharma effluent

Expressing concern over the discharge of effluents into water bodies, the National Green Tribunal has asked the Union Ministry of Environment and Forests to notify the standards for discharge by the pharmaceutical industry. The NGT directive came while it was hearing a petition on alleged discharge of active pharmaceutical ingredients into rivers by pharma industry in Baddi in Solan district in Himachal Pradesh. Baddi is one biggest pharma hubs in the country, with more than 270 functioning companies.

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NPPA to set up digital platform to track availability of essential drugs across the country

The National Pharmaceutical Pricing Authority (NPPA) has initiated efforts to track the availability of essential drugs across the country, by creating a national level digital platform in which the stock positions could be updated by the stakeholders. It may be noted that the regulated markets such as US have its drug regulator updating the details of medicines which are in shortage, on a regular basis. The Authority has floated an Expression of Interest (EoI) to short list an agency for tracking the availability of specified medicines in the supply chain across the country, especially in the backdrop of the challenges it faced in tracking the availability of Covid-19 related medicines in various parts of the country.

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