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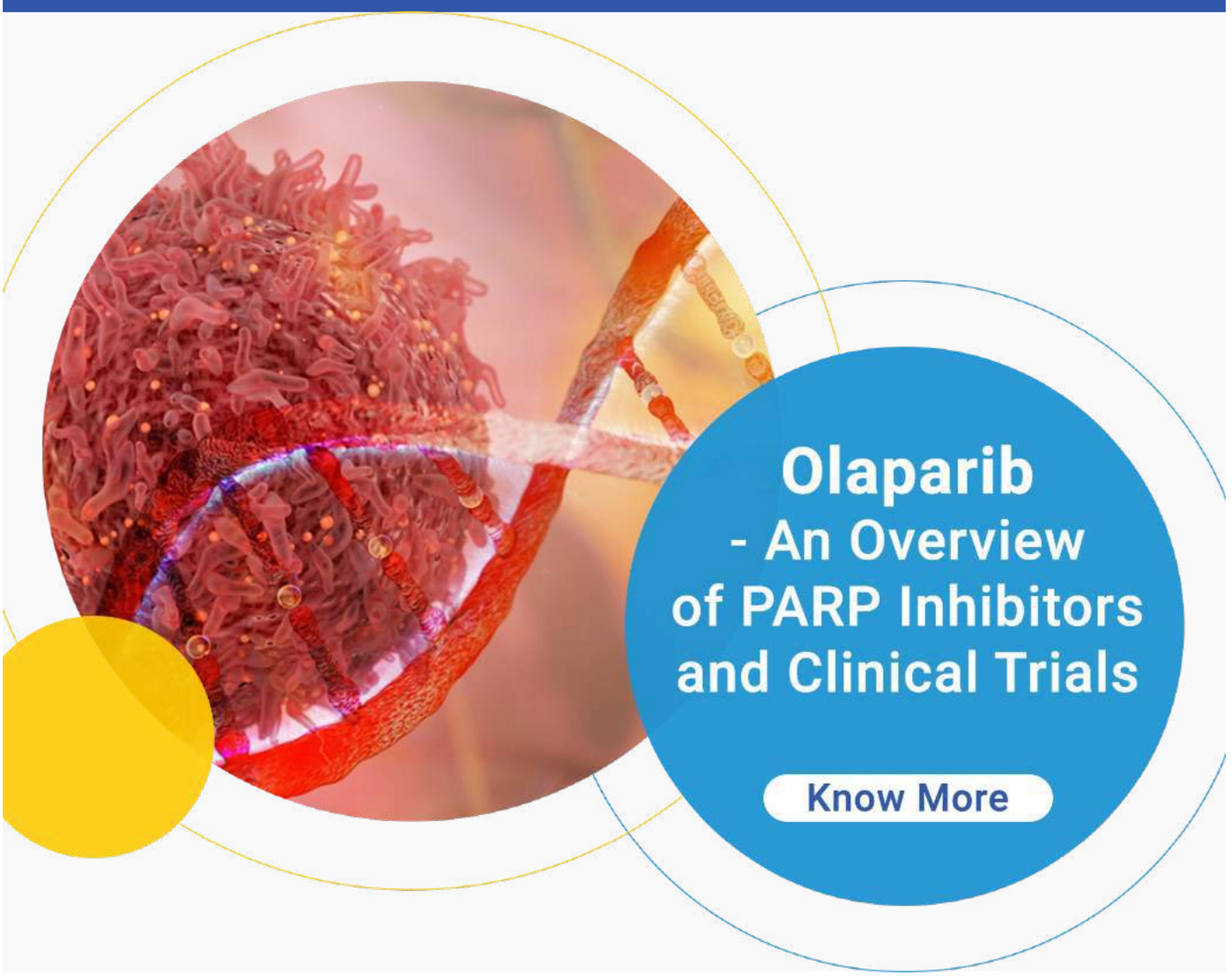
AUGUST 2021: ISSUE 08



16 YEARS OF DELIVERING EXCELLENCE

Veeda News
Glimpse of Veeda Team celebrating Independence Day

Regulatory
US FDA Fully Approves Pfizer-BioNTech COVID-19 Vaccine

Financial
Indian pharma market registers 13.7% growth in July 2021

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To commemorate 75 years of India's Independence, Veeda participated in the Ministry of Culture's country wide campaign - "Azadi Ka Amrit Mahotsav" and was awarded by them for participating in setting a record of maximum people singing the national anthem together. Here's a glimpse of how Veedaites came together for Independence Day celebrations.

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US FDA Fully Approves Pfizer-BioNTech COVID-19 Vaccine

The US health regulator on August 23 gave full approval to Pfizer-BioNTech's COVID-19 vaccine, a key milestone for public health that can instill further confidence in consumers and also spur authorities to make vaccinations mandatory. READ NEXT COVID-19 May Already Be Endemic to India: Soumya Swaminathan A healthcare worker holds a syringe after vaccinating a person with a dose of the Pfizer-BioNTech COVID-19 vaccine, Rome, January 2021. Photo: Reutrs/Guglielmo Mangiapane/File Photo in December 2020, the FDA had granted the Pfizer-BioNTech vaccine an 'emergency use authorisation'.

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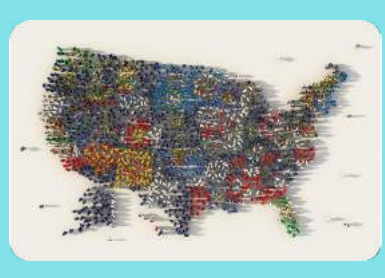
New Research Uncovers Concerning Increases in Youth Living with Diabetes in the U.S.

Diagnosed cases of type 1 and type 2 diabetes are surging among youth in the United States. From 2001 to 2017, the number of people under age 20 living with type 1 diabetes increased by 45%, and the number living with type 2 diabetes grew by 95%. Type 1 diabetes remains the most common type of diabetes in U.S. youth according to a report published today in JAMA, "Trends in Prevalence of Type 1 and Type 2 Diabetes in Children and Adolescents in the United States, 2001-2017external icon." "Increases in diabetes are always troubling – especially in youth.



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CDC Stands Up New Disease Forecasting Center

Today, the Centers for Disease Control and Prevention (CDC) is announcing a new center designed to advance the use of forecasting and outbreak analytics in public health decision making. Once established, the Center for Forecasting and Outbreak Analytics will bring together next-generation public health data, expert disease modelers, public health emergency responders, and high-quality communications, to meet the needs of decision makers. The new center will accelerate access to and use of data for public health decision-makers who need information to mitigate the effects of disease threats, such as social and economic disruption.

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Artificial intelligence in medicine regulation

The International Coalition of Medicines Regulatory Authorities (ICMRA) sets out recommendations to help regulators to address the challenges that the use of artificial intelligence (AI) poses for global medicines regulation, in a report published today. AI includes various technologies (such as statistical models, diverse algorithms and self-modifying systems) that are increasingly being applied across all stages of a medicine's lifecycle: from preclinical development, to clinical trial data recording and analysis, to pharmacovigilance and clinical use optimisation.

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FDA announces plans to regulate certain diagnostic imaging agents as devices, not drugs

In a notice published in the Federal Register on August 9, 2021, the U.S. Food and Drug Administration (FDA) announced it will implement a recent court decision and will begin to reclassify as devices certain diagnostic imaging agents that had been approved as drugs. In April, the U.S. Court of Appeals for the District of Columbia Circuit ruled in Genus Med. Techs., LLC v. FDA, and 2021 U.S. App. Lexis 10928 that the FDA did not have regulatory authority to classify some diagnostic imaging contrast agents as drugs when they also met the definition of a device under the Federal Food, Drug, and Cosmetic Act.

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Indian pharma market registers 13.7% growth in July 2021

The Indian Pharmaceutical Market (IPM) has registered a growth of 13.7 per cent for the month of July 2021, after registering a growth of 14.1 per cent for the month of June 2021. According to AIOCD AWACS report, moving annual total (MAT) for the July was at Rs. 172,588 crore, which has seen a growth of 16 per cent over the corresponding period of last year. Sun Pharma maintained number one position at Rs. 1,132 crore sales followed by Abbott (Rs. 927 crore), Cipla (Rs. 754 crore), Alkem (Rs. 624 crore), and Mankind (Rs. 610 crore).

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PE/VC investment into healthcare grows to $3.01 billion in first half of 2021

Private equity (PE), venture capital (VC) investments into the healthcare industry during the first half of the year 2021 has seen a jump to $3.01 billion, as compared to $1.72 billion in the same period of the previous year. Experts say that while the growth momentum for PE/VC deals continue to grow from last year, in the backdrop of the Covid-19 pandemic and the lockdown, the valuations are a bit stretched now. According to data from venture intelligence, a leading source of data and analysis on private company financials, transactions and their valuations in the country, the investment into the healthcare industry in the whole year of 2020 was $3.07 billion.

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Drug exports grew 4.11% to $2.14 billion in July 2021

Exports of drugs and pharmaceuticals from India during the month of July, 2021, have gone up by 4.11 per cent to $2.14 billion compared to $2.06 billion during the same month last year. Imports of medicinal and pharmaceutical products, on the other hand, have grown by 6.35 per cent during the month, at $785.49 million as compared to $738.62 million in July, 2020. Exports, for the four months from April, 2021, for drugs and pharmaceuticals have shown a significant growth of above 50 per cent.

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Intense price competition in US generics market hits Indian pharma

The first quarter (Q1) of 2021-22 (FY22) saw most Indian pharmaceutical majors struggling to grow revenues and margins in North America. An unprecedented double-digit price erosion in generics had hit them where it hurt most. Companies such as Zydus Cadila, Torrent Pharmaceuticals, Alembic, and Strides posted a dip in US revenue.

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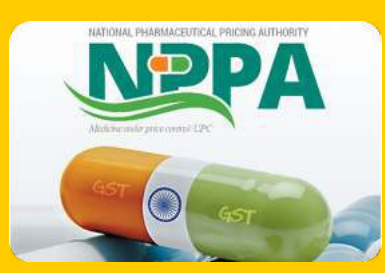
NPPA approves prices of 25 new drugs, opines compulsory regn & standardisation of medical devices

The National Pharmaceutical Pricing Authority (NPPA) has approved retail prices of 25 new drugs under the Drug Price Control Order (DPCO) 2013, in a meeting held in the end of July, 2021. The Authority meeting also opined that compulsory registration and standardisation of the products are required, for better compliance and enforcement of price regulation related to the trade margin capping of medical devices.



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How CRO-Sponsor Partnerships Spurred Innovation In 2020

For decades, operational progress within the clinical research industry has been profoundly shaped by the relationships between sponsor companies and their CRO partners. Among other advances, these relationships have contributed to sponsors' abilities to globalize clinical trial operations, expand therapeutically, manage risk effectively, and optimize processes, impacts that have been studied for nearly 20 years in the annual Avoca Industry Survey.

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Decentralised clinical trials: movers and shakers to watch

While decentralised and hybrid trials are not necessarily a new way of conducting clinical research, the pandemic saw their demand increase massively out of necessity. Covid-19 has kickstarted a renewed focus on digitisation, especially in healthcare as strict lockdown restrictions disrupted the traditional ways of working and highlighted the need for safe, reliable and secure remote capabilities. The past year has seen the research sector abuzz about decentralised clinical trials (DCTs) and their ability to cut costs, reduce the burden on patients and sites and collect more and better data.

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Uniting clinical research, healthcare can benefit both: Biofourmis

An executive from the digital therapeutics specialist discusses the clinical trial landscape, and how clinical care can yield a number of important benefits. While clinical care as a research option (CRAACO) is not a new concept, acceptance of the idea is still growing. Jaydev Thakkar, chief operating officer of Biofourmis, discusses how clinical research and care are intertwined, how they traditionally have butted heads, and how bringing them closer together can benefit multiple stakeholders.

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Demystifying clinical trials: everything you need to know about process, safety, eligibility

Clinical research in India has evolved significantly in the last two decades. As per a study published in the Lancet journal in late 2020, India has gained more than a decade of life expectancy since 1990 with the development of new drugs. The exponential growth of clinical research, which lies at the core of drug development for innumerable diseases, has played a critical role in achieving this feat. However, with India being home to less than two percent of clinical trials conducted globally, there is indeed a need to do more.

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Reducing the gender bias in clinical trials

When I was finishing up my post-doctoral fellowship, I asked myself where I thought my work could have the greatest impact: in the field, working in an academic research setting or working in clinical research with a medical device company on new medical products and technologies that would advance modern medicine. I chose the latter and haven't looked back since. Clinical trials play a significant role in my work; they expand our knowledge of medical science and give researcher's insights into the safety and efficacy of treatments and procedures.

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US Merger Control in the Pharmaceutical Sector

In the United States, mergers and acquisitions are reviewed by the Department of Justice (DOJ) or the Federal Trade Commission (FTC). These agencies are also responsible for imposing and enforcing appropriate remedies to maintain a competitive market. Parties seeking to merge must receive approval from the relevant agency with jurisdiction over the industry.

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Aurobindo Pharma acquiring 51% stake in vet drug firm Cronus

Aurobindo Pharma is acquiring 51% stake in Hyderabad-based generic veterinary pharmaceutical products firm Cronus Pharma Specialities India for ₹420 crore. The acquisition, expected to be completed in eight weeks, will provide it a foothold in the $48 billion global animal health market, Aurobindo said on Thursday.

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Strides Pharma to Buy Endo International New York Facility, ANDAs for Rs 178 Crore

Strides Pharma Science on Friday said it will acquire Endo International plc's manufacturing facility at Chestnut Ridge, New York along with a basket of abbreviated new drug application (ANDAs) for USD 24 million.The wholly-owned subsidiaries of Strides Pharma Science have entered into definitive agreements with the subsidiaries of Endo International plc to this effect.Under the terms of the agreement, Strides will pay USD 24 million for the acquisition, the company said in a regulatory filing.

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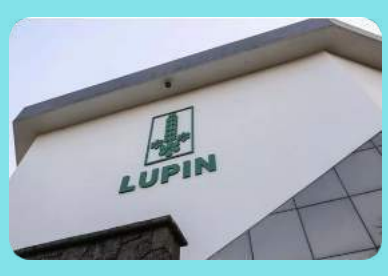
Lupin Acquires Southern Cross Pharma in Australia

Drug major Lupin on Friday said it will acquire Australia-based Southern Cross Pharma Pty Ltd (SCP).Incorporated in Melbourne, Australia, SCP is engaged in developing, registering, and distributing generic products.Generic Health, the Australia based wholly-owned subsidiary of Lupin, has entered into a definitive agreement under which Lupin will acquire 100 per cent of the shares of Southern Cross Pharma Pty Ltd (SCP), Lupin said in a regulatory filing.



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Sanofi boosts its mRNA capabilities with Translate Bio acquisition

French pharma company Sanofi has entered into a definitive agreement to acquire Translate Bio, gaining mRNA technology to use across its vaccines and therapeutics development. Under the terms of the agreement, Sanofi will acquire Translate Bio for approximately $3.2bn, or $38.00 per share in cash. While the deal is still subject to customary closing conditions, the Sanofi and Translate Bio boards of directors have unanimously approved the transaction.

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Big ambitions for India's contract research firms

The diversification effort started before the pandemic, says Ramesh Subramanian, chief commercial officer at Aragen Life Sciences, one of India's leading contract research organizations (CROs). "What we're seeing is a significant focus from companies on diversifying their geographical footprint," he says. "It goes both ways: companies that are fully ensconced in India look to China for diversification. Companies that are fully ensconced in China look to India." But India is the clear winner in the drive to diversify, executives in the country say.

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OPPI working towards building a healthier India through access to innovation

The Organisation of Pharmaceutical Producers of India (OPPI) is working towards building a healthier India through access to innovation and believe the need for innovation must be balanced with the necessity for more accessible medicines, within a robust IP and regulatory environment, stated K G Ananthakrishnan, director-general, OPPI. "We are committed to supporting the nation's healthcare objectives by collaborating with relevant stakeholders to find sustainable solutions. A holistic approach is essential to expand healthcare in India.

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We've successfully made Covid vaccines. Now, India must focus on drug development

India has one of the highest levels of antibiotic resistance, which complicates not only the treatment of life-threatening infections but also endangers outcomes in routine hospital procedures. The benefits gained through medical advances are also put in peril when patients contract drug-resistant bacterial infections. The situation has been further complicated by the pandemic, with 3-4 per cent Covid patients acquiring secondary bacterial infections.

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Scripting independent India's pharma industry journey from non-existent to a world leader

The COVID-19 pandemic resulted in a humanitarian crisis of enormous magnitude. It presented an extraordinary challenge to public health and highlighted the need for better healthcare systems. While it posed several new challenges, it also presented the industry with new opportunities. Supplying medicines to more than 200 countries in the fight against Covid, India met 62 percent of the global vaccines demand.

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Collaboration key to pharma's bright future

The pandemic has brought forth many learnings for the pharmaceutical industry. While in the future, some things may get back to normal and some may change for the better, it's evident that equitable access, sharing best practices and collaboration is the way forward. At the Accenture-ET Pharmaceuticals Leadership Dialogue, top industry leaders shared their learnings from the past one year and what they expect the future to be. The discussion was moderated by Alokesh Bhattacharyya, Senior Editor, ET.

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For any further information or Business enquiry contact us at info@veedacr.com

ADDRESS:

Registered Office

VEEDA CLINICAL RESEARCH® LTD.
Shivalik Plaza-A, Near IIM Ambawadi,
Ahmedabad- 380015, Gujarat, India.
CIN No. U73100GJ2004PLC044023

ADDRESS:

Other Offices

- Block 6, Magnet Corporate Park 100 ft. Thaltej - Hebatpur Road, Nr.Sola Bridge, Off. S.G. Highway, Thaltej, Ahmedabad 380054
- Insignia, Besides Auda Garden, Opp. Zenobia Residency, Sindhu Bhavan Road, Off. S. G. Highway, Bodakdev, Ahmedabad- 380059, Gujarat, India
- Radhe Palladium, Floor 1st (Shop No 9, 10 & 11), 2nd & 3rd Floor Panchot, Nr. Panchot Bypass Circle, N. H. No. 6, Mehsana, Gujarat – 384002
- "Vedant Complex", Nr. YMCA club, S. G. Highway, Ahmedabad- 380051, Gujarat, India