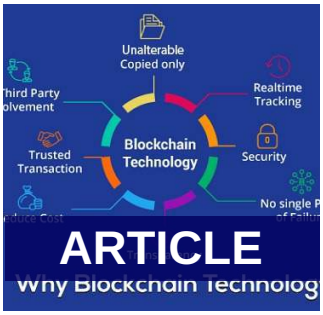
The Veeda Newsletter

APRIL 2018
ISSUE 04

Indian Pharma

NO PROPOSAL FOR NEW DRUG POLICY AT PRESENT: GOVT

CPHI NORTH AMERICA April 24-26, 2018, Philadelphia, PA, USA.



Blockchain technology for improving clinical research quality

Pharmaceutical can exports pharma products without obtaining NOC from regulatory authorities: CDSCO

GSK Gets Full Control of Sensodyne Maker NOVARTIS for $13 Billion

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INDIAN PHARMA

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NO PROPOSAL FOR NEW DRUG POLICY AT PRESENT: GOVT

There is no definite proposal for a new drug policy before the government at present though some stakeholders have discussed the basic contents that should go into a draft pharma policy, Parliament was informed today.
Read More: http://www.dailypioneer.com/business/no-proposal-for-new-drug--policy-at-present-govt.html

India's drug regulatory body to create new database to monitor drug manufacturers

"The Central Drugs Standard Control Organization, India's drug regulatory body, said it will create a national digital database of pharmaceutical manufacturers and their medicines to help address drug shortages and quality issues. **Read More:** https://www.fiercepharma.com/manufacturing/india-s-drug-regulatory-body-to-create-new-database-to-monitor-drug-manufacturers

Why 2018 will be a challenging year for pharmaceuticals

Post two years of significant underperformance, positioning remains light in the India Pharma sector given multiple headwinds and relatively expensive valuations vs. global peers/Nifty.
Read More: http://www.financialexpress.com/industry/why-2018-will-be-a-challenging-year-for-pharmaceuticals/1110705/

Indian pharma market growing strongly in 2018

The report from pharmaceutical market research firm AIOCD AWACS breaks down growth by therapy area, identifying 17 areas with positive growth during the month, highest amongst which was the respiratory market with growth of 21%.
Read More: https://www.thepharmaletter.com/article/indian-pharma-market-growing-strongly-in-2018

India: Health Ministry Releases Draft New Drug & Clinical Trial Rule 2018

The Ministry of Health and Family Welfare of Government of India has released draft Clinical Trial (CT) Rules 2018, which will come in force after its final publication in the Official Gazette. **Read More:** http://www.mondaq.com/india/x/682904/food+drugs+law/Health+Ministry+Releases+Draft+New+Drug+Clinical+Trial+Rule+2018

India, China agree to address trade imbalance

India and China have agreed on a roadmap for addressing the imbalance in bilateral trade, heavily tilted in the latter's favour. **Read More:** http://www.thedailystar.net/business/global-business/india-china-agree-address-trade-imbalance-1554319

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REGULATORY NEWS

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New labeling norms: Drug companies to have larger fonts for generic names

In a bid to promote low-cost generic medicines, the government has made it mandatory for pharmaceutical firms to carry the generic names of drugs on labels with font sizes two times bigger than the brand name.
Read More: https://www.moneycontrol.com/news/business/exclusive-new-labelling-norms-drug-companies-to-have-larger-fonts-for-generic-names-2532295.html

USFDA Issues Final Rule That Requires Medical Device Trials Outside US To Conform To Good Clinical Practices (GCP)

Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.**Read More:**http://www.mondaq.com/india/x/684512/Life+Sciences+Biotechnology/United+States+FDA+Issues+Final+Rule+That+Requires+Medical+Device+Trials+Outside+US+To+Conform+To+Good+Clinical+Practices+GCP

FDA Working To Withdraw Zinbryta From US Market

IBiogen and Abbvie announced a voluntary withdrawal of Zinbryta (daclizumab), a multiple sclerosis (MS) drug, from the global market, noting concern about the drug's evolving benefit/risk profile. **Read More:** https://www.pharmpro.com/news/2018/03/fda-working-withdraw-zinbryta-us-market

FDA moves to limit ingredients for bulk drug compounding

The agency issued draft guidance that officials said prioritized the use of FDA-approved drugs over more risky, custom-made medicines produced in bulk by certain compounding pharmacies for hospitals and doctors' offices. **Read More:** https://www.reuters.com/article/us-usa-fda-pharmaceuticals/fda-moves-to-limit-ingredients-for-bulk-drug-compounding-idUSKBN1GZ2TE

Drug regulator plans national digital database of pharma manufacturers

India's drug regulatory body is creating a national digital database of pharmaceutical manufacturers and their medicines so regulators can be more effective when acting on problems like drug shortages and quality issues, people aware of the development told ET.
ReadMore:https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/drug-regulator-plans-national-digital-database-of-pharma-manufacturers/articleshow/63574136.cms

Pharmaceutical can exports pharma products without obtaining NOC from regulatory authorities: CDSCO

India's drug regulatory body is creating a national digital database of pharmaceutical manufacturers and their medicines so regulators can be more effective when acting on problems like drug shortages and quality issues, people aware of the development told ET.
ReadMore:https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/drug-regulator-plans-national-digital-database-of-pharma-manufacturers/articleshow/63574136.cms

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CLINICAL RESEARCH

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CTRI's new norm of 'registration of clinical trials only prospectively' comes into effect

The Clinical Trials Registry of India (CTRI)'s new rule of registration of clinical trials only prospectively has come into effect from April 1, 2018.

Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=108104&sid=1

Experts hail positive trend of approval of 99 global clinical trials in 2017 in India compared to 38 in 2016

With the Central Drugs Standard Control Organization (CDSCO)'s draft Clinical Trials Rules, 2018 under review, clinical trial experts have hailed the positive trend of approval of 99 global clinical trials (GCTs) conducted in India in India in 2017 as compared to 38 in 2016. **Read more:** http://www.pharmabiz.com/NewsDetails.aspx?aid=107851&sid=1

Leveraging Technology to Bridge Clinical Trial Processes and Real-World Health Care

Technology adoption in health care delivery has already surpassed anything we've done in the drug development industry.

Read More: http://www.appliedclinicaltrialsonline.com/leveraging-technology-bridge-clinical-trial-processes-and-real-world-health-care

Lung transplant drug enters clinical trial after decades of research

The drug, regadenoson, is already commonly used to image cardiac patients' hearts. But the UVA research suggests it could be put to another,

Read More: https://www.news-medical.net/news/20180326/Lung-transplant-drug-enters-clinical-trial-afterc2a0decades-of-research.aspx

World's smallest mechanical heart valve — made in Minnesota — approved by FDA

In a laboratory near Interstate 35E and Minnesota 36, Abbott Laboratories employee Teresa Tollefson peers through a microscope

Read More: https://www.twincities.com/2018/03/25/worlds-smallest-mechanical-heart-valve-made-in-minnesota-approved-by-fda/

Cancer researchers push to relax rules for clinical trials

Now, researchers are pruning the lengthy lists of eligibility criteria for trials, in the hope of nixing unnecessary rules that might be hindering research. On 16 April, representatives of the US Food and Drug Administration (FDA)

Read More: https://www.nature.com/articles/d41586-018-03355-6

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FINANCIAL NEWS

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Chrys Capital may return to Mankind with $400m deal

Indian private equity posterboy ChrysCapital along with its global sponsors have made a surprise late-stage bid to buy a stake of $350-400 million in Mankind Pharma, bankers directly aware of the matter said. **Read More:** https://timesofindia.indiatimes.com/business/india-business/chryscapital-may-return-to-mankind-with-400m-deal/articleshow/63322963.cms

Biocon - $1bn biologics sales in 2025 means Rs1 lakh crore market cap

India's largest biopharma company, Biocon expects to generate annual sales of $1bn from biologics products by 2025. The company has an interesting pipeline that has reached a critical stage and approvals are expected to come in over next 12-18 months.
Read More: https://www.indiainfoline.com/article/news-top-story/biocon-1bn-biologics-sales-in-2025-means-rs1-lakh-crore-market-cap-118032000014_1.html

Elligo Health Research Raises $16M to Improve Access to Clinical Trials

"In a short time Elligo has clearly shown that their approach improves access to clinical trials," said John Crumpler, general partner at Hatteras Venture Partners. "We believe they will build on their current successes and continue to drive positive changes in the health care industry."
Read More: https://www.businesswire.com/news/home/20180320005351/en/Elligo-Health-Research-Raises-16M-Improve-Access

GSK Gets Full Control of Sensodyne Maker NOVARTIS for $13 Billion

SThe new bosses of two of Europe's largest drugmakers are pivoting in different directions, with GlaxoSmithKline Plc doubling down on consumer health as Novartis AG narrows its focus on prescription medicines.
Read More: https://www.bloomberg.com/news/articles/2018-03-27/novartis-to-sell-stake-in-joint-venture-to-glaxo-for-13-billion

BSE Healthcare index dips by 11% in first quarter of 2018

The share price movements of pharmaceutical & healthcare companies remained under pressure on stock exchanges during the first quarter ended March 2018 on account of US FDA actions against top companies
Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=108085&sid=1

Another one's gone: Torrent drops out of Sanofi generics auction over price, report says

Sanofi is out another potential buyer for its European generics business, according to India's Business Standard, as Torrent Pharmaceuticals bowed out of an auction for a unit that could fetch €2 billion.
Read More: https://www.fiercepharma.com/m-a/torrent-drops-out-sanofi-generics-biz-auction-over-price-report

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MERGER & AQUISITION

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Centaur Pharma & Kibow Biotech announce a strategic alliance to market Renadyl in India for CKD

Centaur Pharmaceuticals and Kibow Biotech USA announced a strategic long-term alliance to market Renadyl in India.

Read more at: https://health.economictimes.indiatimes.com/news/pharma/centaur-pharma-kibow-biotech-announce-a-strategic-alliance-to-market-renadyl-in-india-for-ckd/63188807

Cipla To Sell Two Roche Biologics In India

Cipla Ltd. and Roche Pharma India have entered into an agreement under which Cipla will promote and distribute two drugs developed by Roche.

Read more at: https://www.asianscientist.com/2018/03/pharma/cipla-roche-india-biologics/

Teva Pharmaceutical Industries Ltd (TEVA) Shares Bought by Geode Capital Management LLC

Geode Capital Management LLC grew its position in Teva Pharmaceutical Industries Ltd (NYSE:TEVA) by 4.2% in the 4th quarter, according to its most recent filing with the Securities & Exchange Commission. **Read More:** https://macondaily.com/2018/03/19/teva-pharmaceutical-industries-ltd-teva-shares-bought-by-geode-capital-management-llc.html

USV forays into German market with acquisition of Juta Pharma

USV Pvt. Ltd, an Indian pharmaceutical company, headquartered in Mumbai, entered the highly competitive German drug market by acquiring Juta Pharma GmbH.

Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=108034&sid=2

Mankind to sell 10% stake to ChrysCap in Rs 2.3k-cr deal

Mankind Pharma has agreed to sell 10% stake to ChrysCapital and its global sponsors for about $350 million, or Rs 2,280 crore, in the largest private equity deal in Indian healthcare industry till date.

Read More: https://timesofindia.indiatimes.com/business/india-business/mankind-to-sell-10-stake-to-chryscap-in-rs-2-3k-cr-deal/articleshow/63572891.cms

ARTICLE OF THE MONTH

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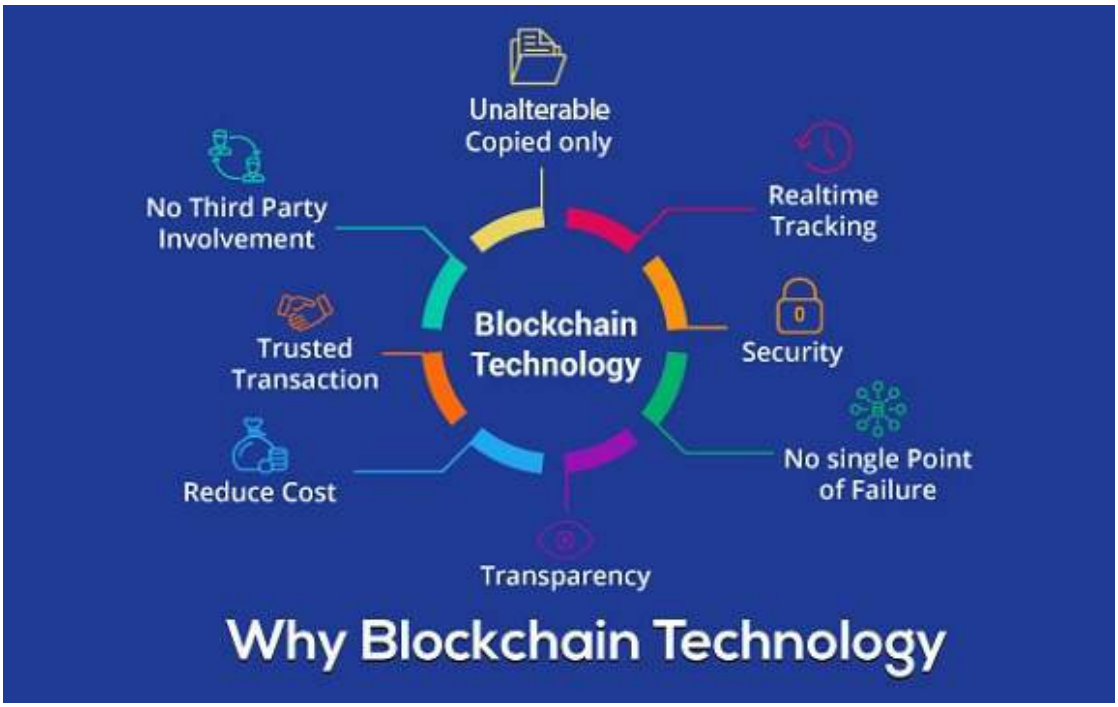
Blockchain technology for improving clinical research quality

Fixing methodology issues is one of the great challenges in contemporary biomedical research. Indeed, lack of reproducibility, related to a wide range of scientific misconduct aspects, from errors to frauds, compromises the outcomes of a clinical study and undermines research quality. Lack of reproducibility has been extensively studied, and medical scientific publications have been found on the whole to be not reproducible: they are full of “bugs”. Ioannidis et al. estimated a rate of about 80% non-reproducible studies [1, 2, 3]. This rate may be related to several types of errors, misconduct or fraud. Improving quality of research by better reproducibility and empowering both researcher communities with secure data sharing and patient communities with tools guaranteeing their privacy are desirable goals that can be achieved in part with Blockchain technology [4, 5].



Blockchain can have a global impact on clinical research because it allows for tracking, sharing and caring for data. Indeed, it involves a decentralized secure tracking system for any data interactions that could occur in the context of clinical trials, with a peer-to-peer inclusive network that enables data sharing on the research side and ensures all the needed transparency and care for privacy concerns on the patient community side.

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

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UPCOMING CONFERENCE

1. CPHI NORTH AMERICA

April 24-26, 2018,
Philadelphia, PA,
USA.

2. 9th-Annual-Clinical-Trials-Summit-2018

24th May 2018,
Mumbai,
India.

3. CPHI CHINA

June 20-22, 2018
Shanghai,
China.

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

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