The Veeda Newsletter

SEPTEMBER 2022: ISSUE 09

Partners in Creating

a healthier tomorrow

Veeda News
Latest webinar on Abatacept Biosimilar Clinical Assays

Regulatory
CBI files charge sheet in Biocon case

Financial
NPPA extends ceiling price fixation on orthopaedic knee implants for one more year

Clinical Research
Pfizer discontinues development of dilated cardiomyopathy drug emprumapimod

Merger and Acquisition
WeTrade enters partnership with Jiqing to sell monkeypox test kits and antigen tests

Indian Pharma
"Baseless": Dolo 650 maker Micro Labs rejects allegations of Rs 1,000 crore worth freebies to doctors

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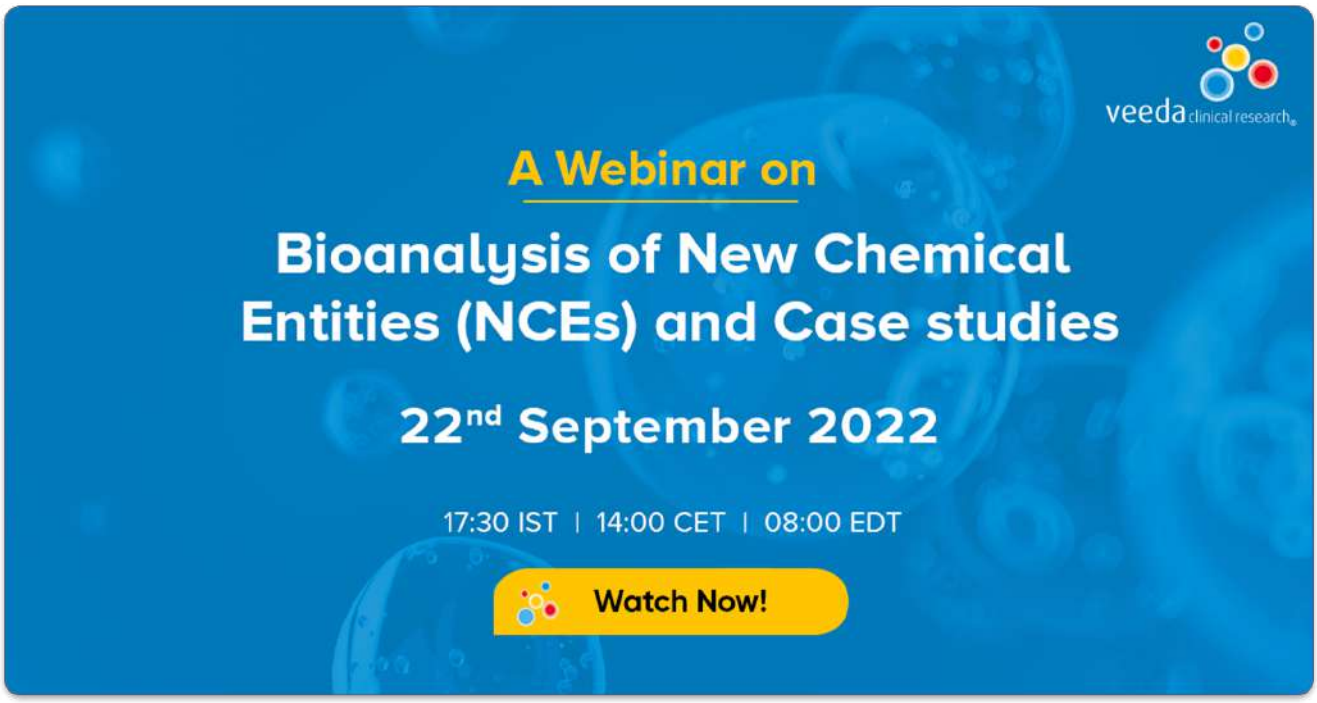
Indian Drug Manufacturers' Association felicitated Dr. Kiran Marthak with the Lifetime Achievement Award at their Annual Conference and 30th Annual General Meeting

Recording of our latest webinar on Bioanalysis of New Chemical Entities (NCEs) and Case Studies



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New co-chairs elected for working parties for healthcare professionals and for patients and consumers

EMA's Patients' and Consumers' Working Party (PCWP) has elected Marilena Vrana of the European Heart Network (EHN) as new co-chair. The Healthcare Professionals' Working Party (HCPWP) has elected Rosa Giuliani of the European Society for Medical Oncology (ESMO) as new co-chair. Together with Juan Garcia Burgos, Head of Public Engagement at EMA, they will co-chair the meetings of their respective working parties for the next three years. The vote took place during the September 2022 meeting of both working parties.

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GSK, Spero ink licence agreement for tebipenem HBr, a late-stage antibiotic that may treat complicated urinary tract infections

GSK plc and Spero Therapeutics, Inc. announced they have entered into an exclusive licence agreement for tebipenem pivoxil hydrobromide (tebipenem HBr), a late-stage antibiotic being developed by Spero, as the first oral carbapenem antibiotic to potentially treat complicated urinary tract infections (cUTI), including pyelonephritis, caused by certain bacteria. Luke Miels, chief commercial officer, GSK, said: "There is a high unmet medical need for a novel oral antibiotic as an alternative to intravenous hospital therapy for drug-resistant complicated urinary tract infections.

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Launch of the WHO guide for integration of perinatal mental health in maternal and child health services

Life altering moments like pregnancy, birth, and early parenthood can be stressful for women and their partners. As a result, women may undergo a period of poor mental health or witness a worsening of previous mental health conditions. Almost 1 in 5 women will experience a mental health condition during pregnancy or in the year after the birth. Among women with perinatal mental health conditions, 20% will experience suicidal thoughts or undertake acts of self-harm. Ignoring mental health not only risks women's overall health and well-being, but also impacts infants' physical and emotional development.

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CDSCO declares 3.4% of drug samples it tested as not of standard quality in August

The Central Drugs Standard Control Organisation (CDSCO) has declared 45 samples of drugs it has tested in the month of August as not of standard quality, almost 3.4 per cent of the total drug samples it has tested during the month. The samples tested as not of standard quality include batches from Boehringer Ingelheim India, Glenmark Pharmaceuticals, Wockhardt Ltd, and USV Pvt Ltd, among others. The drug regulator has tested a total of 1,330 samples during the month of August and declared 45 out of them as not of standard quality. There were no spurious or misbranded drugs among the samples, according to data released by the CDSCO.

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Cervical cancer vaccine a blessing

The approval by the Drugs Controller General of India of an indigenously developed vaccine, Cervavac, against cervical cancer, is an important event in the fight against a major killer disease. The approval has been given after Phase III clinical trials, and the vaccine is expected to be commercially available later this year at an affordable price of Rs 200-Rs 400 per shot. There are two vaccines available in the country now, but both are imported and are prohibitively costly. At over Rs 3,000 per shot, they are not for general use.

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Delhi HC quashes NPPA orders on overcharging against Bharat Serums and Vaccines and Bard Healthcare

The Delhi High Court has quashed four demand notices raised by the National Pharmaceutical Pricing Authority (NPPA) against Bharat Serums and Vaccines Ltd and medical devices manufacturer Bard Healthcare India Pvt Ltd for overcharging on non-scheduled drugs and medical devices, finding the move as unjustifiable as it does not allow rounding off principle to non-scheduled formulations while allowing it for scheduled formulations. Two demand notices issued by the NPPA holding the companies guilty of overcharging and thus liable to deposit the overcharged amount together with interest. Bharat Serum was served demand notices on June 26 and July 5, 2018, related to non-scheduled formulations named Histoglob and U-Tryp.

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NPPA fixes retail price of 36 formulations

The National Pharmaceutical Pricing Authority (NPPA) has fixed the retail price of 36 formulations including several anti-diabetes drugs under the Drugs (Prices Control) Order, 2013, based on the decision of an Authority meeting held this month. The formulations, for which the prices were fixed include type 2 diabetes medications such as dapagliflozin and metformin hydrochloride extended release tablets marketed by Hetero Healthcare; sitagliptin phosphate and metformin hydrochloride tablets marketed by Aprica Healthcare Ltd and Psychotropics India Ltd; sitagliptin and metformin hydrochloride tablets from Hetero Healthcare Ltd, various strengths of sitagliptin and metformin hydrochloride (sustained release) tablets from Aprica Healthcare and Aristo Pharmaceuticals, extended release tablets of the same combination marketed by German Remedies Pharmaceuticals, among others.

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NPPA extends ceiling price fixation on orthopaedic knee implants for one more year

The National Pharmaceutical Pricing Authority (NPPA) has extended the ceiling price it imposed on orthopaedic knee implants for knee replacement system in August, 2017, to one more year from September 16, 2022. The ceiling price was applicable till September 15, 2022, according to an earlier notification. The price regulation was imposed by the NPPA through a notification in August 16, 2017, which was extended through notifications in the subsequent years and the last order was issued on September 10, 2021.

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BMS' preferred drug in its $74M Celgene buy is set to pay dividends, winning its first FDA nod

Back when Bristol Myers Squibb acquired Celgene in 2019 for $74 million, it opted to keep the dermatology and immunology drug deucravacitinib, as opposed to already-approved Otezla. And now, BMS doesn't regret this move in the slightest. Deucravacitinib has won FDA approval for moderate-to-severe plaque psoriasis. And the company believes the drug, now dubbed Sotyktu, could be a new standard of care, said Samit Hirawat, the company's chief medical officer in an interview.

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Pharma exports grew 6.6% in August, 2022

The exports of drugs and pharmaceuticals during the month of August, 2022 has registered a growth of 6.61 per cent as compared to the corresponding month of last year, according to the preliminary data released by the ministry of commerce and industry. The growth comes against a slight decline of around one per cent reported in the month of July, 2022. The sector has reported an export of $2.14 billion as compared to the $2 billion exports registered in August, 2021.

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Epic launches program to 'unify' clinical research with care delivery

Epic stated that it plans to unite each of the stakeholders through the use of a single system, the Life Sciences program. According to the company, providers globally are using Epic to conduct more than 100,000 active research studies, which feature approximately 4.7 million patients. With the Life Sciences program, Epic will focus on matching providers with clinical trials suited to the makeup of their patient populations, which the company states will be available at launch. Extending beyond this, Alan Hutchison, VP, population, health and payer strategy at Epic, told Outsourcing-Pharma that the company's R&D team is currently working on the next components of the roadmap for the Life Sciences program.

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Pandemic ushers in a new era of clinical trials

The global outbreak of COVID-19 has had a significant impact on the conduct of scientific research. According to the ClinicalTrials.gov report, the challenges faced in doing clinical research during the pandemic led to the termination of more than 2000 registered trials. Experts agree that COVID imposed challenges on multiple fronts but also acknowledged the creation of never seen opportunities, especially in the area of clinical trials. To get a deeper insight into these revolutionary changes witnessed in the pharmaceutical industry during the pandemic, ETHealthworld in collaboration with SAS organised a panel discussion on the pertinent topic 'Future of Clinical Trials-Challenges & Opportunities'.

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Two popular diabetes drugs outperformed others in large clinical trial

In a large clinical trial that directly compared four drugs commonly used to treat type 2 diabetes, researchers found that insulin glargine and liraglutide performed the best of four medications approved by the U.S. Food and Drug Administration to maintain blood glucose levels in the recommended range. Blood glucose management is a key component of keeping people with type 2 diabetes healthy. All four medications evaluated were added to treatment with metformin, which is the first-line drug to treat type 2 diabetes. The trial was funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the National Institutes of Health.

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Epic launches program for clinical trial matchmaking in effort to expand access to marginalized participants

EHR giant Epic launched a new life sciences program aimed at facilitating clinical trial matchmaking. The program will work with providers, pharmaceutical companies and medical device manufacturers to recruit participants for research, expand trial access to underrepresented communities and speed up the development of new therapies. Its aim is to connect the disparate parts of the healthcare system, according to a press release.

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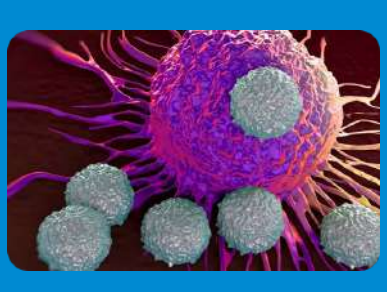
Bugworks Research and Cytecare Cancer Hospitals ink pact to propel development of immuno-oncology therapies

Bugworks, a US, India and Australia based start-up with globally recognized expertise in drug discovery, has set up a dedicated immuno-oncology ex vivo research lab at the Bengaluru-based hospital, Cytecare. The lab bridges the translation from discovery to development, addressing several hard-to-treat cancers such as gastric, colorectal, renal cell, breast, head and neck, non-small cell lung cancers. The partnership paves way for the development of novel immuno-oncology drugs that can be effective in wider patient population.



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RIGImmune subsumes Subintro in nasal drug delivery buyout, secures F-Prime investment

RIGImmune has struck a deal to acquire Subintro, giving it access to novel topical delivery systems. The deal positions the biotech to advance the development of novel RNA therapies and vaccine adjuvants for local mucosal delivery. Connecticut-based RIGImmune grew out of the work of Yale University's Akiko Iwasaki, Ph.D., and Anna Marie Pyle, Ph.D. Building on their research, the biotech set out to develop stemloop RNA therapeutics that selectively activate the innate immune sensor RIG-I. The receptor is activated by RNA agonists and, once in that state, triggers changes that suggest it could be a target for immunomodulatory therapies.

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Aragen collaborates with NeoVac to manufacture lipid products for next generation LNP for RNA vaccines

Aragen Life Sciences Private Limited (Aragen), a global research, development, and manufacturing services provider, announced that it has entered into an agreement with a UK-based company, NeoVac, for manufacturing a lipid product that will support the development of lipid nanoparticles (LNP) for use in developing RNA vaccines for various diseases. Aragen has been working with NeoVac since early December 2021 on process research development (PRD) for the lipid product.

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Australian CRO Avance buys C3 Research to support sponsors as programs advance

Australian CRO Avance Clinical has expanded in North America by acquiring C3 Research Associates, positioning it to continue supporting sponsors as they move into later-phase studies that need US sites. Avance has used the favorable environment for early-phase trials in Australia, which offers a 43.5% tax rebate and has no investigational new drug application requirement, to win business from sponsors that want to accelerate their first steps into the clinic. However, the CRO has then faced challenges as clients have progressed and expanded programs to include US sites, leading to the buyout of Seattle-based C3.

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Avance Clinical Acquires C3 Research Associates

Avance Clinical, an Australia-based contract research organization (CRO) for biotechs, announced on Sept. 6, 2022 that it has expanded its services into North America with the acquisition of C3 Research Associates, a US-based CRO partner company. The acquisition will enable Avance to offer biotech clients an easier transition from early phase to later phase studies.With the acquisition, Avance will have the capability to progress early phase studies in Australia and New Zealand into the United States, allowing biotech clients to continue their clinical development programs while retaining the same CRO services.

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AGC Biologics Partners with Evax

AGC Biologics, a global Biopharmaceutical Contract Development and Manufacturing Organization (CDMO), has announced a new partnership with Evax, a developer of equine vaccines to treat chronic diseases, respiratory disorders and allergies. Through this partnership, Evax advances its Antigen VLP Conjugate product into the clinical stage, and AGC Biologics will supply cGMP support for the pivotal studies. AGC Biologics is providing services at its Heidelberg facility using microbial-based protein biologics systems. The project covers Process Development and Clinical Manufacturing for the Evax Antigen-VLP Conjugate product.

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Vietnam dials India for drug supplies

With covid-19 impacting the pharma sector following supply disruption from China and Europe, Vietnam has sought the help of Indian healthcare, pharmaceutical and beauty product companies to ensure steady supplies. So far, Vietnam had been dependent on Chinese pharma inputs for over 80% of its requirements. Vietnam's pharma market is valued at around $5 billion.India's department of pharmaceutical, which operates under the ministry of chemicals and fertilizers, has received a communication from the high commission of Vietnam for allowing the pharma industry to participate in a healthcare event scheduled for May 2023.

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Drug industry welcomes National Logistics Policy to bring down logistics cost to single digit level

The drug industry has welcomed the National Logistics Policy (NLP) launched by the Union government aiming to reduce the cost of logistics to single digit levels from 13-14 per cent of the gross domestics (DGP) product of the country. The NLP launched by Prime Minister Narendra Modi on September 17 is aimed at easing the movement of goods and boosting the trade sector in the Indian economy. The goal of this policy is to make the logistics industry more efficient and lower its costs. The strategy aims to boost economic growth, provide employment opportunities, and make Indian products more competitive in the global market.

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Kyrgyzstan invites Indian pharma investments; to set up special free zone

Modalities of the zone, tax incentives that might be offered to be discussed at Inter-Government CommitteeKyrgyzstan Government will be setting up a special free economic zone for Indian manufacturers, especially for the pharmaceuticals industry."We have a big interest in promoting Indian pharma investments in our country. The proposed economic zone will offer free infrastructure for manufacturers," Asein Isaev, Ambassador of the Kyrgyz Republic told Business Line at the iPHEX - Global Regulators Conclave being organised by Pharmexcilhere.

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Researchers at IISc develop novel method to deliver vaccine candidate for TB

The Indian Institute of Science (IISc), Centre for BioSystems Science and Engineering, has designed a new method to deliver a vaccine candidate for tuberculosis (TB). The research involves using spherical vesicles secreted by bacteria coated on gold nanoparticles which can then be delivered to the immune cells. This, according to the researchers, can potentially trigger an immune response and offer protection against the disease.Annually, the deadly Tuberculosis caused by the bacterium mycobacterium affects and succumbs over a million people. The only effective vaccine currently in use is the BCG vaccine.

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AKCDA to launch several welfare schemes for its members

As part of its golden jubilee celebrations, the All Kerala Chemists and Druggists Association (AKCDA) will launch a slew of welfare schemes to its members and undertake several projects connected with hospitality and health tourism to be implemented along with the ongoing medicine trade.Health tourism is a project envisioned for the chemists and druggists across the country and it will be introduced in Kerala in association with the district and unit committees of the AKCDA.

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