The Veeda Newsletter

MARCH 2022: ISSUE 03

Our team at the recently concluded

DCAT Week

Partners in Creating

a healthier tomorrow

Veeda News
Update on our latest panel discussion, new webinar and GCP training

Regulatory
WHO establishes the Global Centre for Traditional Medicine in India

Financial
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Clinical Research
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Merger and Acquisition
Aurobindo Pharma acquires business and certain assets of Veritaz Healthcare for Rs 171 crore

Indian Pharma
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Dr. Marthak with other panelists during the panel discussion on Prioritizing Patient Safety Regulations

Our Latest Webinar on Data Safety Assessment in Clinical Trials

Veeda conducted a training on Good Clinical Practices (GCP) earlier this month

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FDA's revised quality metrics plan praised for offering greater flexibility

The US Food and Drug Administration's (FDA) revised quality metrics plan is an improvement over previous iterations as it offers more flexibility to drugmakers by giving them options on what type of metrics data to submit, according to stakeholders who spoke to Focus. FDA also showed responsiveness to industry concerns by asking how metrics data should be submitted, either by site or by product, according to a consultant and a consumer industry group.

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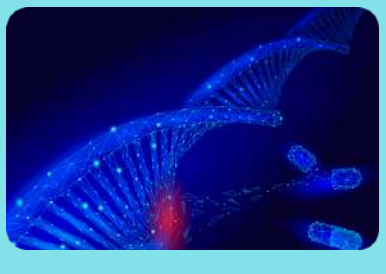
New gene therapy to treat adult patients with multiple myeloma

EMA has recommended a conditional marketing authorisation in the European Union (EU) for Carvykti (ciltacabtagene autoleucel) for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least three prior therapies and whose cancer has worsened since they received their last treatment. Multiple myeloma is a rare cancer of the plasma cells, a type of white blood cell that produces antibodies and is found in the bone marrow.



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WHO establishes the Global Centre for Traditional Medicine in India

The World Health Organization (WHO) and the Government of India today signed an agreement to establish the WHO Global Centre for Traditional Medicine. This global knowledge centre for traditional medicine, supported by an investment of USD 250 million from the Government of India, aims to harness the potential of traditional medicine from across the world through modern science and technology to improve the health of people and the planet.

World Health Organization

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EU and WHO join forces to improve global health security and access to medical products and health technologies in Africa

On 23 March 2022, Jutta Urpilainen, European Commissioner for International Partnerships, and WHO Director-General Tedros Adhanom Ghebreyesus, met in Geneva to deliberate on the EU - WHO partnership in global health and the ongoing preparations for a global accord on pandemic prevention, preparedness and response. The two senior representatives of the partner organizations signed a letter of intent for a € 24.5 million EU contribution to the World Health Organization.

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WHO releases clinical management guidelines for influenza

WHO's new Guidelines for the clinical management of severe illness from influenza virus infections provide recommendations on the use of influenza antivirals, adjunctive therapies and diagnostic strategies. The new guidelines are intended to guide clinicians in their care of patients with or at risk of severe illness from seasonal, zoonotic or pandemic influenza.

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CDC Statement on President's Fiscal Year 2023 Budget

Today, the Biden Administration released the President's FY 2023 budget. The Centers for Disease Control and Prevention (CDC) budget request for FY 2023 includes $10.675 billion in discretionary budget authority, Public Health Service evaluation funds, and Prevention and Public Health Funds, which is $2.3 billion over the FY 2022 appropriation. In addition, the CDC budget includes new proposed mandatory funding to establish Vaccines for Adults program and to invest in pandemic preparedness. This budget request will enable the Agency to invest in the core infrastructure of our country's public health system.

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NPPA expert panel recommends retail price for generic sitagliptin combinations

In a move which may increase the price war in the over $2.3 billion anti-diabetic drugs market in the country, the expert panel for National Pharmaceutical Pricing Authority (NPPA) has recommended price fixation against 10 applications for various strengths of fixed dose combinations (FDCs) of anti-diabetic drug sitagliptin and metformin. The panel noticed that the formulation 'Sitagliptin' is on the verge of becoming off patent.

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Pharma industry in a sweet spot after market correction

The Nifty Pharma index has declined 4.65% in the year so far as market volatility and raw material prices surged following the Russian invasion of Ukraine, but analysts believe that a large part of the concerns have been priced in, and the sector is expected to fare better in the coming quarters. "We expect the raw material overhang and supply chain headwinds to continue in the better part of FY23," said analysts at Antique Stock Broking. The sector outlook, however, remains positive, according to the broking firm, as most companies under its coverage have seen earnings downgrades, and at current stock prices, analysts find the risk-reward ratio favourable for the overall sector.

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NPPA's expert panel recommends retail price for FDCs of anti-diabetic linagliptin

The National Pharmaceutical Pricing Authority (NPPA)'s expert panel has fixed the price of anti-diabetic combination drug consisting of linagliptin, patented by Boehringer Ingelheim, on eight applications filed by Indian manufacturers and marketers, as the medicine is "on the verge of becoming off-patent." The anti-diabetic market, which is over Rs. 14,000 crore according to 2021 reports, has been seeing increased competition owing to some of the major drugs going off-patent in the recent years and the new move is expected to add momentum to this competition in the market.

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Under the Radar Biotechnology Stocks Approaching Clinical Trials

Investors with high-risk appetites gravitate towards the biotechnology sub-sector of healthcare stocks where clinical trials sometimes yield significant share price movement. Depending on the treatment and the market size of the affected population, positive announcements regarding the progress of the trials can reward investors handsomely, at least in the short term. The risk is obvious. Negative announcements can cause the share price to plunge, again at least in the short term.

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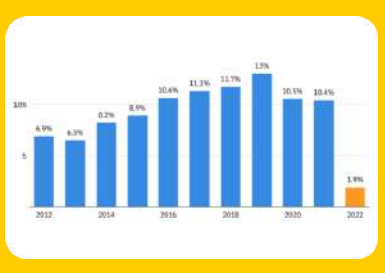
Women's health clinical trials: increase in studies but many opportunities for growth

The past ten years have seen a significant increase in the level of clinical trial activity geared towards women's health studies. But there is still room for improvement, such as more initiations for industry-sponsored trials, as well as Europe and North America needing to host more of such investigations. The period from January 2012 to 17 March 2022 saw a consecutive year-on-year rise in trial initiations between 2013 and 2019, with a record number of initiations observed in 2019. The greatest decline in trial initiations was seen in 2020, with the number of trials falling to a five-year low, demonstrating the impact of the Covid-19 pandemic.



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Race and ethnicity in clinical trials

In order to provide accurate results regarding the safety and efficacy of drugs and devices being tested through clinical trials, a diverse participant pool would work better than one that skewed male and White, for instance. In recent years, a concerted effort has been made to achieve greater parity in clinical trials. A report investigates whether that effort has paid off. The investigators performed a cross-sectional study that looked at the articles reporting on pediatric clinical trials in the United States from January 2011 to December 2020. The medical journals used were the top 5 general pediatric and top 5 general medicine.

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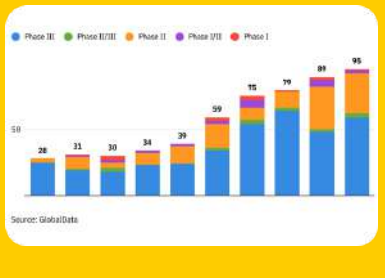
Clinical trials in Russia: big pharma makes moves but what's the pipeline impact?

It's only been a month since the Ukraine war started, yet thousands of lives have been lost, millions have fled into neighbouring countries, and innumerable infrastructure destroyed. In terms of clinical trials, there's been hesitation among pharma companies to react, particularly regarding Russia. Eventually, a notable number of them announced moves that could impact their pipelines and potentially the broader sector. Overall, these moves may potentially delay the delivery of new drugs.



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Digital approaches to enhancing community engagement in clinical trials

Digital approaches are increasingly common in clinical trial recruitment, retention, analysis, and dissemination. Community engagement processes have contributed to the successful implementation of clinical trials and are crucial in enhancing equity in trials. However, few studies focus on how digital approaches can be implemented to enhance community engagement in clinical trials. This narrative review examines three key areas for digital approaches to deepen community engagement in clinical trials—the use of digital technology for trial processes to decentralize trials, digital crowdsourcing to develop trial components, and digital qualitative research methods.

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Improving Clinical Trial Delivery Times: Best Practices

Too often, clinical trials are delayed while waiting for technology implementations, which can significantly increase cost, timelines, and frustration for study teams, sites. And the stakes are high: in the US alone, biopharmaceutical companies spent about $1 billion to bring each of their new drugs to market between 2009 and 2018, according to a 2020 JAMA report 2020.

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Aurobindo Pharma acquires business and certain assets of Veritaz Healthcare for Rs 171 crore

Aurobindo Pharma on March 28, in a regulatory filing, announced that it has acquired the business and certain assets of Veritaz Healthcare for cash consideration of Rs 171 crore. "The transaction is agreed at a consideration of Rs 171 crore on debt-free cash free basis. The transaction comes into effect from 1st April 2022 and expected to close by May, 2022," Aurobindo said. Notably, Veritaz sells branded generic formulations and other healthcare related products in the Indian market. Its sales and distribution network covers around 50,000 retailers, spread across 23 cities.

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Sun Pharma to acquire 11.28 pc stake in Zenotech from Daiichi Sankyo

Sun Pharmaceutical Industries on Monday said it has entered into a share purchase agreement with Japan's Daiichi Sankyo Company to acquire the latter's 11.28 percent stake in Zenotech Laboratories. Sun Pharma said it will pay Rs 5.32 crore for the stake. The primary objective of the transaction from acquirer's perspective is to consolidate its holding in the target company, the Mumbai-based drug firm said in a regulatory filing.

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Fujifilm to Acquire Shenandoah Biotechnology

Fujifilm Irvine Scientific, a provider of development and manufacturing of serum-free and chemically defined cell culture media for life science research, bioproduction and cell therapy manufacturing, will acquire Shenandoah Biotechnology, a manufacturer of recombinant proteins. Terms were not disclosed. Shenandoah Biotechnology is a privately held company located in Warminster, PA, that manufactures recombinant proteins including cytokines and growth factors. The company recently launched their CTG Grade line of cytokines and growth factors that are manufactured according to cGMP guidelines in the company's new state-of-the-art, ISO 9001:2015 certified facility.

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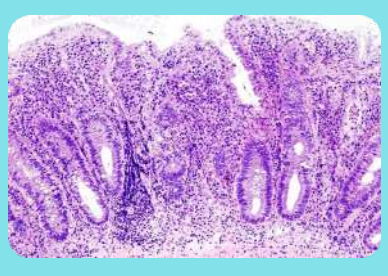
Pfizer concludes Arena Pharmaceuticals acquisition for $6.7bn

Pfizer has concluded the takeover of the complete outstanding shares, options and restricted stock units of clinical-stage firm Arena Pharmaceuticals for an equity price of nearly $6.7bn or $100 for each share in cash. In December last year, Pfizer entered a definitive agreement to acquire Arena.



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Pharmaceuticals, Ucb completes the acquisition of Zogenix

The Belgian multinational Ucb Pharma announces the completion of the acquisition of the Californian company Zogenix for 26 dollars per share plus a right of contingent value related to the achievement of certain predetermined objectives, for a potential cash payment of 2 dollars per share. Overall, the transaction is estimated to be worth up to approximately $ 1.9 billion (€ 1.7 billion).

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Indian pharma sees Efficient Clinical Trial Design Strategies by US FDA for biologicals to spur drug development

Indian pharma sees that the recent US FDA guidance on 'Master Protocols: Efficient Clinical Trial Design Strategies to Expedite Development of Oncology Drugs and Biologics' for industry will support drug discovery and development. The country is home to large cancer and immunosuppressant disease patient population. Therefore, a number of clinical trials are taking place across hospitals in the country. The guidance by the global regulatory authority provides recommendations to sponsors of drugs or biologics for the treatment of cancer. It will also guide on aspects of design and conduct of clinical trials intended to simultaneously evaluate more than one investigational drug.

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Industry captains urge govt to urgently introduce robust OTC drug policy to reduce out-of-the-pocket healthcare spend

Captains of the pharmaceutical industry have urged the government to implement a robust policy with clear guidelines for promotion and sale of over-the-counter (OTC) drugs which will substantially bring down out-of-the-pocket healthcare spend in the country. The robust OTC policy will drive health literacy and responsible self-care among consumers through authentic information, tools and guidance, they added.

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Asia-Pacific Roundup: India consults on voluntary medical device marketing code

The Indian Department of Pharmaceuticals (DoP) is seeking feedback on a proposed Uniform Code for Medical Devices Marketing Practices (UCMDMP). DoP drafted the code in response to a request from the medical device industry, which currently must comply with the rules on pharmaceuticals but wants its own voluntary regulatory requirements. UCMDMP shares a structure and some similarities with the Uniform Code for Pharmaceuticals Marketing Practices, published late in 2014.

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Indian pharma: Partner in quality and cost-effective health

India's pharmaceutical industry has achieved significant growth in both domestic and global markets over the past five decades. Within India, while just 5% of medicine consumption was met by local production in the 1960s, the share of 'Made in India' medicines in the Indian pharma market has today reached more than 80% (2020). Equally significant, during the past few decades, Indian pharma has also established a leading position in the global pharma landscape, leading to the country today being hailed as the "pharmacy of the world." Presently, Indian pharma industry contributes more than 20% by volume of the global generics market.

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Innovation in India's pharma sector matters to the world. Here's why

Until the onset of COVID-19, economic efficiency was the dominant consideration that drove the growth of global supply networks. The pandemic, however, exposed the national security implications of excessive reliance on foreign supplies, especially on a single country, in crucial sectors such as pharmaceuticals. Now, there is an outcry in many countries to reduce dependence on foreign suppliers on active pharmaceutical ingredients (APIs) which are critical inputs into the production of dosified medicines.

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