The Veeda Newsletter

ISSUE 5 : MAY 2019

INDIAN PHARMA

What Modi 2.0 could mean for the Indian pharma industry?

REGULATORY

Interchangeable Biosimilars: FDA Finalizes Guidance

CLINICAL RESEARCH

Innovation Driving New Drug Development in Oncology

FINANCIALS

The global clinical trials market size is expected to reach USD 68.9 billion by 2026

M & A

NETWORK OF CLINICAL RESEARCH SITES ACQUIRED

ARTICLE

India-An attractive hub for clinical research

ISSUE 5 : MAY 2019

THE VEEDA NEWSLETTER

REGULATORY

Impact of New FDA Guidance on Bioanalytical Testing on Drug Development

In this webcast, learn how the FDA Bioanalytical Method Validation Guidance (May 2018), the FDA Immunogenicity Testing of Therapeutic Protein Products (January 2019), and the February 2019 draft International Conference on Harmonisation (ICH) Bioanalytical Method Validation M10 guidelines have changed or are poised to change the landscape of outsourcing bioanalysis to support drug development.
Read more: http://www.pharmtech.com/impact-new-fda-guidance-bioanalytical-testing-drug-development

FDA undercuts $375,000 drug in surprise move

The US Food and Drug Administration created a workaround this week that effectively undercuts the $375,000 price tag of a drug that became the poster child for concerns about the pharmaceutical industry.
Read more : https://www.fox10tv.com/news/us_world_news/fda-undercuts-drug-in-surprise-move/article_54c39b02-d7dc-50bc-82ad-60ba5f9bcf3a.html

When to Submit an ANDA vs. a 505(b)(2)? FDA Explains

The US Food and Drug Administration (FDA) on Thursday finalized guidance to help drug sponsors determine when they should submit an abbreviated new drug application (ANDA) for a generic or a 505(b)(2) application for a drug that partly relies on certain data from an already-approved drug.
Read more : https://www.raps.org/news-and-articles/news-articles/2019/5/when-to-submit-an-anda-vs-a-505b2-fda-explai

Need a new brand name if composition of drug is changed: Pharma regulator

According to a notification issued on Thursday by the CDSCO, the practice of changing the key therapeutic ingredients in a drug formulation without changing the brand name "is not only misleading but may also result in undesirable pharmacological effects as the consumer would take the formulation assuming that it has the earlier composition."
Read more : https://indianexpress.com/article/business/economy/central-drugs-standard-control-organisation-pharma-regulator-drug-controller-of-india-5731908/

Interchangeable Biosimilars: FDA Finalizes Guidance

The US Food and Drug Administration (FDA) on Friday finalized a long-awaited guidance spelling out how biosimilars can achieve an interchangeable status, which means they may be substituted for the reference biologic without a prescriber intervening.
Read more : https://www.raps.org/news-and-articles/news-articles/2019/5/interchangeable-biosimilars-fda-finalizes-guidanc

ISSUE 5 : MAY 2019

THE VEEDA NEWSLETTER

FINANCIALS

AbbVie's Humira hits the wall

Humira's turning point was a long time coming. Basic patent protection expired more than two years ago for the drug, which accounted for 61 percent of AbbVie's $32.8 billion in 2018 revenue. Generics hit the European market last year, driving down international Humira sales 23 percent in the first quarter.
Read more : https://www.chicagobusiness.com/joe-cahill-business/abbvies-humira-hits-wall

Glenmark Pharma expects up to 14 % growth in India revenues in FY20

"We have historically grown at a rate which is faster than the market growth rate. Historical the growth is about 12 to 14 percent annually. That is the kind of growth trajectory we hope will be able to sustain (in FY 20 also).
Read more : https://www.moneycontrol.com/news/business/companies/glenmark-pharma-expects-up-to-14-growth-in-india-revenues-in-fy20-3923821.html

Global generic drug market to hit USD 380.60 billion by 2021

A leading research firm Zion Market research added a recent report on "Generic Drug Market by Brand (Pure Generic and Branded Generic) for Central Nervous System (CNS), Cardiovascular, Dermatology, Oncology, Respiratory and others Therapeutic Applications – Global Industry Perspective, Comprehensive Analysis, Size, Share, Growth, Segment, Trends and Forecast, 2015 – 2021" to its research database.
Read more : http://b2bnewz.com/46543/global-generic-drug-market-to-hit-usd-380-60-billion-by-2021/

Alembic Pharma forms JV to enter a difficult $100 bn Chinese market

Vadodara-based Alembic Pharmaceuticals Limited on Tuesday announced a joint venture (JV) for entering the Chinese market, the world's second largest single country drug market after the US. Indian players like Dr Reddy's Laboratories have presence in the Chinese market while others like Cipla, Sun Pharma and Wockhardt are testing waters.
Read more : https://www.business-standard.com/article/companies/alembic-pharma-forms-jv-to-enter-a-difficult-100-bn-chinese-market-119050700826_1.html

The global clinical trials market size is expected to reach USD 68.9 billion by 2026

The global clinical trials market size is expected to reach USD 68.9 billion by 2026 It is projected to expand at a CAGR of 5.7% during the forecast period. Key drivers impacting the market growth are globalization of clinical trials, development of new treatments such as personalized medicine, augmenting evolution in technology, and rising demand for CROs to conduct clinical trials.
Read more : https://finance.yahoo.com/news/global-clinical-trials-market-size-220200008.html

ISSUE 5 : MAY 2019

THE VEEDA NEWSLETTER

CLINICAL RESEARCH

Innovation Driving New Drug Development in Oncology

The new therapies being researched are spread across three key areas: gene/cellular therapies, precision medicine and immunotherapy, according to the presentation. Of the agents in development, one-third are geared toward specific patient populations defined by a biomarker.
Read more : : https://www.curetoday.com/articles/innovation-driving-new-drug-development-in-oncology

Patient need, drug development, and risk

The decision was based on interim results of the phase 3 BELLINI trial, which showed an increased risk of death for patients who were treated with venetoclax and bortezomib compared with placebo (41 [21•1%] deaths in 194 patients in the venetoclax group vs 11 [11•3%] of 97 in the control group; hazard ratio 2•03 [95% CI 1•04–3•94]). pushed through clinical trials at breakneck speed.
Read more : https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(19)30238-4/fulltext

Evolution of pediatric drug development

In 2019, we tend to take the inclusion of pediatric patients in a drug development program for granted. In fact, pediatric drug development is a new science that has just evolved in the last 20 years. The struggle to make pediatrics part of this multibillion-dollar industry is not only interesting, but it is also informative with regard to continuing pressures to expedite the pediatric component of the drug development process.
Read more : https://www.contemporarypediatrics.com/pediatrics/evolution-pediatric-drug-development

Drafting and Negotiating Clinical Trial Agreements

Clinical trial agreements are one of the most important agreements in the pharma industry as no research can start without the right agreement in place between sponsor and host organization. They provide a contract which manages the relationship and responsibilities of both parties, and provide for the allocation of risk, obligations, the protection of academia, terms of collaboration, IP rights and much more.
Read more : https://finance.yahoo.com/news/drafting-negotiating-clinical-trial-agreements-221500294.html

What Are The Fundamentals Of Good Clinical Research?

Excellent clinical research is needed more so now than ever before, yet countless medical students and aspiring professionals are finding themselves stuck when it comes to brainstorming new ideas and executing thorough research plans that produce useful results.
Read more : https://www.counselheal.com/articles/40127/20190505/what-are-the-fundamentals-of-good-clinical-research.htm

ISSUE 5 : MAY 2019

THE VEEDA NEWSLETTER

MERGER AND AQUISITION

WuXi AppTec Acquires Pharmapace to Enhance Biometrics Services for Clinical Development

WuXi AppTec, a leading global pharmaceutical and medical device open-access capability and technology platform company, today announced that it has acquired Pharmapace, Inc., a US-based clinical research services company with expertise of providing high quality biometrics services for all phases of clinical trials, regulatory submissions, and post marketing support.
Read more : https://www.prnewswire.com/news-releases/wuxi-apptec-acquires-pharmapace-to-enhance-biometrics-services-for-clinical-development-300843939.html

ICON's Acquisition of MeDiNova Research

ICON plc, (ICLR) a global provider of drug and device development and commercialisation services to pharmaceutical, biotechnology, medical device industries, today announced that it has acquired a majority shareholding in MeDiNova Research, a site network with research sites in key markets in Europe and Africa, and that it has the right to acquire the remaining shares in the company by Quarter 3 2020
Read more : https://finance.yahoo.com/news/icon-acquisition-medinova-research-130000223.html

Combining capabilities to grow: Navitas acquires KAI Research

Navitas has acquired KAI Research to expand its trial site footprint in North America and Africa as well as bolster its ability to manage clinical trials in a number of research areas.
Read more : HTTPS://WWW.OUTSOURCING-PHARMA.COM/ARTICLE/2019/05/23/COMBINING-CAPABILITIES-TO-GROW-NAVITAS-ACQUIRES-KAI-RESEARCH

Agreement Reached for ESSA Pharma to Acquire Realm Therapeutics

The Acquisition, subject inter alia to Realm Shareholder approval, is intended to be implemented by means of a United Kingdom ("UK") Court-sanctioned scheme of arrangement under Part 26 of the UK Companies Act 2006 and is expected to be completed by mid-year 2019.
Read more : https://www.prnewswire.com/news-releases/agreement-reached-for-essa-pharma-to-acquire-realm-therapeutics-300851546.html

NETWORK OF CLINICAL RESEARCH SITES ACQUIRED

A Coventry-headquartered network of clinical research sites in the UK and Europe has been acquired by a global provider of drug and device development and commercialisation services.
Read more : https://www.insidermedia.com/insider/midlands/network-of-clinical-research-sites-acquired

ISSUE 5 : MAY 2019

THE VEEDA NEWSLETTER

INDIAN PHARMA

Indian Guide Offers Consolidated Advice On New Clinical Trial Requirements

The Indian drug regulator has issued guidance to facilitate compliance with the latest rules covering the approval of new drugs and the conduct of clinical trials.
Read more : https://pink.pharmaintelligence.informa.com/PS125194/Indian-Guide-Offers-Consolidated-Advice-On-New-Clinical-Trial-Requirements

Indian pharma exports hit $19.14 bn, report double-digit growth after 3 yrs

Pharmaceutical Export Promotion Council (Pharmexcil)'s year-end report has pegged the total pharma exports from India at $19.14 billion for 2018-19 with a growth of 10.72 per cent over $17.28 billion in pharma exports last year.
Read more : : https://www.business-standard.com/article/companies/indian-pharma-exports-hit-19-14-bn-report-double-digit-growth-after-3-yrs-119050201025_1.html

Desi pharma bags 9% more USFDA nods

Domestic pharma companies received 372 approvals to launch generic drugs in the US in fiscal 2019, up 8.6% from 340 in the previous year.
Read more : http://timesofindia.indiatimes.com/articleshow/69191506.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Understanding the biosimilars opportunity for Indian pharma

Biologics, a category of pharmaceuticals which has been around for more than a decade, is back on discussion forums given the huge global market potential in the next three to five years. Several drugs classified as biologics are expected to go off patent during this period thereby making way for their biosimilar counterparts.
Read more : http://economictimes.indiatimes.com/articleshow/69335230.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

What Modi 2.0 could mean for the Indian pharma industry?

The Rs 1,20,000 crore plus Indian pharma industry has been through a churn in the past five years. Over the last year, it has finally seen double-digit growth, after having suffered periods of single-digit growth and even de-growth, post demonetization and implementation of the Goods and Services Tax (GST).
Read more : https://www.businesstoday.in/buzztop/buzztop-feature/what-modi-second-term-could-mean-for-the-indian-pharma-industry/story/349429.html

ISSUE 5 : MAY 2019

THE VEEDA NEWSLETTER

VEEDA CLINICAL RESEARCH® PVT. LTD.

Corporate Office

Veeda House, Beside YMCA club S.G.,
Highway, Vejalpur, Ahmedabad- 380015
Gujarat, India

Registered Office

Shivalik Plaza-A, Near IIM Ambawadi,
Ahmedabad- 380015, Gujarat, India.
CIN No. U73100GJ2004PTC044023

Other Office

Insignia, Besides Auda Garden, Opp. Zenobia
Residency, Sindhu Bhavan Road, Off. S. G. Highway,
Bodakdev, Ahmedabad- 380059, Gujarat, India

For more Information and Business Inquiry contact us at

+91 79 3001 3000 info@veedacr.com

Follow us at: