The Veeda Newsletter

MAY 2018
ISSUE 05

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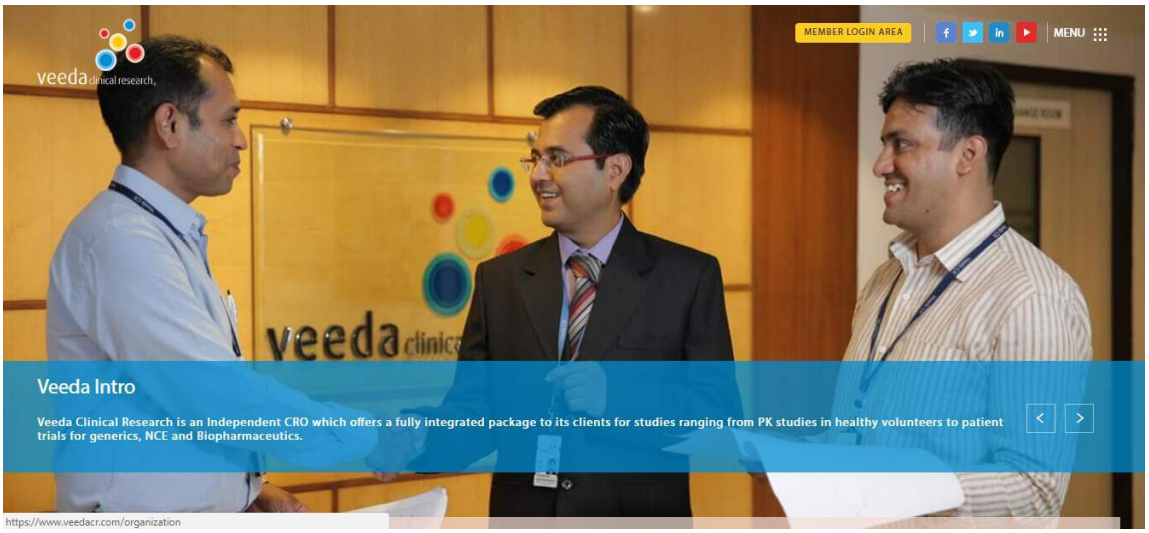
ASSOCHAM Pharma Excellence Awards 2018 privileged Veeda Clinical Research with “BEST CLINICAL RESEARCH 2018 “award.

On 9th May 2018, Veeda Clinical Research an Independent Indian CRO has been honored with BEST CLINICAL RESEARCH 2018 by the Associated Chambers of Commerce and Industry of India (ASSOCHAM) Pharma Excellence Awards held at New Delhi. **Read More:** https://www.veedacr.com/2018/Newsletter/May-2018/ASSOCHAM%20Pharma%20Excellence%20Awards%202018.html

VEEDA CLINICAL RESEARCH LAUNCHED ITS NEWLY REVAMPED WEBSITE.



We are pleased to announce the launch of our newly revamped website - www.veedacr.com that aims to create a user-friendly browsing experience for our trusted and valued customers and business partners.

In addition to aesthetically re-designing our website We have also refined the service category and menu structure keeping our clients and the employees in mind, you can see structured streamlining menus and simplifying navigation; thus building a responsive layout for all platforms and providing more resources and information on our services. We hope visitors will find it more intuitive to navigate and will enhance user experience in accessing information relating to Veeda CRO.

You will be noticing the difference in the new site in terms of quicker response, easy to go navigation and the most important - user friendly as well as mobile responsive.
We encourage everyone to visit and explore the site.And look forward to staying connected.

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INDIAN PHARMA

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Indian Pharmacopeia Commission extends implementation of IP 2018 by 3 months to July 1, 2018

The Indian Pharmacopeia Commission (IPC) has extended the implementation of IP 2018 from April 2018 to July 1, 2018. This is in response to many stakeholders who are affected due to either changes in impurity level or testing methods and certain requirement specifications.
Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=108201&sid=1

Indian pharma market records 9.5% yoy growth in March 2018

As per the AIOCD AWACS report, the Indian pharma market grew by 9.5% yoy in March 2018 vs. 7.1% yoy growth in February 2018. The total sales reported were Rs10,029cr in March 2018.
Read More: https://www.indiainfoline.com/article/news-top-story/indian-pharma-market-records-9-5-yoy-growth-in-march-2018-118041500004_1.html

NITI Aayog backs cap on pharma trade margins

Trade margins charged by drug stockists and chemists must be capped, government think tank NITI Aayog recommended, a move that promises to bring down drug prices while trimming industry profits.
Read More: https://www.livemint.com/Industry/1wpipcSFnhzNDhf03XNVUP/NITI-Aayog-backs-cap-on-pharma-trade-margins.html

India's import of China-made medicines has increased 50 per cent in 4 years

It is likely that the pill you popped last night was made in China. It is not only Chinese electronics and engineering goods that have swamped India, but also medicines made in China.
Read More: https://theprint.in/economy/indias-import-of-china-made-medicines-has-increased-50-per-cent-in-4-years/50109/

Indian Pharma Inc shifts to high gear in filing patents

Indian pharma is thinking beyond generics and is investing considerably in developing new drugs and filing patents. This change is attributed to the post 2014 drug patent guidelines and facilitation by the Indian government for promotion of innovation, manufacturing and developing India as drug hub, according to Ruhan Rajput, Director, Einfolge.
Read More: http://www.pharmabiz.com/ArticleDetails.aspx?aid=108456&sid=11

Indian Pharma's Big Leap

Nagpur-based Zim Laboratories is a non-descript drug company with turnover in excess of Rs 250 crore. In the past two decades, Zim has been silently working on developing innovative and differentiated pharmaceutical products or specialty generic complex drugs.
Read more: https://www.businesstoday.in/magazine/the-hub/indian-pharmas-big-leap/story/275898.html

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REGULATORY NEWS

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FDA Issues Draft Guidance on Pregnant Women in Clinical Trials

The US Food and Drug Administration (FDA) has issued draft guidance for industry outlining the scientific and ethical issues that should be addressed when considering the inclusion of pregnant women in clinical trials of drugs and biological products.
Read More: https://www.medscape.com/viewarticle/895203

US FDA finalizes guidance to accelerate development of reliable, beneficial next generation sequencing-based tests

The US Food and Drug Administration finalized two guidance to drive the efficient development of a novel technology that scans a person's DNA to diagnose genetic diseases, which are usually hereditary, and guide medical treatments. **Read More:** http://www.pharmabiz.com/NewsDetails.aspx?aid=108366&sid=2

U.S. FDA Releases Draft Guidance on Demonstrating Substantial Equivalence

Published in April, the draft guidance "Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria" describes an optional pathway for the recognition of certain types of medical devices under its Abbreviated 510(k) Program. **Read More:** https://incompliancemag.com/u-s-fda-releases-draft-guidance-on-demonstrating-substantial-equivalence/

CDSCO extends WHO's GMP certificate

In a move to improve ease of doing business, India is increasing the validity of the World Health Organization's (WHO) Good Manufacturing Practices (GMP) certificate to three years.
Read More: https://www.biospectrumindia.com/news/22/10899/cdsco-extends-whos-gmp-certificate.html

Govt tweaks certification norms to aid pharma trade

The government has decided to increase the validity of the World Health Organization's (WHO) good manufacturing practices (GMP) certification to three years from the existing two years for companies exporting pharma products to other countries.**Read More:** https://www.livemint.com/Industry/XDwXr8pqrWk78tPdTlO8yJ/Govt-tweaks-certification-norms-to-aid-pharma-trade.html

CDSCO launches exclusive innovator promotion cell to help researchers commercialize scientific breakthroughs faster

Scientists and researchers who are keen on commercializing their breakthrough ideas and technologies in the pharmaceutical and medical devices sector would find the task a lot easier to accomplish as an exclusive cell to expedite the regulatory process has become operational at the (CDSCO). **Read More:** http://www.pharmabiz.com/NewsDetails.aspx?aid=108626&sid=1

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CLINICAL RESEARCH

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Debunking the myths about eCOA in clinical trials

The benefits of electronic Clinical Outcome Assessment (eCOA) have been widely published for decades. Yet, nearly half of all studies that collect patient outcome data do so using primarily paper solutions. **Read More:** https://www.biopharmadive.com/news/debunking-the-myths-about-ecoa-in-clinical-trials/520071/

Early phase clinical trial shows promise for advanced head and neck cancer

For many survivors of head and neck cancer, the disease — and its treatment — leave a lifelong, unmistakable mark. Surgeries to remove tumors in the mouth, neck or throat often leave patients with disfiguring scars and difficulty speaking or swallowing. Some may not even be able to perform these tasks at all.

Read More: https://www.fredhutch.org/en/news/center-news/2018/04/experimental-therapy-promise-head-neck-cancer.html

UMN initiative seeks to increase clinical trial access for rural cancer patients

The Masonic Cancer Center at the University of Minnesota and a network of 18 rural hospitals aims to offer clinical trials to patients outside the Twin Cities and Rochester, where most trials are conducted. Rural hospitals often don't have the money to fund research. This project can give hope to cancer patients who have exhausted other options.

Read More: http://www.mndaily.com/article/2018/04/n-umn-initiative-seeks-to-increase-clinical-trial-access-for-rural-cancer-patients

Novartis app could revolutionise ophthalmic clinical trials

The FocalView app, which will enable patients with mobility issues to take part in clinical trials, means researchers can study and collect data about eye diseases regardless of a person's location.

Read More: https://pharmaphorum.com/news/novartis-app-could-revolutionise-ophthalmic-clinical-trials/

This 'genetic switch' could help to fight cancer

The technique was developed at the Georgia Institute of Technology (Georgia Tech) in Atlanta and uses engineered genes, laser technology, and gold nanoparticles to get T cells inserted into tumors to vastly increase production of specific proteins.

Read More: https://www.medicalnewstoday.com/articles/321646.php

New clinical trial shows safety and efficacy of second generation drug-eluting stents

Results of the PERSPECTIVE trial were presented today as late-breaking clinical science at the Society for Cardiovascular Angiography and Interventions (SCAI) 2018 Scientific Sessions. **Read More:** https://www.news-medical.net/news/20180426/New-clinical-trial-shows-safety-and-efficacy-of-second-generation-drug-eluting-stents.aspx

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FINANCIAL NEWS

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Profit From Record Q1 M&A With These ETFs

Per the preliminary Thomson Reuters data, global mergers and acquisitions had their strongest start ever totaling $1.2 trillion in the first quarter of 2018.

Read More: https://www.zacks.com/stock/news/298633/profit-from-record-q1-mampa-with-these-etfs

Indian pharma market clocks 9.5% growth in March 2018 to Rs. 10,029 crore

The Indian Pharmaceutical Market (IPM) has clocked a growth of 9.5 per cent during March 2018 to Rs. 10,029 crore compared to 7.1 per cent in February 2018.

Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=108358&sid=1

Value of Singapore's pharma market hit $1.22b in 2017: BMI Research

This is thanks to biopharmaceutical giants that still choose the country as their manufacturing headquarters.Singapore's pharmaceutical market could be valued $1.22b, experiencing a 5.6% increase from the previous year, BMI Research revealed.

Read More: https://sbr.com.sg/healthcare/news/value-singapores-pharma-market-hit-122b-in-2017-bmi-research

MENA pharma market to top $44b by 2020

The value of the Middle East and North Africa (MENA) pharmaceutical market is expected to reach US$44 billion by 2020, according to CPhI Middle East & Africa.

Read More: http://timesofoman.com/article/132278/Business/Economy/MENA-pharma-market-to-top-44b-by-2020

Active Pharmaceutical Ingredients (API) Market to Touch US$219,601.9 by 2023, Says TMR

The TMR report has estimated that the global active pharmaceutical ingredients market will be worth US$219,601.9 by the end of 2023, mounting from its evaluated worth of US$151,591.7 as of 2017, showcasing a CAGR of 6.4% during the period of 2017 to 2023.

Read More: http://www.prnewswire.co.uk/news-releases/active-pharmaceutical-ingredients-api-market-to-touch-us2196019-by-2023-says-tmr-679990773.html

AstraZeneca's $90mn investment in tandem with its MNC peers

AstraZeneca has announced to invest $90mn (Rs585cr) in India over the next 5 years. The announcement was made following a meeting between the Indian PM and company's Executive Vice President for International Region during Mr. Modi's visit to Sweden.

Read More: https://www.indiainfoline.com/article/news-top-story/astrazeneca-s-90mn-investment-in-tandem-with-its-mnc-peers-118041800015_1.html

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MERGER & AQUISITION

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Sanofi nears €2B deal with Advent to unload European generics business: report

Other bidders may have dropped out of an auction for Sanofi's European generics unit, but that doesn't mean it hasn't found a buyer.

Read More: https://www.fiercepharma.com/m-a/sanofi-advent-international-nearing-eu2b-deal-for-european-generics-business-report

Novaseek Research and CoxHealth Launch Partnership to Advance Biomedical and Clinical Research

Novaseek Research, Inc., a health IT for life sciences company, today launched its partnership with CoxHealth, a health system nationally accredited by DNV GL-Healthcare. **Read More:** https://globenewswire.com/news-release/2018/04/17/1480087/0/en/Novaseek-Research-and-CoxHealth-Launch-Partnership-to-Advance-Biomedical-and-Clinical-Research.html

SeQuent Scientific announces acquisition of Bremer Pharma in Germany

Sequent Scientific announced that its wholly owned subsidiary Alivira Animal Health through Alivira Ireland, has on 17 April 2018 signed an agreement with simultaneous closing to acquire 100% of Bremer Pharma, Zydus Cadila's Animal Health Business in Germany.

Read more at http://www.uniindia.com/sequent-scientific-announces-acquisition-of-bremer-pharma-in-germany/business-economy/news/1203431.html#rT0EEtYtuUIejdYz.99

Fresenius dumps $4.3B Akorn merger

German drugmaker Fresenius Kabi AG announced Monday it will terminate its $4.3 billion merger agreement with Akorn Inc., citing an internal investigation into practices at the generics maker, including what it contends were "material breaches of Food and Drug Administration data integrity requirements."

Read More: https://www.biopharmadive.com/news/fresenius-dumps-43b-akorn-merger/521932/

Takeda chases global status with $64bn shortcut

Takeda Pharmaceutical appears intent on pushing through a record $64 billion buyout of Irish drugmaker Shire, even if it means defying intense market pressure, because it sees overseas markets as crucial to its survival as government controls on drug prices in Japan limit its top line.

Read More: https://asia.nikkei.com/Business/Business-Deals/Takeda-chases-global-status-with-64bn-shortcut

Novartis AG's $8.7 Billion Acquisition of AveXis, Inc.

AveXis' financial advisors are Goldman Sachs & Co. LLC and Centerview Partners LLC, and Cravath, Swaine and Moore LLP and Cooley LLP are acting as legal counsel for AveXis.

Read More: http://www.globallegalchronicle.com/novartis-ags-8-7-billion-acquisition-of-avexis-inc/

Development of a framework to improve the process of recruitment to randomised controlled trials (RCTs): the SEAR (Screened, Eligible, Approached, Randomised) framework.

Randomised controlled trials (RCTs) are regarded as the most reliable and effective method to evaluate healthcare interventions. However, many RCTs struggle to recruit to target and to time, leading to underpowered studies, costly extensions or the early closure of studies [1, 2, 3]. Qualitative research has shown that the process of recruitment can be complex, protracted and fragile [4, 5]. The Qualitative research Integrated within Trials (QuinteT) Recruitment Intervention (QRI) uses standard and innovative qualitative research methods and simple quantification techniques to understand the recruitment process, and identify and address challenges as they emerge [6]. An integral part of the QRI involves mapping the pathway to recruitment for potential participants, to better understand barriers to recruitment across the trial and between clinical centres in multicentre trials.

Maintaining an accurate record of patients considered for RCT participation is a recommendation in Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines. Trials should present the numbers assessed for eligibility, and excluded because they did not meet the inclusion criteria, they declined to take part, or ‘other reason’. [7]. The CONSORT flowchart does not however, explicitly represent all the steps in the pathway that potential RCT participants can follow. Furthermore, reviews of published RCT results have shown that trials consistently fail to record participant flow accurately, particularly before informed consent and randomisation [3, 8].

The collection of screening data is also a consideration under Good Clinical Practice (GCP), in particular to monitor compliance with the trial protocol inclusion and exclusion criteria [9]. However, the literature on screening logs is sparse and there is little consensus about what to collect or how to collect it efficiently. As the QRI includes analysis of data collected during screening and eligibility assessment, we investigated the range of data collected in eight RCTs with the aim of developing a simple framework that could be applied to most trials, to provide basic information useful to understand recruitment challenges and improve the recruitment process.

READ MORE & SOURCE:
https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-2035-z

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UPCOMING CONFERENCE

1. 9th-Annual-Clinical-Trials-Summit-2018

24th May 2018,
Mumbai,
India.

2. CPHI CHINA

June 20-22, 2018
Shanghai,
China.

3. CPHI WORLDWIDE 2018

Oct 9-11, 2018
Madrid ,
Spain.

CPhI worldwide

For Inquiry & Meeting Appointment please mail us at info@veedacr.com

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