The Veeda Newsletter

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Approach for Rescue Trials

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INDIAN PHARMA

Cheaper versions of blockbuster diabetic drug to hit market soon

There is some good news around the corner for the over 72 million diabetics in India, as cheaper version of a blockbuster drug is expected to hit the market soon.
Read more : https://timesofindia.indiatimes.com/city/mumbai/cheaper-versions-of-blockbuster-diabetic-drug-to-hit-mkt-soon/articleshow/70381993.cms

Govt initiates new process to identify essential medicines

The prices of some drugs used for treating cancer, cardiac diseases and diabetes are likely to be cut as the government initiates a new process to identify essential medicines and bring some of them under price control.
Read more : : https://www.moneycontrol.com/news/business/govt-initiates-new-process-to-identify-essential-medicines-4239241.html

India gears up for making Telangana a pharmaceutical powerhouse

India's Telangana government has unveiled plans to leverage the life sciences and pharmaceutical sector and create a US$100 billion industry in the coming decade, local newspaper Livemint has reported.
Read more : https://www.cleanroomtechnology.com/news/article_page/India_gears_up_for_making_Telangana_a_pharmaceutical_powerhouse/156588

India: Biosimilars- An Emerging Trend In Indian Pharma Industry

India released the draft regulatory guidelines for 'Similar Biologics' at the BIO industry conference in Boston, USA, on 19 June 2012. These guidelines were revised in 2016.
Read more : http://www.mondaq.com/india/x/824462/Life+Sciences+Biotechnology/Biosimilars+An+Emerging+Trend+In+Indian+Pharma+Industry

Opportunities for Indian Life Sciences & Health Companies to Fuel Next Wave of Growth in Indo-Dutch Trade Relations

The Dutch Life Sciences and Health (LHS) sector has identified India as one of the few countries of key focus under its renewed global strategy. LSH is one of the priority sectors designated by the Dutch Ministry of Economic Affairs for its ability to address global social problems.
Read more : https://www.businesswireindia.com/opportunities-for-indian-life-sciences-and-health-companies-to-fuel-next-wave-of-growth-in-indo-dutch-trade-relations-64064.html

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REGULATORY

New FDA Draft Guidance Helps Sponsors Revise or Develop New USP Monographs

The US Food and Drug Administration (FDA) on Wednesday published draft guidance on the US Pharmacopoeial Convention Pending Monograph Process (USP-PMP), outlining how sponsors can revise or create new monographs so they are harmonized with a new product's FDA-approved quality and labeling requirements.
Read more: https://www.raps.org/news-and-articles/news-articles/2019/7/new-fda-draft-guidance-helps-sponsors-revise-or-de

FDA Issues Final Guidance on Live Case Presentations during IDE Clinical Trials

A live case presentation is a live or pre-recorded broadcast of a surgical procedure or procedure done through the skin (percutaneous). This presentation is typically narrated by the person performing the procedure or a commentator other than the person performing the procedure. In some cases, expert panel or audience interaction may occur.
Read more : https://www.dicardiology.com/content/fda-issues-final-guidance-live-case-presentations-during-ide-clinical-trials

FDA Revises 1999 Draft Guidance on Population Pharmacokinetics

The US Food and Drug Administration (FDA) on Thursday released revised draft guidance to help keep sponsors informed on the data and model requirements for population pharmacokinetics (PK) analyses submitted as part of new drug applications and biologic license applications.
Read more : https://www.raps.org/news-and-articles/news-articles/2019/7/fda-revises-1999-draft-guidance-on-population-phar

US and EU Fully Implement Mutual Agreement on GMP Inspections

The US Food and Drug Administration (FDA) and European Medicines Agency (EMA) on Friday said they have now fully implemented a plan that will allow member state regulators and FDA to mutually rely on each other's good manufacturing practice (GMP) inspections of drug facilities.
Read more : https://www.raps.org/news-and-articles/news-articles/2019/7/us-and-eu-fully-implement-mutual-agreement-on-gmp

FDA pushes for more diversity in clinical trials in draft guidance

Officials at the Food and Drug Administration have issued draft guidance aimed at increasing the diversity of clinical trial populations, including adding children and adolescents earlier in drug development and making trial participation less burdensome for patients.
Read more : https://www.mdedge.com/hematology-oncology/article/204512/practice-management/fda-pushes-more-diversity-clinical-trials

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CLINICAL RESEARCH

Patient-centric or site-centric clinical trials: Can you have both?

Improving patient recruitment is one of the top challenges drug developers, research sites and CROs face when managing clinical trials. To find, enroll and retain more patients, many pharmaceutical and biotechnology companies have adopted best practices driven by a patient-centric approach.
Read more : : https://www.biopharmadive.com/spons/patient-centric-or-site-centric-clinical-trials-can-you-have-both/559155/

What to Do If Your Clinical Trial Goes Global

Globalization has had a definitive impact on nearly every industry, and, in recent years, its effects on the clinical trials industry have become apparent. Clinical trials are necessary for public health in every society, developed and developing alike, and the industry has seen major growth in Asia and identified a trend in the movement of study sites into lower-cost areas globally.
Read more : https://www.prnewswire.com/news-releases/fishbat-explains-what-to-do-if-your-clinical-trial-goes-global-300887553.html

Quality by Design for Clinical Trials

Quality by design for clinical trials comprises an independent entity responsible for quality standards and an integrated system where each person is accountable for quality.
Read more : https://www.socra.org/blog/quality-by-design-for-clinical-trials/

Review evaluates how AI could boost the success of clinical trials

Big pharma and other drug developers are grappling with a dilemma: the era of blockbuster drugs is coming to an end. At the same time, adding new drugs to their portfolios is slow and expensive. It takes on average 10-15 years and $1.5-2B to get a new drug to market; approximately half of this time and investment is devoted to clinical trials.
Read more : https://www.eurekalert.org/pub_releases/2019-07/cp-reh071119.php

What Are Virtual Clinical Trials? An Interview with Science 37's Jonathan Cotliar

The majority of clinical trials are conducted at major research institutions or clinics, often based in urban areas. This can create problems of accessibility for many potential patients who live more than two hours from a trial site or who have work and family responsibilities that make it difficult for them to participate. It also creates significant issues in terms of patient diversity.
Read more : https://www.biospace.com/article/what-are-virtual-clinical-trials-an-interview-with-science-37-s-jonathan-cotliar/

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FINANCIALS

Torrent Pharmaceuticals manages to improve Unichem's FY19 profits

After an initial struggle, Torrent Pharmaceuticals has managed to improve the profitability of Unichem, which it acquired in December 2017, from 18 per cent to more than 30 per cent in 2018-19 (FY19). This is in line with the company's domestic margins.
Read more : https://www.business-standard.com/article/companies/torrent-pharmaceuticals-manages-to-improve-unichem-s-fy19-profits-119071400729_1.html

Indian pharma market growth cools off to 7.9% in Q1 FY20

The growth of the Indian pharmaceutical market (IPM) moderated to 7.9 percent in the first quarter of FY20, with sluggish sales across most therapeutic segments, according to market research firm AIOCD-AWACS.
Read more : https://www.moneycontrol.com/news/business/indian-pharma-market-growth-cools-off-to-7-9-in-q1-fy20-4186181.html

Budget 2019: Healthcare gets 15.4% higher allocation despite only passing mention in budget speech

Healthcare may have got a passing mention in the Budget 2019 presented by the Finance Minister Nirmala Sitharaman, but allocation to the sector has jumped 15.4 percent to Rs 62,659.12 crore for FY20, compared toprevious year's revised budget.
Read more : https://www.moneycontrol.com/news/economy/policy/budget-2019-healthcare-gets-15-4-higher-allocation-despite-only-passing-mention-in-budget-speech-4173341.html

Indian pharma industry to grow at 11-13 percent in FY2020, says rating agency Icra

"The growth trajectory for the Indian pharmaceutical industry is likely to remain at 11-13 per cent in FY2020, on the back of healthy demand from the domestic market, given increasing spend on healthcare along with improving access," Icra said in a release.
Read more : https://business.medicaldialogues.in/indian-pharma-industry-to-grow-at-11-13-percent-in-fy2020-says-rating-agency-icra/

State pharma industry records Rs 1,354 cr exports in 10 months

The pharmaceutical industry in Haryana, which was struggling for survival till two years ago, has recorded exports worth US dollars 197.87 million (Rs 1,354 crore) in the past 10 months.
Read more : https://www.tribuneindia.com/news/haryana/state-pharma-industry-records-rs-1-354-cr-exports-in-10-months/798359.html

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MERGER AND AQUISITION

Pfizer to Merge Its Off-Patent Drug Unit With Mylan

Pfizer agreed on Monday to combine its off-patent drugs division, which sells treatments like the cholesterol drug Lipitor, with the pharmaceutical company Mylan, creating a potential powerhouse in the increasingly challenging business of producing generic medicines.
Read more : https://www.nytimes.com/2019/07/29/business/dealbook/pfizer-mylan-deal.html

Carolina Partners Clinical Research Institute, Elligo Announce Partnership

Carolina Partners Clinical Research Institute, a leading outpatient mental and behavioral health practice in North Carolina, and research firm Elligo Health Research, announced a partnership that will expand Carolina Partners' clinical research business, starting with its Situs Court location in Raleigh, North Carolina.
Read more : https://www.behavioral.net/news-item/carolina-partners-clinical-research-institute-elligo-announce-partnership

Meridian Clinical Research Acquires Regional Clinical Research of New York

Meridian Clinical Research, LLC, based in Omaha, NE, has acquired the assets and operations of Regional Clinical Research, Inc., expanding its North American footprint to more than 20 investigative sites.
Read more : https://www.benzinga.com/pressreleases/19/07/n14110981/meridian-clinical-research-acquires-regional-clinical-research-of-new-york

Celltrion Forms Joint Venture to Sell 3 Biosimilars in China

Celltrion said this week it created a joint venture company in order to pursue the commercialization of 3 biosimilars in China. Celltrion formed Vcell Healthcare Limited with Nan Fung Group; Vcell also signed a licensing agreement with Celltrion.
Read more : https://www.centerforbiosimilars.com/news/celltrion-forms-joint-venture-to-sell-3-biosimilars-in-china

MinterEllison acts on major pharma merger

MinterEllison has advised on the merger of Arrow Pharmaceuticals and Apotex Australia to form Arrotex Holdings Pty Ltd (Arrotex).
Read more : https://www.australasianlawyer.com.au/news/minterellison-acts-on-major-pharma-merger-264563.aspx

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