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# The Veeda Newsletter

FEB 2018
ISSUE 02

## VEEDA CRO NEWS

VEEDA CRO celebrates 13 Years of success in serving the clients with best quality services.


**Rotavac: new era for Indian pharma**


**An Exciting New Year for Pragmatic Clinical Trials**


**Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Road map.**


**Budget 2018 expectation: Govt's facilitation a vital cog in pharma industry growth.**


**Indian pharma firms look at M&A opportunities to gain scale, tide over slowdown.**


**FDA to release more clinical trial information for newly approved drugs.**

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# INDIAN PHARMA

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## Budget 2018: Pharma companies want a push on research, innovation.

The government needs to seriously re-think on the ways to promote research and innovation in the country, especially within the Indian pharmaceutical industry. **Read More:** http://www.businesstoday.in/magazine/union-budget-2018-19/expectations/budget-2018-pharma-companies-want-government-to-invest-in-research-innovation/story/267903.html

## 'India - China trade improving in favor of India'.

While appreciating the remarkable turnaround by Indian exports during November 2017, Anil Khaitan, President, **Read More**: http://www.smetimes.in/smetimes/news/top-stories/2018/Jan/15/1501201802.html

## A $300 billion reason India's drug price cap will stay.

When it comes to intellectual property, it's now understood—and grudgingly accepted—that India's use of compulsory licensing won't go away. **Read More:** http://www.livemint.com/Opinion/EINgL3bXqAmntCydtW0MHM/A-300-billion-reason-Indias-drug-price-cap-will-stay.html

## Piramal Enterprises explores re-entry into Indian formulations business.

The company is looking at introducing respiratory and central nervous system formulations in India, the people said. **Read More:** https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/piramal-enterprises-explores-re-entry-into-indian-formulations-business/articleshow/62533012.cms

## Indian drug makers to face 10-12% price erosion in US generic market this year: ICRA

The US generic business is likely to remain challenging in 2018 for Indian pharmaceutical companies, with pricing pressure of 10-12 percent, according to credit rating agency ICRA. **Read More:** http://www.moneycontrol.com/news/business/companies/indian-drug-makers-to-face-10-12-price-erosion-in-us-generic-market-this-year-icra-2490459.html

## Rotavac: new era for Indian pharma

Researchers who worked on developing the rotavirus vaccine, Rotavac, deserve applause. **Read More:** http://www.deccanherald.com/content/656460/rotavac-era-indian-pharma.html

# REGULATORY NEWS

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## Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap

Many of these efforts are already underway, and will be further advanced in 2018, while other policies outlined in this document will be initiated during the coming months..

**Read More:** https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm591993.htm

## Regulator weighs inspection of drug-making facilities in US.

After taking action against drug makers in China for quality lapses earlier this month, the Central Drugs Standard Control Organisation (CDSCO) has turned its attention to other overseas manufacturers.

**Read More:**
https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/regulator-weighs-inspection-of-drug-making-facilities-in-us/articleshow/62514977.cms

## FDA To Hold Meeting On Clinical Trial Criteria

FDA will hold a public meeting to discuss how to improve eligibility criteria for clinical trials to better represent the broader patient population and increase diversity, the agency announced Monday (Jan. 29) **Read More:** https://insidehealthpolicy.com/daily-news/fda-hold-meeting-clinical-trial-criteria

## FDA Should Make Public Its Plans to Issue and Revise Guidance on Nonbiological Complex Drugs.

Generic drugs can save consumers and the health care system billions of dollars. But it can be challenging for drug companies to prove to the Food and Drug Administration that generic versions of certain complex drugs are the same as their brand-name counterparts. **Read More:** https://www.gao.gov/products/GAO-18-80

## FDA plans more restrictive policy for bulk drug compounding

FDA Commissioner Scott Gottlieb said the agency in March will issue draft guidance with new criteria for determining what substances can be used to produce drugs in bulk for hospitals and doctors' offices without individual patient prescriptions.

**Read more at:** https://www.reuters.com/article/us-usa-fda-pharmacies/fda-plans-more-restrictive-policy-for-bulk-drug-compounding-idUSKBN1F739B

## US FDA bans 24 substances from healthcare antiseptics

Manufacturers have not submitted any data to support the substances as safe for use, the agency says. Under the final rule, the ingredients have been classified as not generally recognised as safe and effective (Gras/GRAE) for use. **Read More:** https://chemicalwatch.com/62906/us-fda-bans-24-substances-from-healthcare-antiseptics

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# CLINICAL RESEARCH

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## Novartis Launches Head-to-head Clinical Trial for Secukinumab and Biosimilar.

In part of its rheumatology program for secukinumab, Novartis is also currently recruiting for the EXCEED trial, a head-to-head clinical comparison of brand Cosentyx versus adalimumab (Humira) for psoriatic arthritis (PsA). **Read More:** http://www.mdmag.com/medical-news/novartis-launches-headtohead-clinical-trial-for-secukinumab-and-biosimilar

## FDA Aims to Improve Access to Clinical Trial Info for New Drugs

After approvals of new drug applications (NDAs), the FDA releases certain information used during the reviewing process of the NDA, including summaries written by medical reviewers, proposed labeling or other requirements, and other relevant data on the product's safety and efficacy.
**Read More:** http://www.pharmacytimes.com/product-news/fda-aims-to-improve-access-to-clinical-trial-info-for-new-drugs


## New tactics change clinical trial awareness game.

When Eiger Biopharmaceuticals began looking for patients to enroll in a clinical trial for lymphedema drug Ubenimex, Joanne Quan, M.D., chief medical officer of the Palo Alto, California-based company, kept hitting a wall. **Read More:** http://www.mmm-online.com/pipeline/new-tactics-change-clinical-trial-awareness-game/article/733177/

## FDA to release more clinical trial information for newly approved drugs.

The Food and Drug Administration is taking steps to make it easier for doctors, patients, and researchers to get access to clinical trial data amassed during the process of approving new drugs, Commissioner Scott Gottlieb said Tuesday.
**Read More:** https://www.bostonglobe.com/business/2018/01/16/fda-release-more-clinical-trial-information-for-newly-approved-drugs/cfe8ve9xVmo7QwE5uVyjQN/story.html

## ClinOne Creates World's First Proactive Clinical Trial Patient Engagement Monitoring.

ClinOne, a mobile clinical trial management solution, is revolutionizing how patients manage the complexities of a clinical trial, navigate appointments, and manage their research documents with the first proactive patient engagement monitoring technology of its kind.
**Read More:** https://www.prnewswire.com/news-releases/clinone-creates-worlds-first-proactive-clinical-trial-patient-engagement-monitoring-300591413.html

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# FINANCIAL NEWS

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## Indian, Chinese drugmakers eye Sanofi's European generics unit for $2B deal: report

As Sanofi looks to reshape itself and offload its European generics business, it's reportedly getting some interest around the globe for an outfit that analysts believe could fetch $2 billion.
**Read More**: https://www.fiercepharma.com/pharma/indian-chinese-drugmakers-eye-sanofi-s-european-generics-unit-report

## Lupin forays into OTC segment;eyes Rs 300 crore turnover in 5 years

Drug major LupinBSE 0.56 % today said it has forayed into over-the-counter (OTC) segment in the country with plans to touch Rs 300 crore turnover in the vertical over the next five years.
**Read More:**
https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/lupin-forays-into-otc-segmenteyes-rs-300-crore-turnover-in-5-years/articleshow/62508405.cms

## Jubilant Life Sciences net jumps by 78% to Rs.213 crore in Q3

Shyam S Bhartia, chairman and Hari S Bhartia, co-chairman & managing director, said, “We are happy to report record growth in both revenues and profits.
**Read more at:** http://www.pharmabiz.com/NewsDetails.aspx?aid=106774&sid=2

## Biocon strikes partnership with Sandoz to tap biosimilars opportunity

Biocon has struck a partnership with Sandoz, a unit of pharmaceuticals company Novartis AG, to jointly develop and market biosimilars, or generic versions of existing bio-drugs, in markets around the world, the Mumbai-listed biopharma company said in a press release on Thursday.
**Read more at:** http://www.forbesindia.com/article/special/biocon-strikes-partnership-with-sandoz-to-tap-biosimilars-opportunity/49165/1

## Torrent Pharma acquires US-based generic, OTC player Bio-Pharm

Established in 1992 and based in Levittown Pennsylvania, US, BPI has a proven track record in research and development and manufacturing of oral solutions, suspensions and suppositories.
**Read more at:** http://www.thehindubusinessline.com/companies/torrent-pharma-acquires-usbased-generic-otc-player-biopharm/article10040237.ece

## Budget 2018 expectation: Govt's facilitation a vital cog in pharma industry growth

India with all its leadership talents and skilled workforce has the potential to become key global R&D hub, and with our strong foothold in the sector, we should aim to touch a figure of $150 billion by 2025 with a CAGR of 18 per cent. **Read more at:**
http://economictimes.indiatimes.com/articleshow/62602530.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

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# MERGER & AQUISITION

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## Sun Pharma buys bigger share of growing Malaysian venture

While Sun Pharmaceuticals continues to struggle with its U.S. sales, emerging markets have provided an area of growth for the Indian generics maker.

**Read More:** https://www.fiercepharma.com/manufacturing/sun-pharma-buys-bigger-share-growing-malaysian-venture

## Buy Bliss GVS Pharma; target of Rs 350: Joindre Capital's

Bliss GVS Pharma Ltd. is an Indian pharmaceutical company headquartered in Mumbai, India. Bgvsl primarily develops, manufactures and markets products across various therapeutic categories

**Read More:** http://www.moneycontrol.com/news/business/stocks/buy-bliss-gvs-pharma-target-of-rs-350-joindre-capitals-2478679.html

## Agilent buys Cork's Luxcel Biosciences

This latest acquisition expands Agilent's cell analysis portfolio with the addition of easy-to-use assay kits that are compatible with industry standard plate-readers.

**Read More:** http://optics.org/news/9/1/15

## Ipca Laboratories Acquires US Pharma Manufacturer For $9.65 Mln

Ipca Laboratories Ltd said it is has acquired US-based drug manufacturer Pisgah Labs Inc. for US$ 9.65 millions free of debt.

**Read More:** https://ultra.news/t-t/36634/ipca-laboratories-acquires-us-pharma-manufacturer-9-65-mln/

## Indian pharma firms look at M&A opportunities to gain scale, tide over slowdown

Leading Indian pharmaceutical companies, struggling to cope with a slowdown in growth and reduced profitability over the last couple of years, are expected to try and tap inorganic opportunities globally in order to increase scale of business and rise above challenges.

**Read more at:** https://www.dealstreetasia.com/stories/indian-pharma-firms-look-at-ma-opportunities-to-gain-scale-tide-over-slowdown-91200/

## ICASI Pharmaceuticals Acquires ANDA Portfolio From Sandoz Inc. (Sandoz)

ICASI Pharmaceuticals, Inc. (Nasdaq: CASI), a biopharmaceutical company dedicated to bringing quality pharmaceutical products to the Chinese and U.S. markets announced today that it has acquired a portfolio of 25 U.S.

**Read More:** http://menafn.com/1096393217/CASI-Pharmaceuticals-Acquires-ANDA-Portfolio-From-Sandoz-Inc.-Sandoz

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# VEEDA CR NEWS

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## VEEDA CRO celebrates 13 Years of success in serving the clients with best quality services.

Establishing its core values on high professionalism and always delivering quality services, Veeda Clinical Research is glad to announce its 13th anniversary. This important milestone is a sign of recognition from all our partners for the quality of our services delivered to them across the globe. **Read More:** https://veedacr.com/2018/Newsletter/Feb-2018/VEEDA%20CRO%20celebrates%2013%20Years%20of%20success%20in%20serving%20the%20clients%20with%20best%20quality%20services.html

**From Left to Right : Mr. Venu Madhav, Mr. Apurva Shah, Mr. Binoy Gardi , Mr. Nirmal Bhatia lighting lamp at Veeda's 13th Anniversary Celebration ceremony.**

## Veeda organizing a Seminar on "Understanding Pharmacovigilance Obligations in India"

Veeda CRO, a fastest growing global CRO, is taking a lead in the training of professionals from the Pharmaceutical & Biotech industry by organizing an informational seminar on “Understanding Pharmacovigilance Obligations in India" on 9th Feb 2018.


**Read More: https://veedacr.com/2018/Newsletter/Feb-2018/Veeda%20organizing%20a%20Seminar%20on%20Understanding%20Pharmacovigilance%20Obligations%20in%20India.html**

## An Exciting New Year for Pragmatic Clinical Trials

It's an exciting time in the world of pragmatic clinical trials, as the big data from EHRs and claims data starts to bring back answers to interesting research questions. Last week I saw a great presentation about the design and launch of an effort to improve treatment with oral anticoagulants in patients with atrial fibrillation (AFib) and at risk of stroke. It involves a randomized controlled trial of direct mail to thousands of health plan members with AFib and to their providers to encourage consideration of oral anticoagulation.

I wrote about pragmatic clinical trials a few times last year. They are designed to reflect "real-world" medical care by recruiting broad populations of patients, embedding the trial into the usual healthcare setting, and leveraging data from health systems to produce results that can be readily used to improve patient care.


For instance, I wrote about a presentation at Duke University by Russell Rothman, M.D., the vice president for population health research at Vanderbilt University Medical Center, in which he described some of the informatics infrastructure of one PCORI-funded study, ADAPTABLE (Aspirin Dosing: A Patient-centric Trial Assessing Benefits and Long-Term Effectiveness)..

ADAPTABLE is a $14 million, three-year pragmatic clinical trial that is comparing the effectiveness of two different daily doses of aspirin widely used to prevent heart attacks and strokes in individuals living with heart disease. Its goal is to enroll 20,000 patients. For that project, the Mid-South Clinical Data Research Network (CDRN) takes EHR data from health systems and transforms it into a common data model to run queries against.

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

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## UPCOMING CONFERENCE

### 1. Outsourcing in Clinical Trials West Coast 2018

**Feb 21 - 22 2018,**
**Burlingame,California , USA**


### 2. DCAT WEEK '18

**Mar 19-22 2018,**
**NY, USA**

DCAT Week
March 19–22, 2018
New York City

### 3. 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

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

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