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The Veeda Newsletter

DECEMBER 2022: ISSUE 12

“Public perception about clinical trials has witnessed a drastic change”

Mr Ajay Tandon
Managing Director

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Partners in creating
a healthier tomorrow

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VEEDA NEWS

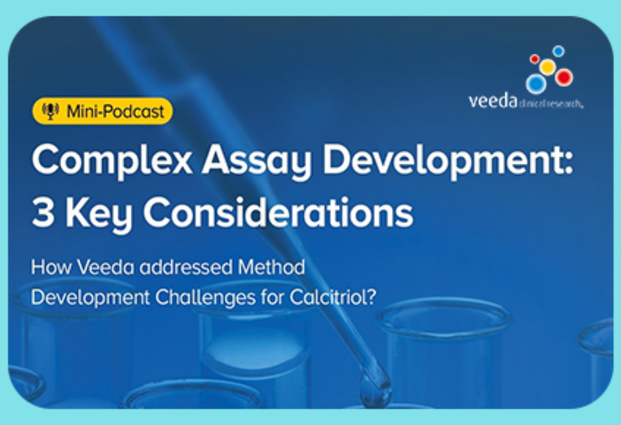
Awarded with “MS Excellence in BABE Services, Largest Indian CRO" in the Shimadzu MS community meet

We would like to thank Shimadzu and SPINCO Group for this recognition and opportunity to share and deliver our scientific research, thoughts, ideas, and expertise in the presence of 500+ industry experts across clinical research and the healthcare industry.

Know More!

Mini-Podcast on Complex Assay Development

Calcitriol is a form of Vitamin D3 used to treat calcium deficiency with hypoparathyroidism and metabolic bone disease in people with chronic kidney failure. Here’s how our experts addressed the method development challenges for Calcitriol Complex Assay.



Listen Now!

Our participation in the 14th annual conference of ‘Indian Society for Rational Pharmacotherapeutics

Veeda’s participation in the 14th Annual Conference of ‘Indian Society for Rational Pharmacotherapeutics’. Dr. Kiran Marthak represented Veeda Clinical Research as a speaker at the conference and delivered the talk on “Safety of subjects in Phase-1 studies”.

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REGULATORY

CDSCO declares sample of Glenmark's blood pressure drug telmisartan failed in quality test in February as spurious

The Central Drugs Standard Control Organisation (CDSCO) informed that a sample of blood pressure drug it has collected through the Drug Control Department, Delhi, in the month of February, 2022, allegedly manufactured by Glenmark Pharmaceuticals, has been now concluded as not a genuine product.The CDSCO, in the month of March, has released a list of drug batches it has tested and identified as not of quality standard (NSQ) during the month of February. One of the batches was of telmisartan 40 mg and hydrochlorothiazide 12.5 mg tablets IP, under the brand Telma H, allegedly manufactured by Glenmark Pharma in its Sikkim factory.

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WHO, WIPO, WTO call for innovation and cooperation to support timely access to pandemic products

The Joint Technical Symposium held on 16 December by the World Health Organization (WHO), World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) highlighted that the world can move quickly when driven by a crisis situation, such as the COVID-19 pandemic. Cooperation is a key factor to foster innovation and timely equitable access to health products – for COVID-19 and in preparation for future pandemics. WIPO Director General Daren Tang, WHO Director-General Tedros Adhanom Ghebreyesus and WTO Director-General Ngozi Okonjo-Iweala opened the Symposium

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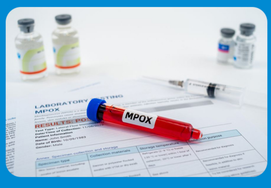
CDC Studies Support Mpox Vaccine as Safe and Effective



New data released today in CDC's MMWR provide additional evidence to support that vaccination with the JYNNEOS mpox vaccine is safe and reduces the risk for getting mpox. CDC recommends vaccination for people at risk for getting mpox.The first report looked at vaccine safety data among children and adults and found no major vaccine safety concerns after nearly 1 million JYNNEOS doses were administered. Common adverse health events reported were consistent with studies before the vaccine was licensed, including injection site redness, swelling, or pain, and dizziness.

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The European Union and WHO further enhance their partnership for stronger pandemic preparedness and response

Today the European Union's Health Emergency Preparedness Authority (HERA) and the World Health Organization (WHO) initiated a new partnership with a € 15 million allocation under the EU4Health programme to boost capacities at national, regional, and global levels for better preparedness for and response to health emergencies. In the framework of this partnership, HERA will fund four global initiatives to support: Epidemic and pandemic intelligence, access to and sharing of data and analytics through the WHO Hub for Pandemic and Epidemic Preparedness to assist decision-making with regards to health emergencies preparedness and response (€ 4 million)

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ECDC and EMA collaborate on vaccine safety and effectiveness monitoring studies

The European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) convened on 6 and 7 December in Amsterdam the first meeting of the Immunisation and Vaccine Monitoring Advisory Board (IVMAB) of the Vaccine Monitoring Platform (VMP).The VMP is a joint initiative of the two Agencies for strengthening the continuous monitoring of the safety and effectiveness of vaccines in the European Union (EU).Through the VMP, EMA and ECDC will coordinate and oversee EU-funded, independent post-authorisation studies on vaccines use, safety and effectiveness conducted in EU countries.

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FINANCIAL

Ayush manufacturing units witness marginal decline in 10 years, GMP compliance registers growth

The number of licensed pharmacies which produce medicines under the Ayurveda, Yoga, Naturopathy, Unani, Siddha, Sowa Rigpa and Homoeopathy (Ayush) has declined by almost 1.6 per cent in the last ten years, even as the ratio between good manufacturing practices (GMP) complied facilities and those which are non compliant has shifted significantly in favour of GMP compliance.According to the latest annual statistical data of the Ministry of Ayush, as of April 1, 2021, there were 8,648 original licensed Ayush drug manufacturing units and 1,294 loan licensed units in the country. The number of original licensed units has seen a decline of 1.6 per cent in 10 years, from 8,785 units in 2012.

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NPPA's expert committee recommends new price for Hetero's local anaesthetic drug lidocaine

The Multi Disciplinary Committee (MDC) of experts of the drug price regulator has recommended revision of the retail price of Hetero Healthcare Ltd adhesive patch of local anaesthetic drug lidocaine aqueous base pack after analysing the market data from other manufacturing and marketing companies. The experts have now recommended a price of Rs. 44.64 per patch, excluding Goods and Services Tax (GST) up from the earlier recommendation of Rs. 9.94 per patch excluding GST.Interestingly, the latest meeting of MDC has worked a price of Rs. 234.61 per patch excluding GST, but considering the retail price claimed by the company was Rs. 50 per batch including GST, the Committee proposed the retail price at the same (Rs. 44.64 per patch along with the GST to total Rs. 50 per patch).

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NPPA further extends mandate to Serum Institute to continue manufacturing of TT injection till Dec 2023

The National Pharmaceutical Pricing Authority (NPPA) has further extended its mandate to Pune-based Serum Institute of India (SII) to continue manufacturing two of its scheduled formulations against Tetanus for another one year, till December 31, 2023. SII has earlier submitted Form IV intimation seeking the drug price regulator's approval to discontinue these two formulations.An Authority meeting held on December 15 noted that its earlier order on June 28, under the provisions of the Drugs (Prices Control) Order, 2013, asking the company to continue production of these two formulations was extended to six months, till December 22, 2022.

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NPPA brings out framework for suo moto corrections in notified prices to improve pricing process

The National Pharmaceutical Pricing Authority (NPPA) has finalised a framework for undertaking suo moto correction in the prices it has already notified, if it comes across any error after they are notified and are duly cross checked with reliable data.The Authority has said that it has come across a few cases of data inconsistency or errors in the Pharmatrac database provided by AIOCD-AWACS, normally falling into the categories.These include error in pack size of formulations, for example, pack of four medicines shown as one in database; formulations apparently not available in a relevant subgroup but recorded under a separate subgroup by Pharmatrac and price fixed by NPPA ignoring items in that other subgroup.

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NPPA releases fifth list of ceiling prices for 69 formulations based on amended Schedule I of DPCO, 2013

The National Pharmaceutical Pricing Authority (NPPA) has released a new list of draft calculation of ceiling price for 69 formulations, as part of fixing the ceiling prices of medicines under the National List of Essential Medicines (NLEM), 2022, which was amended into the Schedule-I of the Drugs (Prices Control) Order, 2013 earlier this year.Along with the 230 formulations for which the Authority released draft ceiling price calculations in four previous lists, the total number of formulations having a ceiling price calculation released for industry response is now 299.

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CLINICAL RESEARCH

The Silver Lining of Failure in Cancer Drug Development

The news often highlights positive clinical trials, in which the outcomes that researchers were hoping for occur, potentially leading to Food and Drug Administration (FDA) approvals. But what happens with trials that miss the mark?One expert said those “misses” should not be considered a loss altogether, but rather, something that is to be expected and does not mean the end of the road for a particular therapy.“We have to accept that reality,” Dr. Nizar M. Tannir, professor in the department of genitourinary medical oncology at The University of Texas MD Anderson Cancer Center in Houston.

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Researchers reveal cell therapy may reduce kidney damage from type 2 diabetes

Researchers have reported positive results from a unique cell treatment experiment for adults with diabetes.In spite of receiving the robust medical care, adults with type 2 diabetes are still developing kidney damage, and the NEPHSTROM clinical study is beginning to examine the possibilities of a new cell therapy to treat them.Results from the NEPHSTROM clinical trial were presented in November at the American Society of Nephrology's Kidney Week meeting in Orlando, Florida. It showed that a single dose of ORBCEL-M, given intravenously to carefully selected adults with worsening kidney disease due to diabetes was safe and associated with better preservation of kidney function compared to a placebo. Patients taking part in the trial were followed closely for 18 months after receiving ORBCEL-M.

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Researchers discover new bacterial therapy approach to treat lung cancer

The most lethal cancer in both the United States and the rest of the globe is lung cancer. Patients have few options because many of the currently available medicines are useless. Bacterial therapy has been a promising new approach to treating cancer, however even though this treatment method has swiftly advanced from laboratory studies to clinical trials in the last five years, the most efficient treatment for some types of malignancies may be in combination with other medications.

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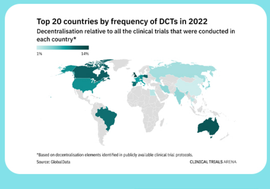
Year in review: who were the main DCT players in 2022?

As we count down to the end of 2022, we look at the sponsors, CROs, and sites that were at the top of the decentralised clinical trial (DCT) race. We also explore the countries where DCTs were frequently conducted.Clinical Trials Arena has established an exclusive taxonomic approach that involves reviewing thousands of drug trial public records from 2022 that mentioned decentralisation terminology in the study protocols, as curated in the Clinical Trials Database by GlobalData, the parent company of Clinical Trials Arena. Decentralisation terminology includes DCT elements such as telemedicine, remote monitoring, digital data collection, and more.



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Inspira™ Technologies Signs Agreement to Conduct Clinical Study of HYLA™ Blood Sensor

Inspira™ Technologies OXY B.H.N. Ltd. (NASDAQ: IINN) (NASDAQ: IINNW) (the "Company" or "Inspira Technologies"), a groundbreaking respiratory support technology company, announced today that it has signed an agreement to conduct a clinical study of the HYLA blood sensor with Sheba Medical Center in Israel. The clinical study, expected to commence in the first quarter of 2023, will be performed in an operating room setting in patients undergoing open heart surgery using a cardiopulmonary bypass machine (CPB).

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MERGER AND ACQUISITION

Advent confirms buying significant stake in Suven Pharma, weighs merger with Cohance

Private equity investor Advent International on Monday confirmed that it has entered into a definitive agreement to acquire a significant stake in Suven Pharmaceuticals.Advent intends to explore the merger of its portfolio company CohanceLifesciences with Suven to build an end-to-end CDMO and merchant APIplayer servicing the pharma and specialty chemical markets, the PE player said in an exchange filing.As part of the transaction, Advent will also be making an open offer to acquire an additional 26percent of the outstanding equity shares of the company from public.

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InSitu Biologics and Mayo Clinic to co-develop anti-cancer therapeutics

InSitu Biologics, Inc. has entered into an agreement with the Mayo Foundation for Medical Education and Research to further develop its prolonged-release drug delivery technology for anti-cancer therapeutics.The company has developed an industry-leading platform technology for loading large doses of a variety of medications into a localized delivery matrix. Once injected, medication elutes from the multi-phase matrix over an extended period. The collaboration with Mayo is both a research and commercial endeavor, and will accelerate InSitu Biologics' work in adapting the technology for anti-cancer therapeutics. The partnership will encompass traditional cancer medications as well as newly-developed novel agents.

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Gilead buys Tmunity, cozying up to a CAR-T pioneer

Looking to further boost its growing cell therapy business, Gilead Sciences on Wednesday said it plans to acquire Tmunity Therapeutics, a private biotechnology company trying to develop newer, better CAR-T treatments.CAR-T uses genetically engineered T cells to help the body fight diseases like cancer. Gilead currently markets two such products, Yescarta and Tecartus, which it obtained through the $12 billion purchase of Kite Pharma in 2017. Combined, sales of Yescarta and Tecartus were just under $400 million in the third quarter, a nearly 80% increase from the same three-month period a year prior.

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Private equity giant KKR to buy Japan's Bushu Pharmaceuticals

Private equity giant KKR & Co Inc said on Tuesday it will buy Japanese drug developer Bushu Pharmaceuticals from Hong Kong-based private equity firm BPEA EQT, but did not disclose financial details of the deal.A Bloomberg report from August stated a transaction may value Bushu Pharma at upwards of 100 billion yen ($749 million), citing people familiar with the matter.None of the parties involved in the transaction immediately responded to a Reuters request for confirmation on deal value.KKR said in a press statement it aims to expand Bushu Pharma into new as well as growth segments such as injectables, invest in further capacity expansion and quality control, and seek further growth opportunities.

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Nykode Therapeutics and Richter-Helm BioLogics Announce Strategic Manufacturing Partnership

Nykode Therapeutics ASA (OSE: NYKD), a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel immunotherapies, today announced that it has entered into a strategic manufacturing partnership with Richter-Helm BioLogics GmbH & Co KG to supply plasmid DNA for Nykode's wholly owned and partnered product portfolio."We are excited about the strategic manufacturing partnership with Richter-Helm BioLogics. As a leading manufacturer of DNA vaccines, they will provide the long-term expertise and capacity needed to support our ambitious growth and pipeline development," stated Mette Husbyn, Chief Technology Officer of Nykode Therapeutics.

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INDIAN PHARMA

Gujarat launches cosmetic manufacturing license portal to make licensing process transparent and less time consuming

Following a trial run of the online system which started from December 1, 2022 for nearly a period of one month, Gujarat Chief Minister (CM) Bhupendra Patel has finally launched the cosmetic manufacturing license portal to make licensing process transparent, accountable and less time consuming as part of Gujarat government's good governance initiative.Gujarat is the first state in the country to launch a web portal for online operation of Cosmetics Licensing.As of today, there are about 826 firms manufacturing cosmetic products in the state of Gujarat. In addition, these manufacturing firms are given various types of certificates like GMP and free sale certificates among others.

Read More

Ramdev's Divya Pharmacy among 16 Indian pharma companies in Nepal blacklist

As many as 16 Indian pharmaceutical companies, including Divya Pharmacy that makes Yoga Guru Ramdev's Patanjali products, have been blacklisted by Nepal's drug regulatory authority.Other than Divya Pharmacy, the blacklist has names like Radiant Parenterals Ltd, Mercury Laboratories Ltd, Alliance Biotech, Captab Biotec, Aglowmed Ltd, Zee Laboratories, Daffodils Pharmaceuticals, GLS Pharma, Unijules Life Science, Concept Pharmaceuticals, Shree Anand Life Sciences, IPCA laboratories, Cadila Healthcare Ltd, Dial Pharmaceuticals and Mackur laboratories.Medicines made by these companies cannot be imported into or distributed in Nepal, it said.

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Goa FDA allows manufacture and marketing of ulipristal acetate tablets 5mg under restricted use

FDA

The Directorate of Food and Drug Administration (DFDA), Goa has issued notice for revocation of suspension of manufacture, sale and distribution of ulipristal tablets 5mg based on the directive of the Drugs Controller General of India (DCGI).This will allow manufacture and marketing of ulipristal acetate tablets 5mg under restricted use subject to conditions that the drug can only be used to treat uterine fibroids in premenopausal women for whom surgical procedures (including uterine fibroid embolisation) are not appropriate or have not worked.Ulipristal acetate is a progesterone receptor modulator used in emergency contraception.

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Widely prescribed neuropathic pain drugs gabapentin & pregabalin to be under pharmacovigilance scrutiny

Indian drug regulators have sought pharmacovigilance (PV) for neuropathic pain drugs gabapentin and pregabalin due to cardiovascular related adverse event citing a study by American medical journal Cardiovascular Diabetology.PV is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine or vaccine related problem, according to the World Health Organization (WHO).Neuropathic pain is caused by damage or injury to the nerves that transfer information between the brain and spinal cord from the skin, muscles and other parts of the body. The pain is usually described as a burning sensation and affected areas are often sensitive to the touch.

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'One Herb, One Standard' policy mandates evaluation of drug standards, quality control in medicinal plants

The Union Ministry of Ayush's 'One Herb, One Standard' policy mandates evaluation of drug standards and quality control in medicinal plants. In August this year, the Ministry of Ayush entered into a 'One Herb, One Standard' memorandum of understanding between the Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H) (Ministry of Ayush) and the Indian Pharmacopoeia (IP) Commission with the primary objective of developing harmonized herbal drug standards.Now, the medicinal plants experts have called for the establishment of a new Ayush Drugs Technical Advisory Board and an Ayush Drugs Consultative Committee to focus on internationally acceptable standards in quality control and enhancing export potential of value-added products derived from medicinal plants.

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