The Veeda Newsletter

ISSUE 3 : MARCH 2019

V-KONNECT

Mr. Jayanta Mandal

Managing Director & CEO

The Founder of FTF Pharma Pvt Ltd.

VEEDA NEWS

Veeda Clinical Research Reaffirms Quality Credentials with Third Successful NPRA (Malaysian Regulatory Agency) Inspection Specific Guidance's

INDIAN PHARMA

New rules sweeten the deal for clinical trials by Indian pharma cos

REGULATORY

FDA Policies Support Shift to Decentralized Clinical Trials

CLINICAL RESEARCH

The Rise of Orphan Drugs: A New Paradigm for the Future

FINANCIALS

Bharat Biotech eyes largest rabies vaccine maker tag after GSK deal

ARTICLE

Challenges in Biosimilar Development

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REGULATORY

‘Regulatory compliance improving in Indian pharma’

Indian pharma industry has seen improved approvals and regulatory compliance over the years. The industry has understood the regulatory expectations and has invested significantly in strengthening its infrastructure to match the regulatory needs, noted Indian pharma industry leaders at the CEO Conclave held at the second day of BioAsia here.
Read more: https://telanganatoday.com/regulatory-compliance-improving-in-indian-pharma

FDA will tighten drug safety rules

The Food and Drug Administration is planning to impose tougher safety requirements on the ingredients in prescription drugs, following an investigation by Bloomberg's Anna Edney into safety and quality issues at overseas facilities.
Read more : https://www.axios.com/fda-drug-safety-ingredient-rules-bloomberg-investigation-70c88f2e-4f13-4943-8fb9-8d1a4fe29902.html

FDA Expands Patient Inclusion Criteria for Cancer Clinical Trials

The FDA this week published 4 draft guidance and 1 final guidance in an effort to broaden patient participation in cancer clinical trials and to promote the inclusion of pediatric patients and patients with comorbidities that can occur alongside cancer, in an effort to increase patient accrual, broaden patients’ access to clinical trials, and lead to trial results that better represent treatment effects in the real world.
Read more : https://www.ajmc.com/focus-of-the-week/fda-expands-patient-inclusion-criteria-for-cancer-clinical-trials-

FDA Finalizes Guidance on Nonclinical Drug Development for Serious Hematologic Disorders

The US Food and Drug Administration (FDA) on Thursday finalized guidance on the nonclinical studies drug makers should conduct when developing products to treat severely debilitating or life-threatening hematologic disorders (SDLTHDs).
Read more : https://www.raps.org/news-and-articles/news-articles/2019/3/fda-finalizes-guidance-on-nonclinical-drug-develop

FDA Finalizes Two Guidance’s on HIV Drug Development

The US Food and Drug Administration (FDA) on Tuesday finalized two guidance documents to support the development of antiretroviral drug products for the treatment of human immunodeficiency virus (HIV) infection in pediatric patients and to aid the development of systemic drugs for the prevention of HIV-1 infection.
Read more : https://www.raps.org/news-and-articles/news-articles/2019/3/fda-finalizes-two-guidances-on-hiv-drug-developmen

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FINANCIALS

Endo terminates $190M deal for sterile injectable player

The Dublin-based Endo and its Par sterile injectables subsidiaries Wednesday said a $190 million agreement to buy sterile injectables company Somerset Therapeutics had been terminated without penalties because it was taking too long to complete.
Read more : https://www.fiercepharma.com/manufacturing/endo-terminates-190m-deal-for-sterile-injectable-player

Biogen to Buy Gene Therapy Developer Nightstar for $800M

The $877 million deal is in-line with management's promise to diversify its drug portfolio with later-stage assets and take some of the risk off next year's closely watched catalyst -- late-stage data for the Alzheimer's treatment aducanumab. Analysts including Jefferies's Michael Yee said Biogen still needs to do more to move the needle.
Read more : https://www.bloomberg.com/news/articles/2019-03-04/biogen-makes-gene-therapy-splash-as-street-wonders-what-s-next?srnd=technology-vp

Branded Generics Market to Garner US$ 410 Bn by 2026

These strategies include establishing sustained local capabilities with the strong local talents, engaging in portfolio marketing, recalibrating regulatory affairs, bolstering sales force with the multi-channel engagement and enhancing contracting capabilities.
Read more : http://www.dailychronicle24.com/2019/03/05/branded-generics-market-to-garner-us-410-bn-by-2026/

C4 poaches new CMO after signing $900M clinical development deal with Roche

C4 Therapeutics has hired Adam Crystal, M.D., Ph.D., a senior director at the Novartis Institutes for BioMedical Research, to be its new chief medical officer and help carry its targeted protein degraders closer to the clinic.
Read more : https://www.fiercebiotech.com/biotech/c4-poaches-new-cmo-after-signing-900m-clinical-development-deal-roche

Generics manufacturers have spent €700m on FMD implementation, says BGMA

In a statement to The Pharmaceutical Journal, the BGMA said it made the calculation based on an estimate from the the generics representitive body Medicines for Europe, which suggests all manufacturers across the EU have spent €1bn on implementing the FMD, including buying the necessary IT systems and serializing packs.
Read more : https://www.pharmaceutical-journal.com/news-and-analysis/news/generics-manufacturers-have-spent-700m-on-fmd-implementation-says-bgma/20206320.article?firstPass=false

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CLINICAL RESEARCH

2018: A year of Advancing Generic Products and Policies, Laying the Foundation for 2019

"First generics," which are approvals for generic equivalents of branded drugs that previously had no FDA-approved generic, made up nearly 10 percent of 2018 approvals and about 14 percent were for "complex generic drugs," or drugs that are particularly difficult to "genericize."
Read more : : https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm632128.htm

Designing a Clinical Trial to Evaluate Multistage Treatment Approaches in CLL

An article published in Annals of Oncology described the design of a phase 3 sequential multiple assignment randomized trial (SMART) for the evaluation of multistage ibrutinib-based treatment approaches for previously untreated older patients with chronic lymphocytic leukemia (CLL).
Read more : https://www.cancertherapyadvisor.com/home/cancer-topics/chronic-lymphocytic-leukemia/designing-a-clinical-trial-to-evaluate-multistage-treatment-approaches-in-cll/

Strategies developed to include more racial and ethnic minorities in clinical trials

Not one size fits all, and nowhere does that show up more than in the recruitment of racial and ethnic minorities into clinical trials, says Hollings Cancer Center researcher Marvella Ford, Ph.D. This is critically important since this population has a high prevalence of certain cancers.
Read more : https://www.eurekalert.org/pub_releases/2019-03/muos-sdt030619.php

Using wearable devices in clinical trials

Globally, more than 325 million people own wearable, connected devices, and more than 2.5 billion own smartphones. Using wearable devices in clinical trials can bring huge benefits, however, there are also concerns
Read more : https://www.massdevice.com/using-wearable-devices-in-clinical-trials/

FDA Works to Improve Clinical Trials Collaboration, Data Sharing

The FDA is working with stakeholders to encourage the use of new technologies, infrastructure, and processes to improve clinical trial collaboration and data sharing, explained FDA Commissioner Scott Gottlieb in a March 14 statement.
Read more : https://hitinfrastructure.com/news/fda-works-to-improve-clinical-trials-collaboration-data-sharing

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INDIAN PHARMA

Government plans to colour code generic drugs

In a move to promote low-cost generic medicines, the government plans to colour code such drugs to enable consumers to differentiate between generic medicines and other drugs and take an informed decision while purchasing them from chemists.
Read more at: http://timesofindia.indiatimes.com/articleshow/68248027.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Indian pharmaceutical Market was valued at USD 19.8B in 2010 and increased to USD 27.6B in 2016 at a CAGR of 5.6%

A new research document is added in HTF MI database of 140 pages, titled as 'Country Focus: Healthcare, Regulatory and Reimbursement Landscape - India' with detailed analysis, Competitive landscape, forecast and strategies. The report will help you gain market insights, future trends and growth prospects for forecast period of 2019 – 2025.
Read more : : https://www.openpr.com/news/1643639/Indian-pharmaceutical-Market-was-valued-at-USD-19-8B-in-2010-and-increased-to-USD-27-6B-in-2016-at-a-CAGR-of-5-6.html

With 2000+ Patent Applications, India has Highest Growth in Innovation Globally

India filed 2,013 international patent applications in 2018 with the World Intellectual Property Organization (WIPO), registering the highest growth of 27% among countries but falling way below China and the US in volume of patent filings.
Read more : https://www.indianweb2.com/2019/03/29/with-2000-patent-applications-india-has-highest-growth-in-innovation-globally

ISCR: New rules for drugs, clinical trials to protect rights, safety of patients

The new Clinical Trial Rules, the ISCR said, has reduced the time for approving applications to 30 days for drugs discovered in India or whose research and development has been done in India and are proposed to be manufactured and marketed in India. For drugs developed outside the country, the approval time has been fixed to 90 days.
Read more : https://indianexpress.com/article/cities/pune/iscr-new-rules-for-drugs-clinical-trials-to-protect-rights-safety-of-patients-5644439/

No clinical trials in India for new drugs approved in select developed markets

The new Drugs and Clinical Trials Rules, 2019, has done away with the formality of conducting local trials so that the drugs can be introduced in Indian markets sooner.
Read more : https://www.livemint.com/industry/manufacturing/no-clinical-trials-in-india-for-new-drugs-approved-in-select-developed-markets-1553553711444.html

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