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The Veeda Newsletter

OCTOBER 2021: ISSUE 10

Veeda Group Experts are virtually attending one of the biggest pharma events

CPhI worldwide® 2021

RAJKUMAR AGARWAL
Head, Business Development

PANKAJ SOJITRA
Sr. Manager, Business Development

Partners in creating

a healthier tomorrow

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Mr. Ajay Tandon's interview in leading Pharma Publications

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First-in-class medicine to treat aggressive form of breast cancer

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Indian Pharma
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Our Managing Director, Mr. Ajay Tandon's interview in leading Pharma Publications

"We are an independent, institutional investors-owned, Board-governed and professionally managed contract research group offering scientific leadership, global quality management systems and long-term operational and financial stability through a continuing investment in our people, processes, systems, infrastructure and technology and a deep commitment to quality" - Ajay Tandon

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FDA encourages industry to adopt modeling tools to ensure stable processes

An official with the US Food and Drug Administration (FDA) encouraged the pharmaceutical industry to adopt advanced process control (APC) modeling tools to ensure that manufacturing processes are operating in a state of control, asserting that these processes are often reactively monitored rather than proactively controlled. “Our process capabilities remain at two or three sigma, because we are relying on manufacturing of the last century,” said Stelios Tsinontides, director of the FDA’s Office of Pharmaceutical Manufacturing Assessment, speaking in an on-demand session from AAPS PharmSci 360.

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Takeaways from FDA’s Approval of the First Interchangeable Biosimilar for Humira®

On October 15, 2021, the U.S. Food and Drug Administration (“FDA”) approved Boehringer Ingelheim’s Cyltezo® (adalimumab-adbm), the first interchangeable biosimilar to AbbVie’s blockbuster immunosuppressant Humira® (adalimumab). We previously discussed Boehringer Ingelheim’s Citizen Petition requesting a change in the FDA’s interpretation of “strength” of biological products under the Biologics Price Competition and Innovation Act (“BPCIA”).

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U.S. FDA says Pfizer’s COVID-19 vaccine is safe, effective for kids aged 5-11

U.S. health regulators said late Friday that kid-size doses of Pfizer’s COVID-19 vaccine appear highly effective at preventing symptomatic infections in elementary school children and caused no unexpected safety issues, as the U.S. weighs beginning vaccinations in youngsters. The Food and Drug Administration posted its analysis of Pfizer’s data ahead of a public meeting next week to debate whether the shots are ready for the nation’s roughly 28 million children ages 5 to 11. The agency will ask a panel of outside vaccine experts to vote on that question.

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FDA issues proposed OTC hearing aid rule

The US Food and Drug Administration (FDA) has issued a long-awaited proposed rule to create a new regulatory category that would allow the sale of over-the-counter (OTC) hearing aids for adults with mild and moderate hearing loss. Implementing the proposed rule would make good on requirements established by the Over-the-Counter Hearing Aid Act of 2017 passed as a provision of the FDA Reauthorization Act of 2017.

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First-in-class medicine to treat aggressive form of breast cancer

EMA has recommended granting a marketing authorisation in the European Union (EU) for Trodelvy (sacituzumab govitecan), a first-in-class medicine to treat adult patients with unresectable (cannot be removed by surgery) or metastatic triple-negative breast cancer who have received two or more prior systemic therapies, at least one of them for advanced disease.

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U.S., India's Biological E. finalise $50 mln financing deal for COVID-19 shots

The United States and India's Biological E. Ltd said on Monday they had finalised a financing arrangement for $50 million to expand the vaccine maker's capacity to produce COVID-19 shots. The agreement was struck in March when leaders of the United States, Australia, Japan and India - the so-called "Quad" countries - met during a virtual summit.

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Biocon eyes $30b US insulin market via its biosimilars

Biopharmaceutical major Biocon has its eyes set on the US insulin market, which is expected to grow to $29.9 billion by 2025, with its interchangeable biosimilar product Semglee that has received approvals and aspart that the company is hoping will be approved by the first quarter of 2022. With the approval of aspart, Biocon says it will become the first company to receive approvals for two interchangeable insulin drugs in the US, helping it make a strong entry into that market.

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NPPA sets up PMRUs in 19 states and Union territories till October

The National Pharmaceuticals Pricing Authority of India (NPPA) has said that it has successfully set up Price Monitoring and Resource Units (PMRUs) across 19 states in the country, in order to strengthen drug security and affordability. The PMRUs, under the Central scheme Consumer Awareness, Publicity and Price Monitoring (CAPPM), are set up with an objective to monitor the prices of medicines, detection of violation, and ensuring availability of medicines.

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NPPA clarifies anti-fungal clotrimazole 1% is a scheduled formulation under DPCO-2013

The multidisciplinary committee of experts, under the National Pharmaceutical Pricing Authority (NPPA) has said that the anti-fungal medication clotrimazole 1% mouth paint is a scheduled formulation based on the Drugs (Price Control) Order, 2013. The matter of whether the particular strength of the medicine would fall under the Scheduled formulation was deliberated in detail by the Committee in its latest meeting held on October 11, at the NPPA office.

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NPPA fixes price caps for 12 anti-diabetic medicines

Drug price regulator National Pharmaceutical Pricing Authority (NPPA) on Monday said it has fixed the ceiling prices for 12 anti-diabetic generic medicines, including glimepiride tablets, glucose injection and intermediate acting insulin solution. In a tweet, the drug price regulator said, "To make it possible for every Indian to afford medical treatment against diseases like diabetes, NPPA has initiated a successful step by fixing the ceiling prices of 12 anti-diabetic generic medicines."

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FDA Clinical Hold Lifted on Clinical Trials Involving Rusfertide

The US Food and Drug Administration (FDA) has lifted a clinical hold that had been placed on the injectable hepcidin mimetic agent rusfertide (PTG-300), it was announced on October 11, 2021, in a press release provided by Protagonist Therapeutics, Inc. With this announcement, ongoing clinical trials involving rusfertide are allowed to resume dosing. A phase 3 registrational trial of the agent is also scheduled to begin in the first quarter of 2022.

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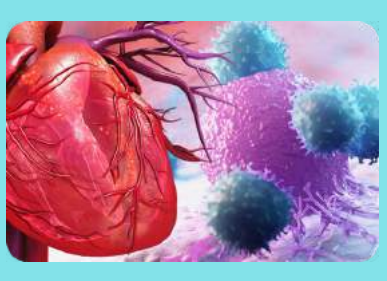
Racial disparities in cancer clinical trials: 'An old problem with new implications'

Racial disparities in cancer clinical trial enrollment have existed for decades, with Black, Hispanic and other underserved populations prevented from accessing the same cutting-edge treatments as their white counterparts. The need to close these care gaps has taken on greater significance with the advent of targeted immunotherapies. As clinical trials are conducted with the aim of securing FDA approval for these novel treatments, it is important to understand the unique biology and pharmacokinetics of these drugs in diverse patient populations, according to experts with whom HemOnc Today spoke.



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How to Run Decentralized Clinical Trials in the Complex Web of Data Protection

The pandemic proved the many benefits of decentralized clinical trials (DCTs). These virtual research models helped accelerate trials while reducing the time, cost, and burden of participation. However, for all the benefits, sponsors will need to consider how to handle patient data in DCTs.It is critical to be aware of global data protection requirements and adapt their trial plans accordingly or risk making seemingly insignificant decisions that have significant impact once implemented.

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All you need to know about clinical research service agreement

Initiation of any business requires an agreement or a contract. Written documents are more favourable when it comes to any business transaction. Contracts or agreements act as a backbone to both parties. If any unfavourable situation arises in future, a contract gives the power to sue and to be sued. A Contract gives legality to any transaction. As per Section 2(e) of the Contract Act, every promise or a set of promises which form the consideration for each other is an agreement.

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Increasing diversity in clinical trials can save lives. Here's how hospitals are doing that.

There's been a lot of talk about increasing diversity in different industries recently, but increasing diversity in clinical trials can save lives. That's why Moffitt Cancer Center is working with the American Society of Clinical Oncology and the Association of Community Cancer Centers to provide feedback about some programs aimed at increasing racial and ethnic diversity in clinical trials. It's one of 75 sites across the country sending data to the ASCO.

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Amgen Acquires Teneobio

Amgen has announced that the company has successfully completed its previously announced acquisition of Teneobio, Inc. Effective as of Oct. 19, 2021, Amgen has acquired all outstanding equity of Teneobio in exchange for a $900 million upfront cash payment, as well as future contingent milestone payments, to former Teneobio equity holders potentially worth up to an additional $1.6 billion in cash.

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Beximco Pharma acquires majority stakes in Sanofi Bangladesh for Tk 400 crore

Beximco acquired the shares as it looks to expand its product base and diversify into new areas. With this, the French pharmaceuticals giant Sanofi will exit Bangladesh ending its presence in the country that spans over more than six decades. Earlier, the central bank gave go-ahead to the Bangladeshi drug maker to acquire Sanofi's shares from Fisons Ltd and May and Baker Ltd of the UK – the two foreign shareholders of Sanofi Bangladesh.

BEXIMCO PHARMA

SANOFI

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Is an Acquisition of Acceleron a Smart Move for Merck?

First, there were rumors that Merck (NYSE: MRK) might acquire Acceleron Pharma (NASDAQ: XLRN). Then those rumors were confirmed, with the big pharma company announcing plans to buy Acceleron for $11.5 billion. In this Motley Fool Live video recorded on Sept. 29, 2021 (one day before Merck's announcement of the deal), Motley Fool contributors Keith Speights and Brian Orelli discuss whether acquiring Acceleron would be a smart move for Merck.

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Syneos Health Acquires RxDataScience

Syneos Health has acquired RxDataScience, a healthcare-focused data analytics, data management and artificial intelligence (AI) company. Syneos gains technology-enabled, insights-powered solutions with the aim of accelerating performance across the product lifecycle – from lab to life. RxDataScience's scalable platform enables biopharma companies to transform vast volumes of data into strategic, actionable insights. Multidisciplinary teams of product managers, data scientists, engineers, developers and domain experts leveraging insights from providers, payers and patients contribute to RxDataScience's innovative software solutions.

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AstraZeneca Acquires Caelum Biosciences

Fortress Biotech, Inc., a biopharmacompany focused on acquiring, developing and commercializing promising products and product candidates cost-effectively, and a company it founded, Caelum Biosciences, Inc., a biotechnology company developing treatments for rare and life-threatening diseases, closed AstraZeneca's acquisition of Caelum for approximately $150 million. The agreement also provides for additional potential payments to Caelum stockholders totaling up to $350 million, payable upon the achievement of regulatory and commercial milestones.

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The Indian healthcare industry will continue to draw investor attention

India's healthcare infrastructure is set for massive growth. By FY 22, the size of India's healthcare infrastructure will reach USD 349.1 billion, growing by 17% on an annual basis, as per the research by "theIndiawatch.com", an India-focused business research advisory. Hospitals and healthcare centres are the biggest categories in the industry, reaching USD 279.2 billion by the end of the current fiscal. Other prominent categories include pharma, medical devices, etc.

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USD 100 billion nutraceutical market of India: An opportunity in making

India is poised to be a $10 trillion economy by 2030. There also exist opportunities to enable and empower industries that have inherent powers to contribute to economy. One such industry is nutraceuticals that stand alone can contribute $100 billion by 2030. Currently, global nutraceutical market is $400 billion. Around 60% of this is in the USA and India currently stands at 2%. India with current contribution of $8 billion has immediate capability to ramp up to $40 billion by 2024 if basic tweaks in policies and supports are given to this industry.

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US' work with India on vaccine manufacturing saving people's lives, says DFC chief

India is a "vaccine powerhouse" and America's work with the country in vaccine manufacturing is saving people's lives, the head of the US International Development Finance Corporation, David Marchick, has said ahead of his India visit. The United States International Development Finance Corporation (DFC) is America's development bank, which invests in developing countries around the world. Leading a high-powered delegation, DFC Chief Operating Officer (COO) Marchick would travel to India from October 24 to 26.

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Indian pharma witnesses shift in skill demand driven by tech advances: Experts

Experts are of the view that Indian pharma is now seeing a shift in skills demand driven by tech advances across R&D, manufacture and marketing. Digital tools such as Augmented Reality (AR) and Virtual Reality (VR) are increasingly being used to design, develop and test new products. Digital tools are also used for remote auditing, supply chain and people management. Artificial intelligence (AI), AR-VR, blockchain, 3D printers, IoT (internet of things), etc are changing the way pharmaceutical companies operate today.

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Indian Pharma Market registers 12.4% growth in September 2021

The Indian Pharmaceutical Market (IPM) has registered a growth of 12.4 per cent for the month of September 2021, after registering a growth of 17.7 per cent for the month of August 2021. According to AIOCD AWACS report, moving annual total (MAT) for the September was at Rs. 150,094 crore, which has seen a growth of 15.2 per cent over the corresponding period of last year. Among the top companies, Sun Pharmaceutical Industries has maintained its top position in the Indian pharma market growth with a market share of 7.23%, while Abbott retained its second position with a market share of 6.17%.

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