The Veeda Newsletter

ISSUE 12: DEC 2019

May this year bring
new happiness and achievements

HAPPY NEW YEAR

Regulatory

New FDA Policy May Speed Biosimilar Insulins to US Market

Financial

Charles River to Acquire HemaCare Corp. for $380M

Clinical Research

How to find molecular glues to effectively target diseases

Merger and Acquisition

Johnson & Johnson acquires TARIS Biomedical

Indian Pharma

Philippines tax reforms will open new opportunities for Indian pharma, say analysts

The Year Gone By

Year in Review: 10 Important Clinical Research Discoveries in 2019

veeda clinical research®

The Veeda Newsletter

ISSUE 12: DEC 2019

FDA Launches New App to Assist Clinical Community

Through an internet-based platform, the clinical community can add to a repository via website, smartphone, or other mobile devices. The platform also allows for “crowdsourcing of medical information from health care providers to guide potentially life-saving interventions and facilitate the development of new treatments for neglected diseases,” the agency said.

Read More

Drug Development Tools: FDA Drafts Guidance on Qualification Process

The 20-page draft guidance comes just ahead of the deadline set in the Cures Act and fulfills some of FDA’s Prescription Drug User Fee Act (PDUFA VI) commitments to enhance its DDT qualification pathway for biomarkers.

Read More

USFDA's new draft guidelines on insulin products to help biosimilar makers like Biocon

The new draft guidelines issued by the USFDA to help facilitate the development of insulin products is expected to give a boost to companies like Biocon who are trying to crack the lucrative US insulin market.

Read More

FDA Drafts Recommendations for IC/BSP Drug Development

The US Food and Drug Administration (FDA) on Wednesday issued draft guidance providing recommendations for the clinical development of new drugs to treat patients with interstitial cystitis/bladder pain syndrome (IC/BPS).

Read More

New FDA Policy May Speed Biosimilar Insulins to US Market

A new US Food and Drug Administration (FDA) policy may help get novel biosimilar insulins to market more quickly, but it will be no guarantee that the products will be significantly less expensive than branded insulins, say analysts.

Read More

veeda clinical research®

The Veeda Newsletter

ISSUE 12: DEC 2019

Astellas Pharma buys Xyphos Biosciences, deal worth up to $665 mln

Stellas Pharma Inc 4503.T has bought U.S.-based Xyphos Biosciences Inc to expand its immuno-oncology business, a deal worth up to $665 million including potential development milestones and its second acquisition in as many months. Japan's second biggest drugmaker by sales paid $120 million upfront for Xyphos, with the rest milestone payments, the companies said in a statement.

Read More

Zydus Cadila in talks to sell two units for Rs 1,200 crore

Zydus Cadila, a group company of listed drug-maker Cadila HealthcareNSE -0.52 %, is in preliminary talks with several strategic and private equity investors to sell two of its divisions — anti-infectives and gynaecology for about Rs 1,000-1,200 crore, seeking to lower debt and strengthen its balance sheet.

Read More

Drug mergers now to think small

Big U.S. drugmakers made some splashy deals over the past year, with Bristol-Myers Squibb Co. snapping up Celgene for more than $70 billion and AbbVie Inc. agreeing to take over Allergan Plc for more than $60 billion. But analysts from JPMorgan Chase & Co. expect that in 2020, the industry's biggest players could take things down a notch.

Read More

Charles River to Acquire HemaCare Corp. for $380M

Charles River Laboratories International, Inc. has entered a definitive agreement to acquire HemaCare Corp. for approximately $380 million in cash.

Read More

India Bio-Pharmaceuticals Industry Expected to Generate a Value of INR 2891.70 Billion Between 2018-2023 - ResearchAndMarkets.com

India caters to nearly 50% of the global demand for pharmaceutical products, most of which are based on the usage of biotechnological applications. Currently, bio-pharmaceuticals is one of the fastest growing biotechnology segments in India. The significant bio-pharmaceutical clusters of India are located in Haridwar, Sikkim, Hyderabad, Vishakhapatnam, Chennai, Pondicherry, Mysore, Mumbai, Ahmedabad, and Delhi NCR.

Read More

The Veeda Newsletter

ISSUE 12: DEC 2019

Shared Decision Making & Its Impact On Clinical Trial Consideration

Patient participation forms the backbone of clinical research. Surveys reveal that up to 80 percent of patients say they are “somewhat or very willing” to join a clinical trial, yet enrollment levels remain low.

Read More

Designing and repurposing cell receptors

EPFL scientists have developed a computational method modeling and designing protein allostery that allows the accurate and rational engineering and even repurposing of cell receptors. The method can be a significant tool for drug development.

Read More

How to find molecular glues to effectively target diseases

Many of the currently available drugs are not specific enough to effectively cure complex diseases such as cancer, neurodegenerative diseases and diabetes. In addition, drug resistance reduces the effectiveness of existing therapies. To address these problems, biomedical engineer Eline Sijbesma designed small molecules that disarm specific disease proteins by gluing them to other proteins.

Read More

Drug Development Process and Growth for Opthea

The process of drug development is launching a new pharmaceutical compound to the market after the lead compound identification through drug discovery. The drug development process includes drug discovery and development, preclinical & clinical research, FDA review and post-marketing safety monitoring. The discovery and development of drug consists of designing a product for reversing or stop the effects of the disease.

Read More

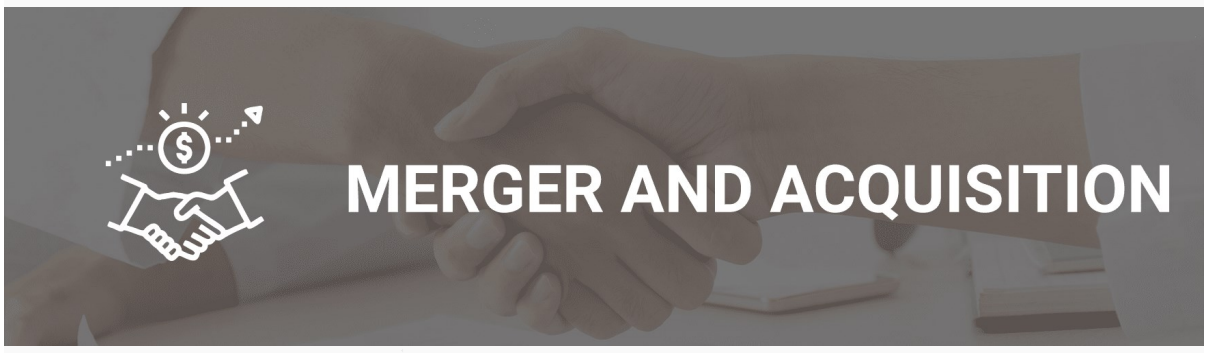
How to implement risk-based quality management into your clinical trial

As clinical trials become more complex and more global, the amount of data they produce has grown exponentially. With that, the challenge becomes not only how to manage volumes of data from multiple sources, but also how to use it more effectively to identify, monitor and mitigate risk.

Read More

The Veeda Newsletter

ISSUE 12: DEC 2019



BASi closes acquisition of Pre-Clinical Research Services

WEST LAFAYETTE, Ind. (Inside INdiana Business) -Inotiv, the newly-rebranded contract research services business of Bioanalytical Systems, Inc. (Nasdaq: BASI) has officially closed on the previously-announced deal to purchase Pre-Clinical Research Services Inc. As part of the transaction, the company also purchased the main facility and a parcel of surrounding property for $2,500,000.

Read More

CenExel Clinical Research Acquires Research Centers of America

CenExel Clinical Research, Inc., ("CenExel") announces the acquisition of Research Centers of America ("RCA") in Hollywood, FL, expanding their Centers of Excellence network to five of the most experienced clinical research sites in the country. Each of the CenExel research units have distinguished records of both assisting with protocol development and conducting Phase I-IV trials to help pharmaceutical sponsors develop new therapeutics to improve patient care.

Read More

PPD acquires unit, expands neurology capabilities for elderly patients

PPD adds clinical research unit with ‘strong’ recruiting track record to its portfolio, enabling studies on patient populations ‘more reflective’ of the products’ end-users.

Read More

Roche Completes Spark Acquisition

Roche has completed its $4.3 billion acquisition of Spark Therapeutics, Inc. following the receipt of regulatory approval from all government authorities required by the merger agreement.

Read More

Johnson & Johnson acquires TARIS Biomedical

US healthcare giant Johnson & Johnson yesterday announced the acquisition of TARIS Biomedical, a privately-owned US biotechnology company specializing in the development of a novel drug delivery technology for the treatment of bladder diseases including cancer.

Read More

veeda clinical research®

The Veeda Newsletter

ISSUE 12: DEC 2019

India emerges as a hub for biotech drug research

The Indian pharmaceutical companies always had strong chemistry skills to work on small molecules to make generic drugs, but they lacked skills, people and ecosystem to work on large molecules to come up with reverse engineered versions of biotech drugs, many experts complain. However, it is beginning to change.

Read More

Philippines tax reforms will open new opportunities for Indian pharma, say analysts

The introduction of the Universal Health Care (UHC) Act coupled with business and corporate tax regulatory

Read More

ICMR developed world's first injectable male contraceptive: MOS Health informs on its features, side effects, expected launch

Read more at Medical Dialogues: ICMR developed world's first injectable male contraceptive: MOS Health informs on its features, side effects, expected launch

Read More

Indian pharma 'sunrise' segment, year 2020 prognosis positive for healthcare sector

Nourished by increasing spending, improving accessibility and growing exports, India's pharma and healthcare sector is poised for another year of robust growth even as pricing and cost headwinds could force players to pause to catch breath.

Read More

Indian Pharma Sector Expected To Grow At 10-12% During Till 2021-22, Says ICRA

Ratings agency ICRA on Wednesday said the Indian pharmaceutical industry is expected to grow around 10-12 percent till 2021-2022 while maintaining a stable outlook on the sector.

Read More

veeda clinical research®

The Veeda Newsletter

ISSUE 12: DEC 2019

Year in Review: 10 Important Clinical Research Discoveries in 2019

People with pancreatic cancer who have mutations in the cancer predisposition genes BRCA1 or BRCA2 may benefit from a type of targeted therapy called a PARP inhibitor. These drugs work by exploiting a weakness in cancer cells' ability to repair DNA damage. Medical oncologist Eileen O'Reilly was co-author of a large phase III study showing that the PARP inhibitor olaparib (Lynparza®) is effective in people with metastatic pancreatic cancer (cancer that has spread to another part of the body) who have an inherited BRCA mutation.

Read More

2019: the year of the pharma mega-merger

2019 will be remembered as the year of the pharma mega-merger. Richard Staines looks back at a year that changed the landscape of big pharma

Read More

Medicinal Chemistry Books, 2019

For histories and broad overviews of the field, there have not been any recent additions. Earlier ones include 2011's The Evolution of Drug Discovery , which still seems to be the biggest history of the field (its author, Jack Li also has a 2014 history of the industry, Blockbuster Drugs, looking at how things have been for previous last twenty years or so).

Read More

THE DECADE IN GLOBAL HEALTH: NEW DRUGS, FASTER TRIALS.

Millions of lives were saved in the 2010s as new ways of tackling global health problems made their debut. But there is a problem with the decade's greatest medical moments. Most medical advances originate in rich countries, so they are sometimes out of reach for the world's poor — even when they address health problems more common in low-income countries. Treatment for HIV, for example, became available in the U.S. in 1996 but the rollout in Africa didn't begin until 2002.

Read More

Five things to watch out for in pharma and healthcare in 2020

It has been a mixed bag for pharmaceutical and healthcare sectors in 2019. Most companies tightened costs and focused on reducing debt. There has also not been any major disruptive policy action with the exception of trade margin caps on 42 cancer medications.

Read More

veeda clinical research®

The Veeda Newsletter

ISSUE 12: DEC 2019

For any further information or Business enquiry contact us at info@veedacr.com

Registered Office

VEEDA CLINICAL RESEARCH® PVT. LTD.

Shivalik Plaza-A, Near IIM Ambawadi, Ahmedabad- 380015, Gujarat, India

CIN No. U73100GJ2004PTC044023

ADDRESS:

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

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

Radhe Palladium, Floor 1st (Shop No 9, 10 & 11), 2nd & 3rd Floor Panchot, Nr. Panchot Bypass Circle, N. H. No. 6, Mehsana, Gujarat - 384002