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The Veeda Newsletter

MAR 2018
ISSUE 03

VEEDA CRO NEWS

VEEDA CLINICAL RESEARCH WINS "CLINICAL TRIAL COMPANY OF THE YEAR"

Drugs Controller General of India plans dedicated cell for start-ups

Drug for Still's Disease Shows Promise in Phase 2 Trial

IPA releases GDP & PV guidelines to help drug makers meet global quality norms

Indian drug firms' growth slowed in 2017 on slow approvals, MNCs' caught up.

'We expect M&A deal numbers to move up in 2018'

FDA Adds 35 New, 22 Revised Product-Specific Guidances for Generic Drugmakers

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INDIAN PHARMA

MAR 2018
ISSUE 03

India is MIA's fourth busiest market in Asia for pharmaceuticals

Leading international freight airport, Miami International Airport (MIA), is the only US airport to sponsor Air Cargo India 2018, the largest air cargo exhibition and networking conference in India, organized by The STAT Trade Times.
Read More: http://www.stattimes.com/india-is-mias-fourth-busiest-market-in-asia-for-pharmaceuticals-air-cargo

'National Health Protection Scheme: 'Universal healthcare has to be co-opted in new pharma policy'

"We are eliciting opinions, we are having discussions and new dimension has been added in this Budget of universal healthcare that also has to be co-opted into this pharma policy. In couple of months, we will finalize it.
Read More: http://indianexpress.com/article/lifestyle/health/national-health-protection-scheme-universal-healthcare-has-to-be-co-opted-in-new-pharma-policy-5065838/

Drugs Controller General of India plans dedicated cell for start-ups

The Drugs Controller General of India (DCGI) plans to set up a dedicated cell for supporting and regulating innovation and start-ups in the pharma sector.
Read More: http://www.newindianexpress.com/business/2018/feb/24/drugs-controller-general-of-india-plans-dedicated-cell-for-start-ups-1778109.html

Indian pharmaceutical industry grown in big way in India as well globally: Suresh Prabhu

Speaking at the 15th edition of the BioAsia, the flagship life sciences and pharmaceuticals conference of the Telangana Government underway at Hyderabad International Convention Centre (HICC), Read More: https://news.webindia123.com/news/Articles/India/20180224/3284727.html

India, Netherlands to partner for innovative vaccine solutions

Life Science and health is priority sector for strategic investment in both the Netherlands and India. Growing market opportunities in India, combined with the Netherlands' strengths in areas such as Therapeutics & Vaccines,
Read More: https://www.biospectrumindia.com/news/79/10527/india-netherlands-to-partner-for-innovative-vaccine-solutions.html

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REGULATORY NEWS

MAR 2018
ISSUE 03

Common Form of Bladder Cancer: FDA Finalizes Guidance

The US Food and Drug Administration (FDA) on Monday finalized guidance providing recommendations to drugmakers for developing new drugs and biologics to treat bacillus Calmette-Guérin (BCG)-unresponsive nonmuscle invasive bladder cancer (NMIBC), the most prevalent form of bladder cancer in the US
Read More: https://www.raps.org/news-and-articles/news-articles/2018/2/common-form-of-bladder-cancer-fda-finalizes-guida

FDA Explains Reasons for Refusing to Approve Another Oxycodone Drug

The notice, published in Monday's Federal Register, offers PMRS an opportunity to request a hearing on the matter and follows the agency's decision to reject a citizen petition filed by the Pennsylvania-based company in May 2017 to stay the approval of Insipirion's recently approved opioid RoxyBond (oxycodone hydrochloride).
Read More: https://www.raps.org/news-and-articles/news-articles/2018/2/fda-explains-reasons-for-refusing-to-approve-anoth

FDA approves new test that could reduce unnecessary CT scans

Imagine not needing a costly CT scan to test if you have a traumatic brain injury. That technology now exists and should be in local hospitals soon. It's something Rockford area families say could help them.
Read More: http://www.wrex.com/story/37541341/2018/02/Monday/fda-approves-new-test-that-could-reduce-unnecessary-ct-scans

IPA releases GDP & PV guidelines to help drug makers meet global quality norms

The Indian Pharmaceutical Alliance (IPA), a representative body of 20 research based pharmaceutical companies in India, has released guidelines on good documentation practice (GDP) and process validation (PV) as part of its ongoing efforts to help the domestic drug makers achieve parity with global benchmarks in quality.
Read more at: http://www.pharmabiz.com/NewsDetails.aspx?aid=107517&sid=1

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CLINICAL RESEARCH

MAR 2018
ISSUE 03

Designing Clinical Studies To Avoid Regulatory Scrutiny

Earlier this year, the Department of Justice (DOJ) announced a $3.5 million settlement against Primex Clinical Laboratories, a California laboratory providing clinical diagnostic testing services.
Read More: https://www.clinicalleader.com/doc/designing-clinical-studies-to-avoid-regulatory-scrutiny-0001

Online Tool Expedites Access To Clinical Trials For Pulmonary Fibrosis Patients

The Pulmonary Fibrosis Foundation (PFF) has launched a new Clinical Trial Finder, the first one of its kind for patients living with the deadly lung disease.
Read More: https://www.prnewswire.com/news-releases/online-tool-expedites-access-to-clinical-trials-for-pulmonary-fibrosis-patients-300594306.html

FDA Adds 35 New, 22 Revised Product-Specific Guidances for Generic Drugmakers

The 35 new and 22 revised guidance documents include what FDA said are 19 guidance documents on complex generics, and add to the 32 new and 19 revised guidance documents issued in October 2017, as well as the 21 new and 16 revised draft guidances released in May 2017 and dozens of others in 2016 and others dating back to 2012.
Read More: https://www.raps.org/news-and-articles/news-articles/2018/2/fda-adds-35-new,-22-revised-product-specific-guida

Lupin To File Its First Biosimilar In Japan, EU In 2019

The drug has been developed by YL Biologics, a joint venture between Lupin and Japanese pharma company Yoshindo. The drug is a copy of drugmaker Amgen's Enbrel, the first such biosimilar with a market size of $11 billion.
Read More: https://www.bloombergquint.com/business/2018/02/09/lupin-to-file-its-first-biosimilar-in-japan-eu-in-2019

Peanut allergy drug nears approval after clinical trial success

A US biotech company is on course to win approval for the world's first peanut allergy drug after reporting impressive results from a large clinical trial.
Read More: https://www.ft.com/content/17cd58b0-165d-11e8-9e9c-25c814761640

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FINANCIAL NEWS

MAR 2018
ISSUE 03

Indian drug firms' growth slowed in 2017 on slow approvals, MNCs' caught up

Home-grown pharmaceutical companies in 2017 saw some erosion in their edge over multinational peers in the domestic drug market. Tempering the past year's trend of a significant lead, Indian drug firms grew at almost the same rate as their MNC counterparts.
Read More: http://www.business-standard.com/article/economy-policy/indian-drug-firms-growth-slowed-in-2017-on-slow-approvals-mncs-caught-up-118020600398_1.html

With private equity bidders lined up, Sanofi's EU generics could go for up to $2.4B: Reuters

After making two sizable buys, Sanofi is moving ahead with a sale of its European generics business, according to multiple reports, and has narrowed down the field of potential buyers to drug companies from Brazil and India, plus several private equity funds, Reuters reports, citing sources.
Read More: https://www.fiercepharma.com/m-a/sanofi-eu-generics-biz-attracts-private-equity-bidders-plus-torrent-and-brazil-s-ems-reuters

Natco Pharma Q3 net up 11% at Rs 2.17 billion

Natco Pharma Limited has reported a 11.54 percent increase in net profit at Rs 2.17 billion for the quarter ended December 2017 as compared with Rs 1.95 billion in the corresponding quarter previous year.
Read More: http://www.business-standard.com/article/companies/natco-pharma-q3-net-up-11-at-rs-2-17-billion-118020600899_1.html

Strides Shasun net dips by 25% in Q3 to Rs. 40 cr

Strides Shasun, a Rs. 2,750 crore pharma major which de-merged API business and divested Indian branded generics business, has suffered a setback during the third quarter ended December 2017 and its consolidated net profit declined by 24.9 per cent to Rs. 40.30 crore from Rs. 53.67 crore in the corresponding period of last year.
Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=107215&sid=2

Zydus Cadila sees 60% of topline from US by FY20 even as rivals lose share

Cadila Healthcare is having a dream run in the US, riding primarily on growth in base business coupled with a steady pipeline of launches lined up for that country.
Read More: http://www.business-standard.com/article/companies/zydus-cadila-sees-60-of-topline-from-us-by-fy20-even-as-rivals-lose-share-118020900225_1.html

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MERGER & AQUISITION

MAR 2018
ISSUE 03

Two Labs Acquires MKO Global Partners

Two Labs, an industry-leading pharma and life science services company, today announced that it has acquired MKO Global Partners (MKO), a strategic global life sciences consulting firm focused on payer strategy, market access, and pricing in the pharmaceutical and biotech markets.
Read More: http://markets.businessinsider.com/news/stocks/Two-Labs-Acquires-MKO-Global-Partners-1001741433

Sino-American collaboration to bring new biosimilars to emerging markets

Californian life sciences firm BioSciencesCorp has partnered with Shanghainese contract manufacturing organization (CMO) Mab-Venture, to develop and manufacture multiple undisclosed biosimilars for emerging markets.
Read More: https://www.thepharmaletter.com/article/sino-american-collaboration-to-bring-new-biosimilars-to-emerging-markets

'We expect M&A deal numbers to move up in 2018'

TAs valuations vaulted on the back of the raging bull-run on Dalal Street in 2017, the merger and acquisition (M&A) segment took a breather. BusinessLine caught up with Girish Nadkarni, MD & CEO of Motilal Oswal Investment Banking, one of the top home-grown investment banks in India, to discuss the scenario, the way forward and the challenges. Excerpts:
Read More: https://www.thehindubusinessline.com/markets/we-expect-ma-deal-numbers-to-pull-up-in-2018/article22799706.ece

Glenmark Pharma inks pact with SCD Pharmaceuticals

Glenmark Pharmaceuticals, a global pharmaceutical company, announced it has entered into an exclusive agreement with Sam Chun Dang Pharm. Co. Ltd. (SCD), to develop, manufacture and market a portfolio of ophthalmic products in the US and Canada. Under this agreement, these products will be developed and manufactured by SCD in South Korea. Glenmark will seek all market authorizations and commercialize the products in North America.
Read More: https://www.indiainfoline.com/article/news-top-story/glenmark-pharma-inks-pact-with-scd-pharmaceuticals-118022200050_1.html

SMS Lifesciences to acquire API maker Mahi Drugs

In its meeting, the board of Hyderabad-based SMS Lifesciences has considered the due-diligence report and approved the acquisition, the firm said in a BSE filing on Friday. In its earlier meeting on 8 February, the board had weighed buying the firm.
Read More: https://www.vccircle.com/sms-lifesciences-to-acquire-api-maker-mahi-drugs/

VEEDA CRO NEWS

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ISSUE 03

VEEDA CLINICAL RESEARCH WINS "CLINICAL TRIAL COMPANY OF THE YEAR" AT THE CLINICAL TRIALS AWARDS ORGANISED BY WORLD HEALTH & WELLNESS CONGRESS.

Veeda CRO an independent global provider of drug development solutions and services to the pharmaceutical, biotechnology and medical device, wins CLINICAL TRIAL COMPANY OF THE YEAR AWARD at the Clinical Trials Awards organized by World Health & Wellness Congress, a group dedicated to high level knowledge exchange through leadership & networking amongst seniors and brand decision makers across industry segments.

While accepting the award on behalf of all the employees, Mr. Apurva Shah MD & Founder of Veeda Clinical Research said "This is a big honor for us, "The hard work, personal sacrifice and passion of Veeda's employees have gone into building a company that's synonymous with quality. Today Veeda is a trusted partner of choice for Clinical Research for our customers and this award is recognition of their talent and dedication."

"We are very proud to be recognized as the industry's best," commented Mr. Binoy Gardi MD & Founder of Veeda Clinical Research "Through innovations in patient recruitment and a strong commitment to ethical conduct and delivery; we have exceeded customer expectations in a wide range of studies and have achieved industry benchmarks in clinical research. It is very pleasing to see the efforts of our employees being rewarded."

This award follows a series of earlier wins. Veeda CRO has also been crowned as Best Indian CRO of the year four times last year by Frost & Sullivan, Times Network & Health & Safety Awards & AI Global Media. Veeda has an exemplary regulatory track record of completing 28 USFDA, 5 ANVISA, 4 WHO, 3 MHRA, 1 AGES, 1 ANSM, 1 MCC, 11 DCGI audits successfully till date.

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ARTICLE OF THE MONTH

MAR 2018
ISSUE 03

Drug for Still's Disease Shows Promise in Phase 2 Trial

In the movie The Big Sick, based on real events that happened to its two Academy Award-nominated scriptwriters, the character Emily falls gravely ill and is put into a medically induced coma as doctors race to treat what they believe is an antibiotic-resistant infection. When they finally diagnose her with a rare autoimmune condition called adult-onset Still's disease, treating the symptoms seems trivial, and Emily is soon out of the coma and back on her feet.

It turns out that treating Still's in real life isn't always so simple. Some patients' symptoms aren't immediately resolved by first-line treatments, and many experience periodic flare-ups after the initial bout of symptoms. But a Swiss trial reported last month (February 22) in the Annals of the Rheumatic Diseases moves a potential new treatment for the condition closer to the market. It blocks the inflammatory cytokine interleukin 18 (IL-18), which is elevated in Still's patients.

"We still don't really understand adult onset Still's disease very well," says University of California, San Francisco, rheumatologist Andrew Gross. Its causes aren't known, although there may be an infectious trigger. And as depicted in the movie, the condition can be challenging to diagnose. With symptoms such as high fever, fluid around the lungs, and liver inflammation, "it mimics a lot of different things, including cancer as well as infections," Gross tells The Scientist. But, he adds, the severity of the fictional Emily's condition, true to the filmmaker's, is unusual: It's more typical that patients aren't ill enough to be hospitalized, but spend months or even years visiting doctors before they are correctly diagnosed.

READ MORE & SOURCE:
https://www.healthcare-informatics.com/blogs/david-raths/exciting-new-year-pragmatic-clinical-trials

The Veeda Newsletter

MAR 2018
ISSUE 03

UPCOMING CONFERENCE

1. DCAT WEEK '18

Mar 19-22 2018,
NY, USA

2. CPHI NORTH AMERICA

Mar 19-22 2018,
Philadelphia, PA,
USA

CPhI north america
ICSE FDF InnoPack
April 24-26, 2018
Pennsylvania Convention Center
Philadelphia, PA, USA

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