The Veeda Newsletter

JUNE 2018
ISSUE 06

VEEDA CRO NEWS

Veeda CRO discussed about "Developing effective partnerships and vendor relationships "at 9th Annual Clinical Trials Summit 2018.

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GSK exploring merger, may sell Indian entity entirely.

CONFERENCE

CPHI CHINA
June 20-22, 2018
Shanghai , China.

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VEEDA CRO deliberated a talk on Study Design Considerations of Bio equivalence Studies in the workshop organized by CDSCO – New Delhi

On 2nd June 2018, New Delhi , A workshop was organized by CDSCO office - New Delhi for all state drug controllers to deliberate issues regarding the implementation of bioavailability and bioequivalence studies of Pharmaceutical formulations.

As per recently amended DCC rules, 1945 applicants shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of drugs under the category II and IV of the Biopharmaceutical Classification System.

In the workshop Honorable DCGI Dr. Eswar Reddy discussed the objectives of CDSCO office in implementing newly amended DCC rules and also shared his vision on the way forward pertaining to the implementation of the same. **READ MORE:** https://www.veedacr.com/2018/Newsletter/Jun-2018/CDSCO%20workshop.html

VEEDA CRO DISCUSSED ABOUT "DEVELOPING EFFECTIVE PARTNERSHIPS AND VENDOR RELATIONSHIPS "AT 9TH ANNUAL CLINICAL TRIALS SUMMIT 2018.

On May 24th 2018, Mumbai, 9th Annual Clinical Trial Summit 2018 was organized by Virtue Insight to positively learn and educate about clinical trials.

Veeda's Head Medical Affairs and Pharmacovigilance, Dr. Pranjal Bordoloi was invited as a Guest Speaker for a panel discussion titled – "Developing effective partnerships and vendor relationships". The panel discussed on various aspects on constructing an effective model for a successful partnership, various ways to deal with the evolve business frameworks and insuring efficient management and governance in such partnership relationships.

The Summit brought together top pharmaceutical, biotechnology and regulatory representatives under one roof. The event deliberated at the multiple facets of Clinical Trials with presentations and discussions on topics like, data analytics for next-generation clinical trials, formulating a risk based inspection plan, Key strategies to globalizing clinical trials into emerging markets, Clinical Development of Biologics, New clinical trials rules and its impact, etc.

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INDIAN PHARMA

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India Emerges As Top Five Pharmaceuticals Markets Of The World

India's pharmaceutical industry has grown by leaps and bounds in the last three decades. As a result, it has emerged as world's third largest producer of drugs in terms of volume.
Read More: http://businessworld.in/article/India-Emerges-As-Top-Five-Pharmaceuticals-Markets-Of-The-World/05-05-2018-148349/

Invest more in R&D, develop new markets to boost pharma exports: Prabhu to industry

He also called for finding ways to make healthcare more affordable to people by reducing costs.Regions like Latin America and Africa hold huge export potential for Indian pharmaceutical products,
Read More: http://www.business-standard.com/article/pti-stories/invest-more-in-r-d-develop-new-markets-to-boost-pharma-exports-prabhu-to-industry-118050800348_1.html

India leads globally for 'online medicine apps' search on google

A dominant internet search engine, Google's analytical platform Google Trends shows India is searching 'online medicine apps' more than other countries do.
Read more at: https://www.newsbarons.com/pharma/india-leads-globally-for-online-medicine-apps-search-on-google/

ePharmacy market to grow upto 10-15% by 2025

India is searching for 'online medicine apps' more than any other country, points out Google Trends, that is a Google's analytical platform and a dominant internet search engine.
Read more: http://www.dnaindia.com/jaipur/report-epharmacy-market-to-grow-upto-10-15-by-2025-2616436

Pharma Industry In India: From Government Policies To Future Concerns

India is the largest provider of generic drugs globally with the Indian generics accounting for 20 per cent of global exports in terms of volume, according to pharma industry experts. The country is more focused on quality of drugs and medicines.
Read More: https://www.ndtv.com/business/pharma-industry-in-india-from-government-policies-to-future-concerns-1858220

Pharma industry seeks implementation of label change norms at one go

The Union health and family welfare ministry's decision to introduce change in drug label twice in less than a span of two months between September and November this year has become a cause of concern for pharmaceutical companies as it will result in multiplication of art work and subsequently increase cost.
Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=109118&sid=1

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REGULATORY NEWS

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Govt tweaks certification norms to aid pharma trade

The government has decided to increase the validity of the World Health Organization's (WHO) good manufacturing practices (GMP) certification to three years from the existing two years for companies exporting pharma products to other countries.

Read More: https://www.livemint.com/Industry/XDwXr8pqrWk78tPdTlO8yJ/Govt-tweaks-certification-norms-to-aid-pharma-trade.html

Commerce Ministry in talks with Chinese FDA for speedy approval of Indian pharma products

Indian pharma companies may look forward to speedy product registrations with the Chinese Food and Drug Administration (CFDA).

Read More: https://www.thehindubusinessline.com/economy/commerce-ministry-in-talks-with-chinese-fda-for-speedy-approval-of-indian-pharma-products/article23885103.ece

FDA issues final guidance in effort to protect clinical trial participants

The FDA has published a final guidance today in its efforts to improve protection for participants in clinical trials and reduce regulatory burden.

Read more: HTTPS://WWW.OUTSOURCING-PHARMA.COM/ARTICLE/2018/05/17/FDA-ISSUES-FINAL-GUIDANCE-IN-EFFORT-TO-PROTECT-CLINICAL-TRIAL-PARTICIPANTS

DCGI soon to be empowered to issue drug-specific labeling requirements for new drugs even after completion of 4 years

The Central government is getting ready to make product-specific labeling requirements mandatory for new drugs even after the end of four years from the date of approval by the Drug Controller General of India (DCGI) to prevent unapproved products and prescription medicines entering the market, sometimes as over-the-counter medications.

Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=109119&sid=1

Pharma analysts need to show strong commitment to ensure quality of generic drugs, says DCGI

It has been argued that branded drugs are superior in quality and efficacy as compared to generic drugs. Pharmaceutical analysis determine the quality of drug products through the test of analytical chemistry. They are responsible for release of batch and play a crucial role in ensuring quality medicines reach patients.

Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=109179&sid=1

FDA issues two new policies to stop drug makers from blocking generics

Food and Drug Administration Commissioner Scott Gottlieb, MD, has released new policies to crack down on brand drug manufacturers that try to block the entry of generic drugs to the market.

Read More: http://www.healthcarefinancenews.com/news/fda-issues-two-new-policies-stop-drug-makers-blocking-generics

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CLINICAL RESEARCH

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India Making Way For Separate Clinical Trials Rules

The key law that governs the pharmaceutical industry in India is the Drugs and Cosmetics (D&C) Act, 1940 and Rules, 1945. Over time, several amendments have been made to the D&C Act and rules. **Read more at:** https://www.clinicalleader.com/doc/india-making-way-for-separate-clinical-trials-rules-0001

Block chain could be a game changer in medical clinical trials, says top expert

Block chain has been one of the biggest tech disrupters in the past year – and industries such as pharmaceuticals and med-tech are realizing the potential benefits.
Read More: https://stockhead.com.au/special-report/blockchain-could-be-just-the-game-changer-clinical-trials-have-been-waiting-for/

Digital R&D: 4 Ways To Maximize Patient Engagement In Clinical Trials

The Deloitte Center for Health Solutions recently interviewed 43 biopharmaceutical industry stakeholders to explore where the industry sees value and opportunities for using digital technologies in the clinical development process;
Read More: https://www.clinicalleader.com/doc/digital-r-d-ways-to-maximize-patient-engagement-in-clinical-trials-0001

Fewer women meet eligibility criteria for clinical trial of heart failure drugs, study finds

Clinical trial enrolment favors men, according to a study presented today at Heart Failure 2018 and the World Congress on Acute Heart Failure, a European Society of Cardiology congress. The study found that fewer women meet eligibility criteria for trials of heart failure medication.
Read More: https://www.news-medical.net/news/20180528/Fewer-women-meet-eligibility-criteria-for-clinical-trial-of-heart-failure-drugs-study-finds.aspx

After a lull of five years, clinical trials on the rise in India

There is a gradual revival in the number of clinical trials being done in India. From an all-time low of 17 clinical trials approved by the Drug Controller General of India (DCGI) in 2013, the number has slowly increased to 97 in 2017, a more than 400% jump in five years.
Read More: http://www.thehindu.com/news/national/after-a-lull-of-five-years-clinical-trials-on-the-rise-in-india/article24069487.ece

India's drug regulator expects to finalize new clinical trial rules in two months

The country's 1.2 billion people and large burden of diseases make for an attractive patient pool for global pharmaceutical companies looking to test new drugs
Read More: https://uk.reuters.com/article/us-india-clinical-trials-regulations/indias-drug-regulator-expects-to-finalize-new-clinical-trial-rules-in-two-months-idUKKCN1IV1JX

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FINANCIAL NEWS

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India Inc invests over $4 billion in South Africa

As many as 140 Indian companies with operations in South Africa have invested more than USD 4 billion and created 18,000 direct jobs, according to a report released today.

Read more at: http://economictimes.indiatimes.com/articleshow/64050286.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

A new pharma giant —Takeda acquires Shire for $62B

Takeda Pharmaceutical Co. acquired its much larger rival Shire for $62 billion in cash and stock — a deal that catapults the Japanese company into a new league of drug industry giants, according to Bloomberg.

Read More: https://www.beckershospitalreview.com/supply-chain/a-new-pharma-giant-takeda-acquires-shire-for-62b.html

Fosun joins Aurobindo, PE firms in final bids for Novartis' $2B U.S. generics assets: report

Novartis definitely has some Sandoz products it will keep. In a statement sent to FiercePharma, Novartis said it has no intention to selling off the Sandoz business in the U.S. altogether,

Read More: https://www.fiercepharma.com/pharma/fosun-joins-aurobindo-pe-firms-final-bids-for-novartis-2b-u-s-generics-assets-report

Lupin incurs net loss of Rs. 778 crore in Q4, sales dips by 4.4% to Rs. 3,976 crore

Lupin, the second largest Indian pharma major, has suffered heavy setback during the fourth quarter ended March 2018 an it incurred a net loss of Rs.778 crore mainly on account of impairment provision of Rs. 1,464 crore on certain intangible assets acquired as part of the Gavis Group acquisition.

Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=108904&sid=2

Cognition Therapeutics gets $6.6M in grants to fund Alzheimer's clinical studies

The studies will be made of Elaya (CT1812), which has shown in previous clinical studies to reduce concentrations of synaptic damage proteins in people with Alzheimer's disease, according to Cognition Therapeutics.

Read More: https://www.bizjournals.com/pittsburgh/news/2018/05/23/cognition-therapeutics-gets-6-6m-in-grants-to-fund.html

CCI approves USD 66 billion Bayer-Monsanto deal

Fair trade regulator CCI has approved the German giant Bayer's proposed USD 66 billion acquisition of US-based biotech firm Monsanto, subject to certain modifications to the long-pending deal.

Read more at: http://www.newindianexpress.com/business/2018/may/22/cci-approves-usd-66-billion-bayer-monsanto-deal-1818087.html

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MERGER & AQUISITION

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Aurobindo launches $1.6 billion bid to buy Novartis generics unit

Aurobindo Pharma Ltd has submitted an initial bid to buy Novartis AG's dermatology generics drug business for about $1.6 billion, two people directly aware of the development said on condition of anonymity.**Read More**:https://www.livemint.com/Companies/fM1pV2whSzzxjPQl0MNVvL/Aurobindo-launches-16-billion-bid-to-buy-Novartis-generics.html

Mycoplasma Testing Market Grows Due to Increasing Focus on R&D of Biopharmaceuticals | Technavio

The growing M&A and partnerships between CROs, and pharmaceutical and biotechnology companies are one of the major trends being witnessed in the market.
Read More: http://www.nonpareilonline.com/mycoplasma-testing-market-grows-due-to-increasing-focus-on-r/article_31d150e2-5444-5eea-a47b-4853e7bd028b.html

LMC Manna Research Acquires Omnispec Clinical Research

LMC Manna Research – the largest network of fully-owned and integrated clinical research sites in Canada providing Phase I-IV clinical trial services – recently announced the acquisition of leading Montreal-based research centre Omnispec Clinical Research.
Read More: https://www.wateronline.com/doc/lmc-manna-research-acquires-omnispec-clinical-research-0001

Altasciences Establishes Strategic Alliance with Altreos Research Partners

Vince & Associates Clinical Research, an Altasciences company, announced today their strategic alliance with Altreos Research Partners.
Read More: https://globenewswire.com/news-release/2018/05/23/1511042/0/en/Altasciences-Establishes-Strategic-Alliance-with-Altreos-Research-Partners.html

GSK exploring merger, may sell Indian entity entirely

Exposing GlaxoSmithKline's (GSK) to huge 40% tax burden might hamper the sale of British pharma giant's Indian consumer products division.
Read More: https://www.indianretailer.com/news/GSK-exploring-merger-may-sell-Indian-entity-entirely.n8815/

Elligo Health Research Announces Acquisition of ePatientFinder Clinical Trial Exchange Technology Platform and Practice Network

Elligo Health Research, which improves clinical trial access by engaging the 97 percent of physicians currently not offering clinical research to their patients, has acquired ePatientFinder's Clinical Trial Exchange technology platform and referring practice network, which is the largest of its kind.
Read More: https://www.oaoa.com/news/business/article_4e1efef0-1013-57cb-a409-02791c611fbc.html

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UPCOMING CONFERENCE

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