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REGULATORY

FDA Moves to Modernize Drug Review Process

Under a new "knowledge management" approach for the Center for Drug Evaluation and Research (CDER), sponsors will submit applications that present data in a structured format so that it can be transmitted to teams of experts from multiple disciplines able to assess applications for new drugs and biologics in a timely and efficient manner.
Read more: http://www.pharmexec.com/fda-moves-modernize-drug-review-process

Regulator orders antibiotic drug makers to carry safety warnings

The Pharmacovigilance Programme of India (PvPI) that collects and evaluates reports of adverse drug reactions (ADRs) has reported that people using common antibiotic Ofloxacin are at greater risk of developing Stevens-Johnson Syndrome, a rare and fatal disorder of skin and another potentially life-threatening dermatologic disorder called toxic epidermal necrolysis.
Read more : https://www.livemint.com/companies/news/regulator-orders-antibiotic-drug-makers-to-carry-safety-warnings-15552682551 39.html

Govt makes it mandatory for all medical devices to get CDSCO certification

All imported, as well as locally manufactured medical devices sold in India will soon be required to clear specific safety and quality standards. The move is aimed at preventing fiascos such as the one involving Johnson and Johnson hip implants.
Read more : https://www.livemint.com/companies/news/govt-makes-it-mandatory-for-all-medical-devices-to-get-cdsco-certification-155 5271040953.html

FDA's Efforts to Advance the Development of Biologics

The safety and efficacy of the biological products regulated by the FDA are inextricably linked to the quality and consistency of their manufacturing.
Read more : https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm635819.htm

Regulator directs drug manufacturers to incorporate new recorded adverse effects in leaflets

The Drug Controller General of India (DCGI) has written to all state drug regulators to direct manufacturers of certain antibiotics and anti-psychiatric drugs to include their new recorded adverse effects in the leaflets inside the package to promote patients' safety.
Read more : https://health.economictimes.indiatimes.com/news/pharma/regulator-directs-drug-manufacturers-to-incorporate-new-recorded-adverse-effects-in-leaflets/68945880

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FINANCIALS

Biosimilars Market Size to Reach $26.7 Billion by 2024: P&S Intelligence

According to the market research report published by P&S Intelligence, biosimilars market is expected to generate $26.7 billion revenue by 2024, advancing at a CAGR of 29.6% during the forecast period.
Read more : https://www.globenewswire.com/news-release/2019/04/15/1803693/0/en/Biosimilars-Market-Size-to-Reach-26-7-Billion-by-2024-P-S-Intelligence.html

UIC Receives $65M to Commercialize New Drugs

The University of Illinois at Chicago and Deerfield Management, a health care investment management firm, are launching a new company to accelerate the commercialization of therapeutics developed at UIC.
Read more : https://news.wttw.com/2019/04/23/uic-receives-65m-commercialize-new-drugs

Riding on biosimilar sales, Biocon Q4 profit up 64% at Rs 214 crore

Buoyed by strong performance in the biologics business, Biocon's net profit rose 64 percent year-on-year to Rs 214 crore for the fourth quarter ended March 31, 2019.
Read more : https://www.moneycontrol.com/news/business/earnings/riding-on-biosimilar-sales-biocon-q4-profit-up-64-at-rs-214-crore-3891581.html

Samsung Bioepis' biosimilar sales in EU topped $170 million in Q1

According to the first three-month earnings report of Biogen, Samsung Bioepis' marketing partner in EU, the sales of three biosimilar products – Benepali, Flixabi, and Imraldi -- totaled $174.4 million in the first quarter of 2019, up 12 percent from the previous quarter.
Read more : http://www.koreabiomed.com/news/articleView.html?idxno=5623

Biocon sees strong growth for generics biz in US in FY20, expects rise in R&D spends

Biocon's Pegfilgrastim is doing very well in the US market because they have garnered about 18 percent market share in Fulphila, said Kiran Mazumdar Shaw, chairman and managing director. In emerging markets, other biosimilars did well like Trastuzumab and insulin, she added
Read more : https://www.cnbctv18.com/healthcare/biocon-sees-strong-growth-for-generics-biz-in-us-expects-rise-in-rd-spends-3093871.htm

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CLINICAL RESEARCH

Community oncology to play vital role in future clinical trials

Misinformation about clinical trials in the oncology community setting continues to hamper patient accrual, according to a presentation at Community Oncology Alliance Annual Conference.
Read more : : https://www.healio.com/hematology-oncology/practice-management/news/online/%7B667c16de-8e62-4518-a916-0913df290434%7D/community-oncology-to-play-vital-role-in-future-clinical-trials

Scientists Develop 'Exciting' New Road Map for Cancer Cell Weakness to One Day Replace Chemo

In a study that was published in Nature this week, the team used CRISPR technology to disrupt every gene in over 300 cancer models from 30 cancer types and discover thousands of key genes essential for cancer's survival.
Read more : https://www.goodnewsnetwork.org/scientists-develop-exciting-new-road-map-for-cancer-cell-weakness-to-replace-chemo/

A Patient-Centric Approach to Increase Recruitment and Retention In Clinical Trials

Good recruitment and retention is critical to the success of clinical trials. Get it right, and a trial will likely achieve its primary objective; get it wrong, and the time, effort, expense, and any patient participation is likely wasted.
Read more : https://www.clinicalleader.com/doc/a-patient-centric-approach-to-increase-recruitment-and-retention-in-clinical-trials-0001

Addressing the diversity challenge in clinical trials

Studies have shown that certain populations can respond to the same medical therapy very differently. Multiple studies in various therapeutic areas provide compelling evidence that disparities exist resulting in worse outcomes for minority patients.
Read more : http://www.pharmatimes.com/web_exclusives/addressing_the_diversity_challenge_in_clinical_trials_1285691

All-digital clinical trial demonstrates the feasibility of siteless studies

Virtual trials are poised to scale, says the CEO of Transparency Life Sciences, which recently conducted a siteless study to assess the feasibility and ease of collecting research-grade clinical data from subjects remotely.
Read more : HTTPS://WWW.OUTSOURCING-PHARMA.COM/ARTICLE/2019/04/17/ALL-DIGITAL-CLINICAL-TRIAL-DEMONSTRATES-THE-FEASIBILITY-OF-SITELESS-STUDIES

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MERGER AND AQUISITION

Vayam Research Solutions Ltd signs CRO service agreement with Emcure Pharmaceuticals Ltd

Vanta Bioscience Limited (BSE: 540729) has announced that its step-down subsidiary 'Vayam Research Solutions Limited' has entered into a non-exclusive CRO Service Agreement with Emcure Pharmaceuticals Limited, Pune, for providing services of Bio-Analytical and Bio-Equivalence services to the Company for a period of three years from 2019 to 2022.
Read more : https://www.equitybulls.com/admin/news2006/news_det.asp?id=248486

Alnylam inks broad R&D deal with Regeneron

Alnylam Pharmaceuticals on Monday announced a major drug development collaboration with Regeneron, taking its expertise in RNA interference to a new partner as it winds down research under an existing alliance with Sanofi.
Read more : https://www.biopharmadive.com/news/alnylam-inks-broad-rd-deal-with-regeneron/552243/

Clinerion's network expands into India with AlphaMD partnership

Clinerion expands into India's hospital ecosystem to accelerate trial recruitment and site selection as it partners Alpha MD.
Read more : HTTPS://WWW.OUTSOURCING-PHARMA.COM/ARTICLE/2019/04/09/CLINERION-S-NETWORK-EXPANDS-INTO-INDIA-WITH-ALPHAMD-PARTNERSHIP

Dr. Reddy's (RDY) Inks Deal to Acquire Portfolio of 42 ANDAs

Dr. Reddy's Laboratories Ltd. RDY entered a definitive agreement to acquire the yet-to-be-marketed portfolio of 42 non-marketed Abbreviated New Drug Applications (ANDAs) in the United States. The portfolio includes more than 30 generic injectable products.
Read more : https://www.nasdaq.com/article/dr-reddys-rdy-inks-deal-to-acquire-portfolio-of-42-andas-cm1129457

LabCorp to buy Envigo's non-clinical research services in $485M deal

LabCorp (NYSE:LH) says its Covance Drug Development segment agrees to buy Envigo's non-clinical research services business, while Envigo's Research Models Services business will acquire the Covance Research Products business.
Read more : https://seekingalpha.com/news/3451725-labcorp-buy-envigo-s-non-clinical-research-services-485m-deal

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INDIAN PHARMA

Rs 8,700 cr dermatology market is the new king in the pharma sector

Chronic therapies to treat blood sugar levels and heart conditions have dominated the growth charts in the Rs 1.3-trillion Indian pharma market for a long time.
Read more at: https://www.business-standard.com/article/companies/dermatology-is-the-new-growth-king-in-the-pharma-sector-119040800531_1.html

Indian Pharma sector growth to moderate at 8-10% CAGR over FY'2018-21: ICRA

The growth trajectory for the Indian pharmaceutical industry is likely to be moderate at eight-10 per cent over FY2018 to FY2021, on the back of healthy demand from the domestic market given increasing spend on healthcare along with improving access.
Read more : : http://www.expressbpd.com/pharma/latest-updates/indian-pharma-sector-growth-to-moderate-at-8-10-cagr-over-fy2018-21-icra/409078/

India to be one of the world's 'fastest growing bio' hubs in 2019: CPhI

India's biologics market is set for robust growth in 2019 driven by biosimilars production despite ongoing reputational challenges, shows new data from CPhI.
Read more : http://www.expressbpd.com/pharma/latest-updates/india-to-be-one-of-the-worlds-fastest-growing-bio-hubs-in-2019-cphi/409213/

Pharmaceutical exports rise 11% to $19.2 bn in 2018-19

The country's pharmaceutical exports rose by 11 per cent to USD 19.2 billion in 2018-19, mainly driven by higher demand in regions such as North America and Europe, as per a commerce ministry data. The pharma exports in 2017-18 stood at USD 17.3 billion and USD 16.7 billion in the previous fiscal.
Read more : https://www.moneycontrol.com/news/business/economy/pharmaceutical-exports-rise-11-to-19-2-bn-in-2018-19-3875211.html

Veeda Clinical Research Achieves ISO 27001:2013 Certification Validating the Quality of its Information Security Management System

Veeda Clinical Research Pvt. Ltd., India's leading independent CRO, is pleased to announce that Bureau Veritas has awarded the ISO 27001:2013 Certification to Veeda Clinical Research thereby certifying the compliance of the company's Information Security Management System (ISMS) with the required international standards.
Read more : https://www.prnewswire.com/in/news-releases/veeda-clinical-research-achieves-iso-27001-2013-certification-validating-the-quality-of-its-information-security-management-system-823584498.html

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