The Veeda Newsletter

OCT 2018
ISSUE 10

INDIAN PHARMA

With a large pool of patients and availability of large hospitals, the India CRO Market estimated to grow 12% CAGR between 2016 and 2023.

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FDA proposes stiff fines for failing to report clinical trials

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Clinical trial cost is a fraction of the drug development bill, with an average price tag of $19m

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Global pharma firms' 2017 R&D investment in Korea up 5.9 percent: KRPIA

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The state of pharma mergers and acquisitions in 2018

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Emerging Trends in Oncology Clinical Trials

Greater Emphasis on the Data security by implementing the practices of ISO 27001

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VEEDA UPDATES

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1. IT Infrastructure and Data Security

- Greater Emphasis on the Data security by implementing the practices of ISO 27001
- We are developing Cronos an EDC platform for a paperless digital conduct of studies.

2. Different studies executed in Clinics

- Conducted 5 Inhalation studies for Beclomethasone dipropionate 40mcg
- Derma PK study: Lidocaine + Prilocaine Cream
- Biosimilars/Glucose Clamp: Insulin Glargin 100 IU/mL + human insulin 100 IU/mL
- Patch Studies: Ethinyl estradiol + Norelgestromine and Rivastigmine
- Challenging studies: Potassium Chloride ER tablets USP, 20 mEq and 10 mEq (17 days housing) with 94% compliance of volunteers completed study and Octreotide acetate injectable suspension 30 mg (sample collection up to 77 days post-dose) with 91% of compliance for ambulatory sample collection.

3. Complex assay developed in Bio analytical

Name	Complexity
Fluticasone	0.8 pg/mL sensitivity chromatography optimized to handle interference issue (RT>11 mins)
R and S praziquantal	Chiral separation of enantiomer (RT<10mins), dynamic L inearity range 2-2000 ng/mL
Formeterol	0.4 pg/mL LLOQ, RT>8 min,
Alpha-1 Acid Glycoprotein	74 K Dalton Mass, method was developed on HPLC-UV
Human Insulin	MS method in advanced development stage.

4. Regulatory Audit in the last 1 year

- 9 USFDA inspections in 2017 & 2018 for patient trails.
- Healthy subject BE studies - A data integrity inspection for bio analytical in 2017.
- Successful audit by Malaysian authority in April 2018
- ANVISA accreditation status with validity till Mar 2020.

5. Updates on Patient trials

- Completed 5 global multi-centric phase II clinical trials in Oncology, 2 phase III studies of injectable implants and 21 patient based PK trials.
- Worked with more than 130 sites and recruited 1270 patients in the different trials.
- Laid down strategies to overcome the trial challenges in PK and endpoint studies in indications like cataract, open-angle glaucoma, age-related macular degeneration.
- With database of more than 75 dermatologists and team experience in this therapeutic area, well-equipped to cater dermatology studies in indications like, atopic dermatitis, tinea pedis, acne vulgaris, psoriasis vulgaris.

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REGULATORY NEWS

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FDA launches export certification initiative to make trading easier

FDA commissioner Scott Gottlieb said: “While American food standards are among the most stringent in the world, the FDA recognises that some US trading partners seek additional assurance that imported food products are produced under applicable requirements, and may request specific language or product information on export certificates.

Read More: https://www.foodbev.com/news/fda-launches-export-certification-initiative-to-make-trading-easier/

FDA piloting innovative clinical trial designs

The design has been called the complex innovative trial design (CID) and highlights the sixth iteration of the Prescription Drug User Fee Act (PDUFA VI). This was signed into law last year as part of the FDA Reauthorisation Act.

Read More : https://www.europeanpharmaceuticalreview.com/news/78749/fda-innovative-clinical-trial/

FDA Issues 54 New and Revised Product-Specific Guidances

Among the documents are 42 new and 12 revised guidances providing specific recommendations for the studies FDA believes are necessary to demonstrate that the products are therapeutically equivalent to their reference listed drug (RLD).

Read More: https://www.raps.org/news-and-articles/news-articles/2018/9/fda-issues-54-new-and-revised-product-specific-gui

U.S. FDA Launches Pilot Program to Expedite 510(k) Applications

The FDA also says that applications prepared using the eSubmitter software under the Quik Review Program pilot will not be subject to a “Refuse to Accept” decision by the agency, and that a final decision on the application will be made within 60 days of its original submission.

Read More: https://incompliancemag.com/u-s-fda-launches-pilot-program-to-expedite-510k-applications/

FDA proposes stiff fines for failing to report clinical trials

The US Food and Drug Administration (FDA) is proposing heavy fines for pharmaceutical companies that fail to report clinical trial results online.

Read More: https://www.nature.com/articles/d41586-018-06801-7

End of the eCTD? FDA Pushes for New KASA System to Improve Assessments

The US Food and Drug Administration’s Pharmaceutical Science and Clinical Pharmacology Advisory Committee met Thursday to discuss the positive aspects of adopting a Knowledge-aided Assessment & Structured Application (KASA) platform.

Read More: https://www.raps.org/news-and-articles/news-articles/2018/9/end-of-the-ectd-fda-pushes-for-new-kasa-system-to

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INDIAN PHARMA

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Mexico keen to enhance bi-lateral trade relationship with India says Mexican Ambassador in Kolkata

To enhance the relationship, Kolkata-based Bengal Chambers recently organized an interactive session with Melba Pria, Ambassador of Mexico in India.

Read More: https://www.indiablooms.com/finance-details/9193/mexico-keen-to-enhance-bi-lateral-trade-relationship-with-india-says-mexican-ambassador-in-kolkata.html

Indian pharma market grew 8.7% in August on slower offtake of anti-infectives

The Indian pharmaceutical market (IPM) grew at 8.7 percent in August, much slower than in July due to lacklustre sales of anti-infective drugs, according to market research firm AIOCD-AWACS.

Read More: https://www.moneycontrol.com/news/business/companies/indian-pharma-market-grew-8-7-in-august-on-slower-offtake-of-anti-infectives-2942821.html

India bans 328 combination drugs in setback for pharma companies

The Indian government had in 2016 banned about 350 such drugs, referred to as fixed-dose combinations (FDCs), but the industry mounted various legal challenges that prompted the Supreme Court to call for a review by an advisory board.

Read More: https://www.reuters.com/article/us-india-health-drugs/india-bans-328-combination-drugs-in-setback-for-pharma-companies-idUSKCN1LT155

Larger picture: Joining PICS a big boost for drug quality

Given how serious a problem Not of Standard Quality (NSQ, or sub-standard) is—a clutch of studies puts the former at between 4% and 10%

Read More: https://www.financialexpress.com/opinion/larger-picture-joining-pics-a-big-boost-for-drug-quality/1325399/

In The Pink Of Health: India's Generic Drug Exporters On A Growth Curve

The fortunes of large Indian generic pharma export companies have visibly changed recently, and the once 'bitter' pill has turned sweet again.

Read More: https://swarajyamag.com/ideas/in-the-pink-of-health-indias-generic-drug-exporters-on-a-growth-curve

With a large pool of patients and availability of large hospitals, the India CRO Market estimated to grow 12% CAGR between 2016 and 2023

Market Research Future with their unique quality of simplifying the market research study, announces a deep study report on 'India CRO Market Research Report- Forecast to 2023' Gives industry size, top players and worldwide demand

Read More: https://menafn.com/1097478827/With-a-large-pool-of-patients-and-availability-of-large-hospitals-the-India-CRO-Market-estimated-to-grow-12-CAGR-between-2016-and-2023

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CLINICAL RESEARCH

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Europe ‘needs uniform policy’ to help generic pharmaceuticals market grows: report

Its report – Emerging Generic Pharmaceuticals Markets in Europe – focuses on the key factors promoting growth in the sector,

Read More : https://www.europeanpharmaceuticalreview.com/news/78743/europe-needs-uniform-policy-for-generic-pharmaceuticals-market-growth/

FDA on Pace for Record Generic Approvals in 2018

According to FDA's latest generic drugs program activity report, the agency has approved 666 ANDAs in the fiscal year through July and has tentatively approved another 162 ANDAs.

Read More : https://www.raps.org/news-and-articles/news-articles/2018/9/fda-on-pace-for-record-generic-approvals-in-2018

Wearable’s set to transform clinical research

In their earliest iteration, wearable devices were largely viewed as lifestyle and fitness tchotchkes. Did some of their features lend themselves to health and medical applications?

Read more at: https://www.mmm-online.com/home/channel/technology/wearables-set-to-transform-clinical-research/

Understanding the complexities of global serialisation & traceability regulations

Most falsified medicines that reach the market do so because of inefficiencies in the supply chain. The complexity of the supply chain, in which drugs change ownership multiple times before reaching the patient, leads to these inefficiencies.

Read more at: https://www.europeanpharmaceuticalreview.com/webinar/79102/understanding-the-complexities-of-global-serialisation-traceability-regulations/

Clinical trial cost is a fraction of the drug development bill, with an average price tag of $19m

According to the researchers, clinical trials that support US Food and Drug Administration (FDA) approvals of new drugs have a median cost of $19m

Read more: https://www.outsourcing-pharma.com/Article/2018/09/26/Clinical-trial-cost-is-a-fraction-of-the-drug-development-bill

House Passes Key Components of the Biosimilars Competition Act of 2018

In July, Congressman John Sarbanes, D-Maryland, introduced the Biosimilars Competition Act of 2018 in the United States Congress House of Representatives. Key components of the bipartisan bill authored by Congressman Sarbanes were passed this week by the House.

Read More: https://www.centerforbiosimilars.com/news/house-passes-key-components-of-the-biosimilars-competition-act-of-2018

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FINANCIAL NEWS

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UC San Diego partners in $65 million project to speed drug development

Seeking to speed up development of new drugs, UC San Diego has partnered with a New York investment management firm that has committed $65 million to the project.

Read more at: http://www.sandiegouniontribune.com/business/biotech/sd-me-ucsd-deerfield-poseidon-20180905-story.html

Ugandan unit of Indian drugs firm Cipla raises $43.8 mln in IPO - Renaissance Capital

The Ugandan unit of India's pharmaceutical giant Ciplaraised 167 billion Ugandan shillings ($43.8 million) from its oversubscribed initial public offering (IPO), an investment bank that helped advise on the transaction said on Monday.

Read more at: https://health.economictimes.indiatimes.com/news/pharma/ugandan-unit-of-indian-drugs-firm-cipla-raises-43-8-mln-in-ipo-renaissance-capital/65852493

Global pharma firms' 2017 R&D investment in Korea up 5.9 percent: KRPIA

Global pharmaceutical companies operating in South Korea locally invested a combined 271 billion won ($242 million) in clinical research and development in 2017, marking a 5.9 percent increase in R&D funding from the previous year, according to the Korea Research-based Pharma Industry Association.

Read More: http://www.koreaherald.com/view.php?ud=20180920000645

Senate bill to encourage generic drug development would yield $3.3 billion in savings

A Senate bill that would give generic companies a pathway for suing brand-name rivals when denied access to needed samples would lower federal government spending by $3.3 billion on medicines, according to a new analysis.

Read More: https://www.statnews.com/pharmalot/2018/09/20/senate-bill-generics-cbo/

Make it large—a significant trend in the Indian pharmaceutical industry

The pharmaceutical sector recorded deals worth over $2.1 billion so far in 2018, compared with $1.9 billion across the 12 months of 2017.

Read More: https://www.livemint.com/Industry/aGPiYBKo0xJbvKgJm0zx3J/Make-it-largea-significant-trend-in-the-Indian-pharmaceutic.html

Pharma Startup Elbrit Life Sciences Raises $3 Mn from Its Parent & Qatar-based Investment Firm

Mumbai-based Elbrit Life Sciences has announced today that it is expanding its footprint in the domestic pharmaceutical industry.

Read More: https://www.indianweb2.com/2018/10/03/pharma-startup-elbrit-life-sciences-3-mn-from-its-parent-qatar-based-investment-firm/

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MERGER & AQUISITION

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Aurobindo buys US units of Sandoz for $900 million

Hyderabad-based Aurobindo Pharma on Thursday announced it had entered into an agreement to acquire the commercial operations and three manufacturing facilities in the US from Sandoz, a Novartis NSE 0.00 % generics division, for $900 million.

Read more at: http://economictimes.indiatimes.com/articleshow/65713712.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

Novartis to sell off part of generics business for $1B

Swiss pharma giant Novartis will sell part of its generic drug business, Sandoz, in a deal valued at $1 billion, reports the Wall Street Journal.

Read more at: https://www.beckershospitalreview.com/pharmacy/novartis-to-sell-off-part-of-generics-business-for-1b.html

Actavis to Sandoz, Aurobindo Pharma is scaling up biz one acquisition at a time

India's second-largest drug maker by sales Aurobindo Pharma last week acquired Sandoz's dermatology business and a portfolio of oral solid products along with commercial

Read More: https://www.moneycontrol.com/news/business/companies/actavis-to-sandoz-aurobindo-pharma-is-scaling-up-biz-one-acquisition-at-a-time-2939071.html

Veristat Strengthens Clinical Operations Capabilities with The Acquisition of Topstone Research

Veristat, a full-service Clinical Research Organization (CRO), announced today that it has completed the acquisition of Topstone Research, a Canadian-based specialty contract research organization

Read More: https://www.tullahomanews.com/news/business/veristat-strengthens-clinical-operations-capabilities-with-the-acquisition-of-topstone/article_642211cb-a32e-57e8-b4eb-cee218cf4eb7.html

The state of pharma mergers and acquisitions in 2018

In the age of spiralling research and development costs and the pressure to minimize risk and maximize

Read More: https://www.thepharmaletter.com/article/the-state-of-pharma-mergers-and-acquisitions-in-2018

CVS Health and Aetna $69 Billion Merger Is Approved With Conditions

The Justice Department's approval of the $69 billion merger between CVS Health and Aetna on Wednesday caps a wave of consolidation among giant health care players that could leave American consumers with less control over their medical care and prescription drugs.

Read More: https://www.nytimes.com/2018/10/10/health/cvs-aetna-merger.html

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ARTICLE

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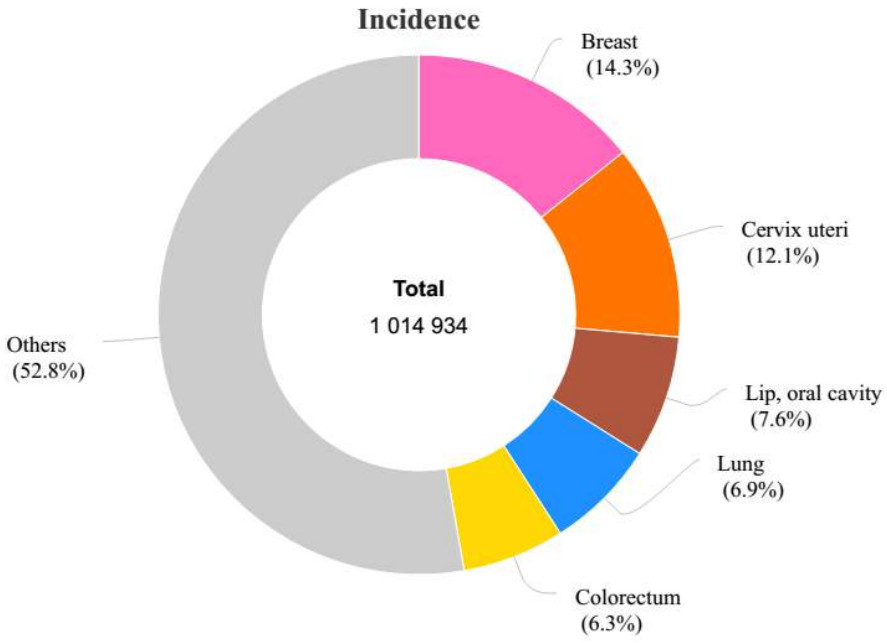
EMERGING TRENDS IN ONCOLOGY CLINICAL TRIALS

Therapeutic innovation in cancer treatment has always been in focus. Based on WHO data, worldwide, there were 14.1 million new cancer cases, 8.2 million cancer deaths, and 32.6 million people living with cancer within 5 years of diagnosis by year 2012. Top 5 most frequent cancers in world (ranked by number of new cases) are breast, prostate, lung, colorectal, and cervical cancers per 2012 WHO data (International Agency for Research on Cancer, WHO). For countries like India, the top 5 most frequent cancers (ranked by number of new cases) are breast, cervical, oral cavity, lung and colorectal cancers (International Agency for Research on Cancer, WHO). Reported age-adjusted incidence rates for cancer are still quite low in the demographically young country. Little more than 1 million new cases of cancer are diagnosed every year in India. An estimated 600 000–700 000 deaths in India were caused by cancer in 2012. In age-standardized terms this is close to the mortality burden seen in high-income countries. Such figures are somewhat indicative of low rates of early-stage detection and poor treatment outcomes (Mallath MK, et al. 2014).

The cancer burden continues to increase due to aging population and increasing adoption of behavioral patterns mainly smoking, sedentary lifestyle and dietary changes with inclination towards junk foods, in economically developing countries. By year 2030, countries like India may see more than 50 % rises in incidence of cancers, compared to data available for the year 2012 (GLOBOCAN 2012 data) (Ferlay J et al., 2012).



READ MORE: https://www.pharmatutor.org/articles/emerging-trends-in-oncology-clinical-trials

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UPCOMING CONFERENCE

1. Bio Europe

Nov 5 - 7Nov , 2018

Copenhagen, Denmark

2. 17th-Pharmacovigilance

Nov 15, 2018

Mumbai, India

3.CPhI India 2018

12-14 Dec, 2018

New Delhi , India

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

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