The Veeda Newsletter

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ISSUE 12

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V- KONNECT

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“V-KONNECT" with WHO TEAM.

Veeda through its V-Konnect series interacted with Dr. Elham Kossary - (Lead inspector for WHO) and Ms. Joy van Oudtshoorn - (Co-inspector for WHO) during their Inspection at Veeda Clinical Research.

About the V- Konnect

V-Konnect interview series, is a program to get in touch with specialized industry experts to know their views on opinions on current relevant subject matters.

Below is the transcript of the Interview.

Q.Looking to the current scenario and regulatory standard what according to you are the biggest challenges to comply with digital and electronic systems in the industry.
A: Proper validation of the computerized system used by the CROs, specifically based on their own User Requirement Specification (URS), presents a challenge for many organizations. Also, the management of data privacy and protection of source data, together with the arrangement of proper backup and later restoration for control purposes, are often compromised.

Q. What additional measures industry should take for improving the transparence in clinical research and strengthen the scientific data integrity.
A: Organizations should ensure that all data and modifications made to any generated data in the clinical research are adequately and consistently traceable. Sufficient audit trail for each step of the activities should be implemented. Audit trails should be designed to facilitate searching by different categories.

Q. How effective do you think is the designing of clinical studies in terms of risk is to benefit ratio across the industry?
A: The question is not clear. However, it can be mentioned that in designing bioequivalence studies, the availability of adequate in vitro methods should also be considered to minimize the risk of the study.

Q. Looking to the clinical trial registration part trends from which country do you think the registration of new trials is increasing?

A: The majority of the WHO-inspections take place in India, so we don't have that information.

Q. How do you see India in terms of GxP compliance across the world?

A: A. Considering the abovementioned limitation and also my area of expertise (Only GCP and BE-studies' inspection), I don't have that information either. But, out of my experience, the overall GCP and GLP compliance of the CROs is acceptable.

Q. What is your view on the reporting of the study results from Clinical trials and recommendation to improve the reporting?

A: The study reports and results are received by the assessment team of the WHO-pre qualification team. They make an assessment whether the report and the study results are complete. Inspectors verify the study report and results by checking the source data and compliance with the relevant guidelines. Ensure that the study reports are compiled in accordance with the applicable guidelines and adequate quality control and quality assurance of the study activities, documents/records and results are performed.

Disclaimer:

The opinions expressed in this publication are those of the Interviewee and are not intended to malign any ethic group, club, organization, company, individual or anyone or anything. The responses have been provided to the best of interviewee's knowledge, and are the personal view of the inspection team in general. Examples of analysis performed within this publication are only examples. They should not be utilized in real-world analytic products as they are based only on personal views of the Interviewee. They do not purport to reflect the opinions or views of the VEEDA CRO or its management. Veeda CRO does not guarantee the accuracy or reliability of the information provided herein.

VEEDA CRO NEWS

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CX Partners Acquires Equity Stake in Veeda Clinical Research

A consortium of growth oriented private equity investors led by CX Partners Fund 2 Limited have acquired a significant equity ownership in Veeda Clinical Research Private Limited. The investors will make additional investments in the company over a period of time to fund the growth requirements of the company.

The Board of Directors of the company will be reconstituted to have representatives from the incoming investors. Mr. Apurva Shah and Mr. Binoy Gardi, the promoters, will continue on the Board of the company and lead the management team.

Veeda is the largest independent Clinical Research Organization in India established in 2004 with its headquarters in Ahmedabad. Veeda offers a diverse range of clinical studies including healthy volunteers and patient trials for Generics, NCE and Biopharmaceuticals. Veeda is a partner of choice for many global pharmaceutical companies and is reputed for its knowledge, quality and ethics.

CX Partners Fund 2 Limited is a Mauritius-based growth oriented private equity investment fund focusing on high growth mid-market companies that are industry leaders in India. CX Partners had, from its prior Fund 1, invested in leading healthcare companies including Natco Pharma Ltd, Thyrocare Technologies Ltd and Healthium Medtech Pvt Ltd. Other past investments where CX Partners took a significant equity stake include Minacs Group, a leading Business Process Outsourcing firm, Sapphire Foods India Pvt. Ltd, a leading franchisee of Yum! Brands, Barbeque Nation Hospitality Ltd and Mrs Bectors Food Specialties Ltd.

Please contact the following for any clarifications that you may need regarding this communication:

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You can also read on: https://www.prnewswire.co.uk/news-releases/cx-partners-acquires-equity-stake-in-veeda-clinical-research-874374630.html

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INDIAN PHARMA

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Pharma lobby for hiking cost of drugs under govt price control

A sharp rise in prices of commonly used drug raw materials from China has prompted a pharmaceutical industry lobby to seek higher retail prices of medicines that are under government price control. The group has warned that failure to do so may lead to a shortage of medicines.
Read More: https://www.livemint.com/Industry/KWguVuixHn1KrnathcgLbI/Pharma-lobby-for-hiking-cost-of-drugs-under-govt-price-contr.html

India: Centre Proposes Draft e-Pharmacy Rules to Regulate Online Sale of Drugs

The Central Government proposed ePharmacy draft rules under Drugs and Cosmetics Act 1945 (the Act). The draft rules are proposed to regulate the online sale of medicine or ePharmacy business in India.
ReadMore: http://www.mondaq.com/india/x/747792/food+drugs+law/Centre+Proposes+Draft+ePharmacy+Rules+To+Regulate+Online+Sale+Of+Drugs

Pharma sales growth on double-digit track, back to pre-GST disruption level

According to data from AWACS, the market research wing of the All India Organization of Chemists and Druggists (AIOCD), which represents over 550,000 medicine sellers across the country, the pharma market clocked 12.2 per cent year-on-year growth in October, against 7.5 per cent in September and 8.7 per cent in August
Read More: https://www.business-standard.com/article/companies/pharma-sales-growth-on-double-digit-track-back-to-pre-gst-disruption-level-118111201413_1.html

PharmaHopers (Pharma Franchise Portal) Explains the Indian Future of Pharma Franchise & PCD Pharma Business in 2019

Rightly said by Leon C. Megginson, "It is not the strongest of the species that survives, nor the most intelligent, but the one most adaptable to change." Ten years down the lane, Pharma Franchise & PCD Pharma wasn't the term heard by many but today, it has emerged as potential business sector in Pharmaceutical Industry
Read More: http://www.prnewswire.co.in/news-releases/pharmahopers-pharma-franchise-portal-explains-the-indian-future-of-pharma-franchise--pcd-pharma-business-in-2019-700887482.html

Indian pharma's window of opportunity

Call it opportunistic volume gain at better margins or seeking new growth options under adverse market conditions. Either way, some of the leading Indian pharma companies are pitching in to cater to the markets that some of the big global pharma companies are vacating as part of their product optimization strategies.
Read More: https://www.businesstoday.in/sectors/pharma/indian-pharma-is-window-of-opportunity/story/293106.html

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REGULATORY NEWS

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FDA Launches App to Support Clinical Trials, Real-World Evidence Collection

The FDA has introduced the new My Studies app, which will collect real-world evidence through mobile devices and increase the diversity of information available for clinical trials and other healthcare research.

Read More: https://healthitanalytics.com/news/fda-launches-app-to-support-clinical-trials-real-world-evidence-collection

India: Central Government to Increase Regulatory Fee for Various Drug Licensing Activities

The Central Government, in consultation with the Drugs Technical Advisory Board (DTAB), proposed rules to amend Drugs and Cosmetics Rules,

ReadMore: http://www.mondaq.com/india/x/757264/food+drugs+law/Central+Government+To+Increase+Regulatory+Fee+For+Various+Drug+Licensing+Activities

FDA Loosens the Reins on Informed Consent Requirements for Certain Clinical Studies

Importantly, the only clinical investigations affected by the Proposed Rule are those that are FDA-regulated and “minimal risk”

Read More: https://www.natlawreview.com/article/fda-loosens-reins-informed-consent-requirements-certain-clinical-studies

New Product-Specific Guidance Focus on Drugs Without Generic Competition

The US Food and Drug Administration (FDA) on Tuesday issued 63 new and revised draft product-specific guidance detailing its expectations for companies looking to develop generic versions of those products.

Read More: https://www.raps.org/news-and-articles/news-articles/2018/11/new-product-specific-guidances-focus-on-drugs-with

FDA publishes post CRL guidance for generic companies

The US Food and Drug Administration (FDA) has published final guidance for the generics industry on post-complete

Read More: https://www.thepharmaletter.com/article/fda-publishes-post-crl-guidance-for-generic-companies

FDA issues draft guidance on NASH drug development

“Currently, there are no approved drugs for the treatment of NASH. Given the high prevalence of NASH, the associated morbidity, the growing burden of end-stage liver disease, and the limited availability of livers for organ transplantation, FDA believes that identifying therapies that will slow the progress or, halt, or reverse NASH and NAFLD will address an unmet medical need,” FDA writes.

Read More: https://endpts.com/fda-issues-draft-guidance-on-nash-drug-development/

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CLINICAL RESEARCH

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FDA seeks to remove dogs from some clinical trials

"The aim is this: by doing a single study to help establish a non-animal-based model, we can potentially replace much of the need to use dogs in future trials with new informatics tools," FDA Commissioner Scott Gottlieb, MD, said in a release

Read More: https://www.healio.com/family-medicine/practice-management/news/online/%7Bee94df81-dc76-4d76-abe0-979ea6a8ad08%7D/fda-seeks-to-remove-dogs-from-some-clinical-trials

Building Disease Management Teams to Harness Clinical Trial Growth

To ensure the successful absorption and growth of new trials, two nurses drove an initiative to reorganize LVCI's framework of their current disease management teams.

Read More: https://www.oncnursingnews.com/web-exclusives/building-disease-management-teams-to-harness-clinical-trial-growth

Novartis CEO Bets on Cutting-Edge Science to Remake Drug Giant

Novartis AG's recent acquisition streak is pivoting the company toward new treatments that bear little resemblance to traditional drugs.

Read More: https://www.wsj.com/articles/novartis-ceo-bets-on-cutting-edge-science-to-remake-drug-giant-1542629461

New FDA Proposed Rule Alters Informed Consent for Clinical Studies

If finalized, the proposed rule — an amendment of FDA's regulations to implement a provision of the 21st Century Cures Act — would allow the Institutional Review Board (IRB) responsible for the review and approval of the research to waive or alter certain elements of informed consent, or to waive the requirement entirely, under limited conditions.

Read More: https://www.dicardiology.com/content/new-fda-proposed-rule-alters-informed-consent-clinical-studies

First generic EpiPen enters the market at half the cost

Teva's EpiPen generic will reach market at a cost of $300 per pack, which matches the price of Mylan's own generic version.

Read More: HTTPS://WWW.IN-PHARMATECHNOLOGIST.COM/ARTICLE/2018/11/29/FIRST-GENERIC-EPIPEN-ENTERS-THE-MARKET-AT-HALF-THE-COST

Study discovers 40 new genetic variants associated with colorectal cancer risk

The most comprehensive genome-wide association study, or GWAS, of colorectal cancer risk to date, published today in Nature Genetics, has discovered 40 new genetic variants and validated 55 previously identified variants that signal an increased risk of colon cancer.

Read More: https://www.sciencedaily.com/releases/2018/12/181203111548.htm

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FINANCIAL NEWS

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India's Aurobindo Pharma Q2 profit falls nearly 22 pct

Aurobindo Pharma Ltd, India's second-largest drugmaker by market capitalisation, posted a 21.7 percent fall in its second-quarter profit on Monday,

Read More: https://www.nasdaq.com/article/indias-aurobindo-pharma-q2-profit-falls-nearly-22-pct-20181112-00485

Nigeria Pharmaceutical market is projected to expand at a CAGR of 9.1%

According to Goldstein Research, regional government initiatives to curb the import and distribution of counterfeit medicines and significant investment

Read more: https://www.whatech.com/market-research/medical/532183-nigeria-pharmaceutical-market-is-projected-to-expand-at-a-cagr-of-9-1

Comerica Bank Has $1.91 Million Stake in Teva Pharmaceutical Industries Ltd (TEVA)

Comerica Bank lifted its holdings in shares of Teva Pharmaceutical Industries Ltd (NYSE:TEVA) by 9.5% during the third quarter, according to the company in its most recent Form 13F filing with the SEC.

Read More: https://www.fairfieldcurrent.com/2018/12/01/comerica-bank-has-1-91-million-stake-in-teva-pharmaceutical-industries-ltd-teva.html

India registers 10% growth in containerised trade in Q3 2018, says report

The demand for India-made goods such as vehicles and mechanical appliances as well as refrigerated cargo such as onions, meat, seafood, and pharmaceuticals have driven exports, the company said.

Read More: https://www.financialexpress.com/industry/india-registers-10-growth-in-containerised-trade-in-q3-2018-says-report/1402399/

Argenx in US$1.6bn deal with J&J affiliate Janssen

Under the deal, Janssen will pay US$300m in cash to argenx for the global commercialisation rights of cusatuzumab, currently developed in in AML,

Read More: https://european-biotechnology.com/up-to-date/latest-news/news/argenx-in-us16bn-deal-with-jj-affiliate-janssen.html

India Pharmaceutical market projected to reach USD 76.7 billion by 2024 according to forecasts

According to Goldstein Research, India pharmaceutical market size is anticipated to cross USD 76.7 billion by 2024, growing at a CAGR of 15.9% over the forecast period 2016-2024.

Read more: https://www.whatech.com/market-research/medical/532166-india-pharmaceutical-market-projected-to-reach-usd-76-7-billion-by-2024-according-to-forecasts

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MERGER & AQUISITION

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Cipla acquires US-based Avenue Therapeutics for $215 million

Cipla, India's fourth-largest drug maker on November 13, said its subsidiary , InvaGen Pharmaceuticals has entered into definitive agreements to acquire Nasdaq-listed specialty business firm Avenue Therapeutics for up to $215 million

Read more at: https://www.moneycontrol.com/news/business/cipla-acquires-us-based-avenue-therapeutics-for-215-million-3164341.html

Takeda inches closer to $62B takeover of Shire

Japanese drugmaker Takeda Pharmaceutical is expected to gain European Union antitrust approval for its $62 billion acquisition of Shire, a London-based pharmaceutical company, according to Reuters.

Read more at: https://www.beckershospitalreview.com/pharmacy/takeda-inches-closer-to-62b-takeover-of-shire.html

Sinclair Pharma Announces Acquisition of the Company by Huadong Medicine Co., Ltd

Sinclair Pharma Limited, a global aesthetics company headquartered in London, UK, has announced the close of a transaction in which Huadong Medicine Company Limited (HMC) acquired the company in a deal worth approximately $222 million.

Read More: https://www.apnews.com/10510b29dc6642fa9b0d437e2d3549d9

Synteract acquires KinderPharm to be ‘one-stop shop’ for pediatric clinical trials

Synteract’s clients will benefit from a single source model, says CEO, following the acquisition of KinderPharm, a PA-based CRO focused on all phases of pediatric drug development.

Read More: HTTPS://WWW.OUTSOURCING-PHARMA.COM/ARTICLE/2018/11/19/SYNTERACT-ACQUIRES-KINDERPHARM-TO-BE-ONE-STOP-SHOP-FOR-PEDIATRIC-CLINICAL-TRIALS

Medlife Acquires HealthTech Startup EClinic24/7; To Invest $100 Mn for E-Pharma Expansion.

Bangalore-based online e-pharmacy firm Medlife has announced that it has acquired EClinic24/7, a Bengaluru-based health technology startup company.

Read more: https://www.indianweb2.com/2018/11/22/medlife-acquires-healthtech-startup-eclinic24-7-to-invest-100-mn-for-e-pharma-expansion/

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UPCOMING CONFERENCE

1. **BIO One-on-One Partnering™ @ JPM**
   San Francisco, California.
   Jan 6 - 10, 2019

2. **Drug Delivery partnership**
   Florida.
   Jan 28-30, 2019

3. **Outsourcing in Clinical Trials West Coast 2019**
   Burlingame, CA.
   Feb 12 - 13 , 2019

For Inquiry & Meeting Appointment please mail us at info@veedacr.com

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