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The Veeda Newsletter

NOVEMBER 2021: ISSUE 11

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Veeda News

Veeda managing the study of Phase II Clinical Trial in India of Second-Generation COVID-19 Vaccine

Regulatory

A vision for use of real-world evidence in EU medicines regulation

Financial

Indian pharma eyes affordable antiviral medicines to treat Covid-19

Clinical Research

Roundtable: the future of AI in clinical research

Merger and Acquisition

Merck Concludes Acquisition of Acceleron Pharma

Indian Pharma

Technology is the most effective way to transform healthcare industry in India: Gaurav Gupta, Navia Life Care

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Veeda managing the study of Phase II Clinical Trial in India of Second-Generation COVID-19 Vaccine

Akston Biosciences Corporation, a developer of new classes of biologic therapeutics, announced today that the first of 100 subjects were dosed in an open-label bridging study of AKS-452, its protein subunit COVID-19 vaccine candidate, in India. AKS-452 is shelf stable for at least six months at room temperatures (up to 25° Celsius or 77° Fahrenheit) and maintains its potency for one month at 37° Celsius (99° Fahrenheit).

India's Drug's Controller General of India (DCGI), Ministry of Health and Family Welfare, approved the open-label bridging study, being conducted by the Supe Heart & Diabetes Hospital and Research Centre, in Nashik, India along with four other sites in the state of Maharashtra. Veeda Clinical Research Ltd., a CRO with experience overseeing complex clinical trials, is managing the study.

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The Veeda Newsletter

NOVEMBER 2021: ISSUE 11

A vision for use of real-world evidence in EU medicines regulation

Enabling the use of real-world evidence (RWE) and establishing its value for regulatory decision-making on the development, authorisation and supervision of medicines in Europe by 2025: this is the vision of European regulators as outlined in an article from Peter Arlett, Head of Data Analytics and Methods at EMA, Jesper Kjær, Director of Data Analytics Centre at the Danish Medicines Agency, Karl Broich, President of the Federal Institute for Drugs and Medical Devices (BfArM), and Emer Cooke, EMA's Executive Director, published in Clinical Pharmacology & Therapeutics.

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WHO releases HIV drug resistance report 2021

WHO's latest HIV Drug Resistance Report gives an in-depth picture of the extent to which drug resistance is growing, and the steps that countries are taking to ensure people will receive effective medicine to treat and prevent HIV. The report reveals that in 2020, 64% of focus countries (countries with a high burden of HIV infection) had national action plans to prevent, monitor and respond to HIV drug resistance.

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FDA shares research to improve dose selection in pediatric drug development

Dose selection is a significant challenge in pediatric drug development; commonly used renal function equations can overestimate glomerular filtration rates and result in inaccurate predictions of drug elimination. In a Regulatory Science in Action article, scientists from the US Food and Drug Administration's Center for Drug Evaluation and Research (CDER) shared findings about how adjustments to the estimated glomerular filtration rate (eGFR) equations could help improve the accuracy of predicted renal function in pediatric drug studies.

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FDA Expands Eligibility for COVID-19 Vaccine Boosters

Today, the U.S. Food and Drug Administration amended the emergency use authorizations (EUA) for both the Moderna and Pfizer-BioNTech COVID-19 vaccines authorizing use of a single booster dose for all individuals 18 years of age and older after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine. The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices will meet later today to discuss further clinical recommendations.

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FDA could do more to enforce ClinicalTrials.gov reporting requirements

The US Food and Drug Administration (FDA) hasn't been notifying most clinical trial sponsors they are in violation of reporting requirements. That's according to results of a Freedom of Information Act (FOIA) investigation by Reshma Ramachandran, of the Yale School of Medicine in New Haven, CT, and colleagues in a recent Viewpoint published in JAMA. In January 2017, a final rule issued by the National Institutes of Health (NIH) determining ClinicalTrials.gov trial submission and reporting requirements went into effect, clarifying requirements outlined in Section 801 of the FDA Amendments Act (FDAAA) of 2007.

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The Veeda Newsletter

NOVEMBER 2021: ISSUE 11

Indian pharma eyes affordable antiviral medicines to treat Covid-19

A myriad of domestic pharma companies are eyeing antivirals as the focus shifts to treating Covid-19 through oral pills. The coronavirus is headed to the endemic stage in certain countries, giving these new drugs a potentially huge market, along with the ability to be a game changer for mild to moderate infections. With plans to manufacture the antivirals in the country, they will be available at a fraction of the global price.

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Pharma exports witness marginal decline of 0.88% in October

Exports of drugs and pharmaceuticals have registered a marginal decline of 0.88 per cent during the month of October, compared to the same month last year, owing to various factors including multifold increase in freight rates and a decline in exports to the US. The quick estimates of exports released by the Department of Commerce for the month of October, 2021, shows that the exports of drugs and pharmaceuticals was at $2.06 billion, as compared to $2.08 billion during the same month, last year.

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Innovation Fund Denmark: attracting investment in clinical trials

Innovation Fund Denmark (IFD) is a public grant agency that part funds entrepreneurs, students and companies to make new products and solutions that better the lives of Danish people. The agency currently has over a million euros in active investments. In 2020 alone IFD funded 1002 projects, with 90+ funded projects aimed at improving the health of the population. For 2021 the agency has been allocated DKK180m (€24.2m) for health investment through the Grand Solutions Program, which focuses on challenge-driven research and innovation projects that create new solutions, technologies and valuable new knowledge in life science, health, welfare and clinical research.

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Biden intends to rein in soaring drug prices — including insulin. Here's how

Here are some soul-crushing numbers that millions of Americans are sadly all-too familiar with: The price of insulin more than tripled between 2009 and 2019, according to Truven, a health analytics firm. Price hikes like this have proven deadly for some cash-strapped diabetics, who made fatal decisions to ration insulin because they couldn't afford to take full doses of the lifesaving drug. But good news could be on the way—I'll get to that in a moment. It's an example of the effect that soaring drug prices are having on Americans, particularly seniors.

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U.S. government will buy more of GlaxoSmithKline and Vir's COVID antibody drug

The U.S. government has agreed to buy more doses of an antibody drug for the early treatment of Covid-19 developed by GlaxoSmithKline and Vir Biotechnology bringing its total order to nearly $1 billion for a treatment found to reduce the risk of hospitalization. Even as vaccination rates tick up, antibody drugs, which imitate part of the body's natural immune response to the virus, have proven useful in fighting Covid-19 and preventing hospitals from being overwhelmed when cases surge.

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The Veeda Newsletter

NOVEMBER 2021: ISSUE 11

Decentralized Clinical Trials: Data Considerations & Value-Added Taxes

Clinical trials are critical to life sciences innovation, providing the indispensable framework for developing new medicines and validating their effectiveness. But the rapidly changing regulatory, tax, and global business landscape, driven in part by COVID-19 and ongoing economic and political shifts, means that biopharma executives must keep careful watch over how they implement and monitor decentralized clinical trials (DCTs). As industry leaders face looming losses of exclusivity and the need to replenish the therapeutic pipeline, the successful execution of DCTs is paramount.

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Why You Should Volunteer For a Clinical Trial

I'm not sure how many tubes of blood I donated in the end—not being fond of needles, I fixed my gaze over the nurse's left shoulder throughout the proceedings. But it felt like a lot. And yet it also felt like it was the least I could do to give back. I'm now one year into a five-year clinical trial studying my emotional response to the results of genomic sequencing, a relatively new type of test that digs into nearly every letter of your DNA code (unlike traditional genetic testing, which only looks at a few genes at a time).

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Roundtable: the future of AI in clinical research

Artificial Intelligence (AI) is quickly weaving itself into the fabric of our lives across all industries. The life sciences have seen a dramatic leap forward into the digital age in recent years and as such, AI is being recognised for its potential to reduce costs and accelerate every stage of clinical research and drug development – from matching patients with clinical trials and handling data to discovering drugs themselves. In general, pharma has been quite slow to adopt AI but an increasing number of companies are now partnering with smaller AI start-ups for their expertise in drug discovery and others are actively hiring internally for AI roles.

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Clinical Trials Enter a New Digital Era

The life sciences industry has been undergoing a transformation. Its seen advancements in how therapies are developed and improvements in how the industry works together. One development that has helped the industry evolve is the shift to digital technologies. The COVID-19 pandemic forced companies to adopt decentralized technologies to enable remote trial execution. The shift introduced more technologies into the trial ecosystem, which has created challenges for companies.

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Hybrid Trials Are Impacting Clinical Research, But Do Patients Want Them?

Clinical trials continue to evolve and have become increasingly complex. Studies now have more procedures, visits, and time spent at clinics during those visits. Studies also have narrower inclusion criteria and longer travel times to clinics. Those factors have been building for years and have created additional burdens for patients. The Center for Information and Study on Clinical Research Participation (CISCRP) is celebrating its eighth year of focusing on the patient experience in clinical trials via its Perceptions and Insights study.

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The Veeda Newsletter

NOVEMBER 2021: ISSUE 11

Ipca Labs approves acquisition of 26.5% stake in Lyka Labs

The board of Ipca Labs has approved the acquisition of 26.574% of the paid-up share capital of Lyka Labs Limited and entering into a joint management control agreement with the promoters of Lyka Labs. Ipca said it has acquired 26.574% shareholding of Lyka from secondary market for Rs. 97.89 crore. Shares of Ipca Labs were trading 1% lower at ₹2037.80 while Lyka were locked in 5% upper circuit as compared to a 0.5% gain in Nifty pharma index.

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Merck Concludes Acquisition of Acceleron Pharma

Merck, known as MSD outside the United States and Canada, has recently announced the successful completion of the acquisition of Acceleron Pharma Inc."This is an important and strategic opportunity for our company to continue growing our cardiovascular portfolio and pipeline, that builds on our long and proud legacy in cardiovascular disease and further bolsters our business development strategy," said Rob Davis, chief executive officer and president, Merck.

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Twist Bioscience agrees to acquire Abveris for $190m

Twist Bioscience has signed a definitive agreement to acquire in vivo antibody discovery services firm Abveris for up to $190m to boost its biopharma expertise. Previously known as AbX Biologics, Abveris focuses on developing drugs, vaccines, cell therapies, and diagnostics in collaboration with international biopharma companies. Leveraging the DiversimAb family of hyperimmune mice models, Abveris provides complete antibody discovery and characterisation services.

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Pfizer acquires Trillium Therapeutics for $2.22bn

Pfizer has completed the acquisition of all outstanding shares of clinical-stage immuno-oncology firm Trillium Therapeutics in a deal worth about $2.22bn, or $18.50 per share, in cash. Pfizer has completed the acquisition of all outstanding shares of clinical-stage immuno-oncology firm Trillium Therapeutics in a deal worth about $2.22bn, or $18.50 per share, in cash.

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Amneal acquires Ahmedabad-based injectibles facility for ₹700 crore

Buys Puniska Healthcare to expand and increase its existing injectibles capabilities. US-headquartered pharma player Amneal Pharmaceuticals Inc announced acquisition of Ahmedabad-based injectibles company, Puniska Healthcare Pvt Ltd. The deal, which is valued at $93 million (approx ₹700 crore), will enhance Amneal's injectibles manufacturing capabilities in India and will also support its US market. Speaking to BusinessLine, Sanjay Kumar Jain, President (India Operations), Amneal, said, "Amneal wants to expand its business in the injectibles space.

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The Veeda Newsletter

NOVEMBER 2021: ISSUE 11

Technology is the most effective way to transform healthcare industry in India: Gaurav Gupta, Navia Life Care

In this unprecedented health care crisis caused by Covid-19, hospitals across India faced multiple challenges of access, safety, supply chain logistics and financial stress, all this resulted in huge patient loads and fatalities, heavy financial losses and a sharp decline in revenues. Elective procedures were cancelled or postponed to prioritise hospital capacity, while patients limited hospital visits because of concerns about potential exposure to infections. Many of them died from the lack of care for non-Covid diseases.

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Uzbekistan invites Indian pharma companies to set up manufacturing units

Uzbekistan has asked Indian pharmaceutical companies to explore its USD 1.3 billion medical drug market by setting up their manufacturing base and make this industry a key driver of Uzbek economy, said Alisher Temirov, Deputy Minister, Pharmaceutical Industry Development of Uzbekistan during a meeting on 'Doing Business with Uzbekistan' organized by the MVIRDC World Trade Center – a trade facilitating body and All India Association of Industries – an industry body.

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Innovation will Propel Indian Pharmaceutical Industry on Path to become Global Leader – Echoed at Global Innovation Summit-2021 organised by IPA

The two-day Global Innovation Summit -2021 organised by India's largest industry body, the Indian Pharmaceutical Alliance (www.IPA-India.org) successfully concluded late last night with industry leaders from across domestic and global pharma industries, policy makers, investors and researchers unanimously agreeing that innovation will act as the backbone for propelling the Indian pharmaceutical industry into becoming the global leader and further committed to enhancing its innovation ecosystem.

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ICMR invites research proposals of ad-hoc project under research program for 2021

The Indian Council of Medical Research (ICMR) has invited research proposals of ad-hoc project under research program for the year 2021, ICMR scientist Dr Lokesh Kumar Sharma said. To promote research in the country in the field of biomedical research, ICMR provides financial support in the form of ad-hoc projects to scientists/professionals who have a regular employment in the medical college, research institute, university, recognized research and development laboratory, government and semi government organization and NGOs.

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Indian Pharma Market Grows By 9.7% in October

According to total sales data from IMS, the Indian Pharmaceutical Market (IPM) grew by 9.7% yoy in Oct'21 vs. 12.7% yoy in Sept'21, Emkay Global has said in a report. On a MAT basis, IPM grew by 17%, driven by volume growth (8%), new product growth (5%), and pricing growth (4%). 'Within our coverage, Ipca grew the fastest at 17% yoy, followed by DRL at 12% and Sun at 10%. Lupin and Cipla both grew at 8% each.

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The Veeda Newsletter

NOVEMBER 2021: ISSUE 11

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