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The Veeda Newsletter

Issue 01: Jan 2020

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15 years of excellence in Clinical Research

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Our 15th Anniversary
Veeda celebrates 15 glorious years of Excellence in Clinical Research

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DCA cracks down on pharma portals

Drug Control Administration (DCA) officials cracked the on the online sale of medicines and initiated action against leading pharmacy portals like 1mg.com, phareasy.com, zoylo and netmeds.com. The director general of DCA, Kripa Nand Tripathi Ujela, in a statement on Wednesday, said that selling medicine online is not allowed according to the injunction order given by the Delhi high court.

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FDA's Section 804 Prescription Drug Importation Program and 801(d) (1) (B) Guidance

The U.S. Food and Drug Administration (FDA) published in the Federal Register a set of proposed rules covering the requirements and procedures for importing under Section 804 of the federal Food, Drug, and Cosmetic Act (FDCA) prescription drugs from Canada.

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MHRA Updates Guidance on Clinical Investigations of Devices

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) on Monday published the fifth version of a guidance document meant to help manufacturers provide the necessary clinical data to CE mark a device.

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CDSCO releases list of 139 reference products to conduct BE studies

The Central Drugs Standard Control Organization (CDSCO) has released the list of 139 drug formulations and their reference products to conduct bio-equivalence (BE) studies falling under bio-pharmaceutical classification system (BCS) II and IV.

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FDA Drafts 510(k) Guidance for Arthroscopy Pump Tubing Sets

The US Food and Drug Administration (FDA) on Monday issued draft guidance explaining its expect ations for premarket notification (510(k)) submissions for arthroscopy pump tubing sets intended for multiple patient use.

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BSE Healthcare Index dips by 3.7% in 2019, Sensex surges by 14.4%

As the pharmaceutical and healthcare scrips remained under pressure during the year 2019, the BSE Healthcare index nosedived by 3.7 per cent in 2019. Despite better financial performance by major players during first half ended September 2019 and higher US FDA approvals, pharma shares could not offer better returns from stock market operations in 2019.

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Indian shares rebound as Middle East tensions appear to ease

By 0432 GMT, India's NSE Nifty 50 index .NSEI, which tracks blue-chip equities, was up 1.09 % at 12,124.75 while the benchmark S&P BSE Sensex .BSESN rose 1.12% to 41,131.40. The spike in crude prices roiled Indian equities, with the nifty falling just over 2% on Monday, recording its worst intraday fall since Sept. 3.

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Indian pharma market sees growth of 9.6% in Q3FY20

The Indian pharmaceutical market (IPM) registered a growth of 9.6 percent for the quarter ended December 31, according to market research firm AIOCD-AWACS, much slower than the preceding quarter, and below industry expectations.

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Budget 2020: Package to encourage drug discovery and develop medical devices likely

In a bid to give a fillip to the pharmaceutical sector and to encourage the manufacturing of drugs and medical devices in the country, the government is working on a comprehensive pharmaceutical package, parts of which could feature in the upcoming Budget 20-21.

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Pfizer, AbbVie and Gilead among drugmakers boosting prices to start 2020

While the pharmaceutical industry has largely refrained from taking double-digit increases in recent years, price hikes remain a central part of drugmakers' business models, due in part to demands from insurers for heftier rebates.

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Top 5 questions asked about clinical trials

Clinical trials are a valuable but often misunderstood part of healthcare. At the Sandra and Malcolm Berman Cancer Institute at GBMC, a multidisciplinary team uses clinical trials to bring progressive treatments and state-of-the-art care to cancer diagnoses. Clinical Research Nurse Manager Judy Bosley, RN, BSN, CCRP, says a stigma still surrounds clinical trials.

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Traditional vs. Pragmatic: Changing the Trial Model with Real-World Evidence

Studies based on real-world evidence (RWE) don't have to be a replacement for randomized clinical trials but rather an integral part of an overall trial strategy. Both pragmatic and randomized trials have their pros and cons, but when combined they can produce more effective results.

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3 myths that may be sabotaging your clinical trial enrollment effort

Myths are stubborn, persistent, and can easily put your well-intentioned clinical trial enrollment efforts at risk. But spotting and correcting them can be a challenge. To help the industry discern fact from fiction, BBK Worldwide assembled its own MythBusters team, dedicated to confirming or busting common clinical trial myths.

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New Clinical Trial Models Make Studies an Option for More People

The advent of precision medicine, marked by the need to recruit relatively rare cohorts of patients into studies, has ignited interest in new, more efficient models of clinical development ranging from "just-in-time" rapid enrollment to trials requiring no sites at all, according to Gaurav Singal, chief data officer at molecular insights company Foundation Medicine.

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How Clinical Trial Sponsors Manage their Critical Documentation: A Recent Acquisition

Data and associated documents represent the fundamental manifestation of drug development work product that ultimately becomes massive digital dossiers for regulatory authority review and approval.

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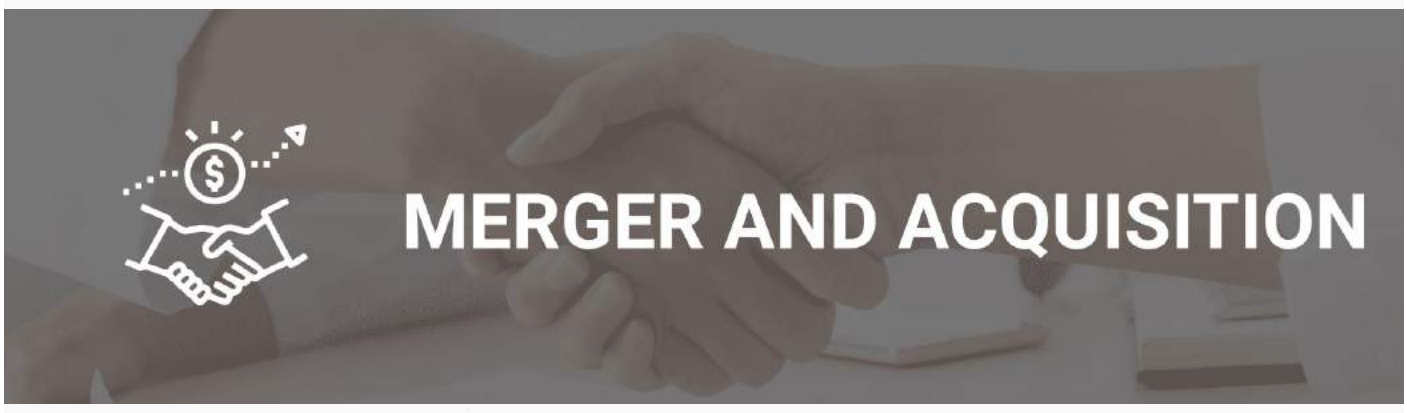

Sanofi Completes Acquisition of Synthorx

Sanofi has announced the successful completion of its acquisition of Synthorx, Inc. for $68 per share in cash. "The acquisition of Synthorx perfectly aligns with our R&D strategy, enhancing our position as an emerging leader in the area of oncology and immunology," says Paul Hudson, Chief Executive Officer, Sanofi.

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Frontage Acquires CRO BRI

Frontage Holdings Corp., a CRO with a presence in both the U.S. and China, through 11736655 CANADA LTD., a subsidiary of the group, and Frontage Laboratories, Inc., entered into a share purchase agreement with J&J Corporate Services, Inc., an independent third party.

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Dechra Pharma To Acquire Worldwide Rights To Osurnia From Elanco - Quick Facts

Elanco Animal Health Inc. (ELAN) has agreed to divest Osurnia, a treatment for otitis externa in dogs, to Dechra Pharmaceuticals (DPH.L) for $135 million. This deal is related to Elanco's acquisition of Bayer AG's (BAYZF.PK, BAYRY.PK, BYR.L) animal health business, which is subject to regulatory approval from the European Commission and the Federal Trade Commission.

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Astellas has announced its acquisition of Xyphos for $665m

Astellas Pharma has announced that it has acquired Xyphos Biosciences for a total transaction value of $665 million. Xyphos will become a wholly owned subsidiary of Astellas. $120 million was paid upon the closing of the acquisition, with the rest of the payments to be completed in milestones.

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Ergomed Acquires Ashfield Pharmacovigilance for $10M

Ergomed plc, a provider of specialized services to the pharmaceutical industry, has acquired Ashfield Pharmacovigilance Inc., a specialist pharmacovigilance services provider based in RTP, NC, from UDG Healthcare plc for $10 million in cash.

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Pharma City to be launched this year

Industries Minister K.T. Rama Rao said that there were no more obstacles in the way of grounding the Pharma City project at Mucherla, 40 km from here, as the State government had obtained the National Investment and Manufacturing Zone (NIMZ) approval and the environmental clearance for it from the Centre.

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India emerges as a hub for biotech drug research, says report

The Indian pharmaceutical companies always had strong chemistry skills to work on small molecules to make generic drugs, but they lacked skills, people and ecosystem to work on large molecules to come up with reverse engineered versions of biotech drugs, many experts complain. However, it is beginning to change.

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Industry urges Govt to defer implementation of newly inserted Rule 36(4) in CGST till April 1, 2020

The pharmaceutical industry in the country has urged the union government to defer the applicability of newly inserted Rule 36(4) in Central Goods & Services Tax (CGST) till introduction of new system of invoicing which is scheduled to be applicable from April 1, 2020.

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Industry Body Calls For Reduction in GST on Active Pharmaceutical Ingredients

Industry body Confederation of Indian Industries (CII) has called for a reduction in Goods and Services Tax (GST) applicable to Active Pharmaceutical Ingredients (APIs) in line with pharma formulations.

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CDSCO strengthens oversight of clinical trials, 145 trials inspected in 3 years

In a bid to ensure compliance of good clinical practice guidelines for clinical studies in India, the Central Drugs Standard Control Organisation (CDSCO) has stepped up inspection of clinical trial sites of biological products as well as new drugs in the country.

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Veeda Clinical Research is proud to announce its fifteenth year of fulfilling its mission of striving for excellence in Quality by following a value system to deliver quality without compromising on safety while upholding ethics, good clinical practices, and regulatory compliance.

We are thankful to all our sponsors and stakeholders to allow us to serve them and placing their trust in us for these many years.

To commemorate the glorious 15 years of success, we organized a grand party to recognize our long-serving members and celebrated the memorable night with smashing performances and DJ party.

Here is a glimpse of celebration:

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