The Veeda Newsletter

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V- KONNECT

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“V-KONNECT" with Mr. Ashish Dasgupta - Director Anregen Healthcare Pvt. Ltd.

Veeda through its V-Konnect series interacted with Mr. Ashish Dasgupta and discussed about “India as preferred destination for conducting clinical trials”

About the V- Konnect

V-Konnect interview series, is a program to get in touch with specialized industry experts to know their views on opinions on current relevant subject matters.

About Mr. Ashish Dasgupta

With over 35 years of experience in Clinical Pharmacology and Pharmacokinetics, Mr. Ashish Kumar Dasgupta have handled varied position in operations, business development and strategic organizational development in his past assignments. Anregen Consulting in New Delhi is the consulting group established by Mr. Ashish Dasgupta which is an advisory capacity for several companies from India and overseas. . He has been felicitated with 'Udyog Ratna' award for his precious contributions to CRO industry and honored with 'Best Leadership' at Jubilant for exhibiting exemplary leadership qualities.

Below is the verbatim transcript of the interview.

Q. Do you feel that India is a preferred destination for conducting Clinical studies in comparison to the other developing countries? And Why?
A: Undoubtedly, India is a preferred destination in compared to other developing countries. There were some regulatory hurdles in past; however things have improved now. Also due to factors like availability of patient population, Good investigational sites and very good awareness of GCP India becomes preferred destination in comparison to other developing countries.

Q. Do you think that there is a hesitation in Global MNC’s with respect to outsourcing their clinical development to India considering issues highlighted by various regulatory bodies?
A: Yes, there is definitely hesitation amongst global MNC’s. People are aware that there are lot of regulatory non-compliance by the manufacturing units. And some of the BE centers have also come into limelight in past 3-4 years with problems. Data integrity is always an issue and it is apparent that people have resorted to shorter routes leading to Non-Compliance which does not work.

Q. What should Global MNCs be aware of when choosing a CRO in India?
A: First thing is they have to do a very good due diligence audit of a CRO. While CRO attract the attention of sponsors on cost front it is the quality performance that take precedence. Consistence quality with measurable parameters will always be the first criteria for selection.

Q. What advice would you give to international pharmaceutical companies planning to work with an Indian CRO? How would you differentiate one CRO in India from another especially when they all seem to have good regulatory track record?

A: I would suggest to use a correct independent third party & not the one who is associated with any CRO. To get a better confidence over the CRO, sponsor should get 2-3 audits conducted per year by the third party auditor.

Differentiation would be challenging if all the CRO(s) have good regulatory track record. However, CRO's value addition to the Sponsor can be one of the factors. In addition to the execution of studies from Sponsor, CRO can portray as differentiator in the market in terms of providing scientific inputs, better responsiveness & communication as well ensuring the Quality of project management and bio pharmaceutics support. I would add here that don't over sell; instead have right systems & provide quality work.

Q. What are the emerging trends in BE studies and do you think that Indian CROs are gearing up to meet the requirements of emerging trends?

A: Sponsors are just not looking for conduction of BE studies, they are looking beyond that. Sponsors seek opinion from the CRO(s) on the expertise in designing the product which is bioequivalent. Many small and mid-sized companies are looking for CRO(s) which can assist them in scientific designing of the study by evaluation of the supporting data closely. In addition, CRO(s) who do have expertise in complex bio-studies which are challenging to execute, can be one of the emerging trend in clinical research. The CRO(s) who showcase their expertise in the domain of special studies segments like inhalation, dermatology, ophthalmic, complex bio-analysis, etc. in addition to the conventional BE studies would be able to adapt the emerging trends in the industry.

On a closing note, Mr. Dasgupta mentioned that "Quality is the only way we can support and deliver to the global Pharma Industry. If anybody falls apart than there is black spot on the entire industry".

Disclaimer:

The opinions expressed in this publication are those of the Interviewee and are not intended to malign any ethic group, club, organization, company, individual or anyone or anything. Examples of analysis performed within this publication are only examples. They should not be utilized in real-world analytic products as they are based only on personal views of the Interviewee. They do not purport to reflect the opinions or views of the VEEDA CRO or its management. Veeda CRO does not guarantee the accuracy or reliability of the information provided herein.

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Veeda Clinical Research Scores Another Perfect NPRA (Malaysian Regulatory Agency) Audit

This Inspection was a routine study Inspection performed by the NPRA Inspectors with the purpose to verify the compliance of the facility and study conduct to the principles of Good Clinical Practices. The audit outcome confirmed that the activities in Veeda CRO are in compliance with the SOPs and regulatory guidelines.

Veeda CRO have successfully faced 50 regulatory audits in last 13 years wherein 18 USFDA Inspections were conducted successfully in last 24 months which demonstrates our commitment levels towards Quality and Regulatory Compliance.

Read More: https://www.prnewswire.com/news-releases/veeda-clinical-research-scores-another-perfect-npra-malaysian-regulatory-agency-audit-833240365.html

Veeda Clinical Research Successfully Completed its 5th WHO Audit.

Veeda Clinical Research Pvt. Ltd., a leading independent CRO is proud to announce that our Shivalik, Insignia and Vedant (except bio analytical) facility had successfully completed fifth Inspection by WHO (World Health Organization) without any critical observations.

After successful inspection by NPRA (Malaysian Regulatory Agency), Veeda CRO faced another Inspection in the same month by WHO. This inspection was the fifth WHO inspection at Veeda. WHO Inspectors did thorough inspection of all three Veeda facilities, wherein they reviewed various BE studies submitted as part of pre-qualification of BE-studies applications program. The Inspection team also covered various other study related activities as well as different facilities.

Veeda CRO have successfully faced 50 regulatory audits in last 13 years wherein 18 USFDA Inspections were conducted successfully in last 24 months which demonstrates our commitment levels towards Quality and Regulatory Compliance.

Read More: https://www.prnewswire.com/news-releases/veeda-clinical-research-successfully-completed-its-5th-who-audit-817487191.html

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INDIAN PHARMA

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India: The Sunshine Sector In "Make In India" – Medical Device Industry Shines As Never Before

With the rapidly expanding Indian pharmaceutical and healthcare sector over the years, the growth in demand for advanced and innovative medical devices seems to be a natural next step to meet the needs of the sector.

ReadMore: http://www.mondaq.com/india/x/745722/Inward+Foreign+Investment/The+Sunshine+Sector+In+Make+In+India+Medical+Device+Industry+Shines+As+Never+Before\\

India: CDSCO Proposes Good Distribution Practices Draft Guideline For Pharmaceutical Products

The Central Drugs Standard Control Organization (CDSCO) has released the draft guidelines on 'Good Distribution Practices' (GDP) to regulate the quality of pharmaceutical products over entire chain of distribution in the country.

Read More:
http://www.mondaq.com/india/x/747802/Healthcare/CDSCO+Proposes+Good+Distribution+Practices+Draft+Guideline+For+Pharmaceutical+Products

India: Centre Proposes Draft e-Pharmacy Rules To Regulate Online Sale Of Drugs

The Central Government proposed ePharmacy draft rules under Drugs and Cosmetics Act 1945 (the Act). The draft rules are proposed to regulate the online sale of medicine or ePharmacy business in India.

Read More:
http://www.mondaq.com/india/x/747792/food+drugs+law/Centre+Proposes+Draft+ePharmacy+Rules+To+Regulate+Online+Sale+Of+Drugs

Complex Generic Guidance by US FDA to benefit Indian Pharma Formulators: Ind-Ra

India Ratings and Research (Ind-Ra) believes that increased guidance from the United States Food & Drug Administration (US FDA) on complex generics will provide increased clarity to US-focused Indian pharmaceutical formulators in preparing and submitting abbreviated new drug applications (ANDAs).

Read More: http://www.expressbpd.com/pharma/latest-updates/complex-generic-guidance-by-us-fda-to-benefit-indian-pharma-formulators-ind-ra/406651/

Indian pharma industry to grow at 7-9 pct between 2018-21: Report

The domestic pharmaceutical industry is likely to register a moderate growth at 7-9 per cent in the period between FY18 and FY21, a report said.

Read More: https://www.devdiscourse.com/Article/business/227625-indian-pharma-industry-to-grow-at-7-9-pct-between-2018-21-report

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REGULATORY NEWS

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FDA announces guidance on complex generics

US Food and Drug Administration (FDA) Commissioner Scott Gottlieb has championed the cause of generics

Read More: https://www.thepharmaletter.com/article/fda-announces-guidance-on-complex-generics

U.S. FDA Issues Draft Guidance on Special 510(k) Program

The U.S. Food and Drug Administration (FDA) has published a draft guidance intended to aid certain medical device manufacturers in retaining approval of previously authorized devices when making certain modifications to those devices.

Read More: https://incompliancemag.com/u-s-fda-issues-draft-guidance-on-special-510k-program/

FDA approving generic drugs at record pace, report finds

The FDA is continuing to set records for the number and speed of its generic drug approvals. In fiscal year 2018, the agency approved 781 generics, up 90 percent from 2014,

Read More: https://www.beckershospitalreview.com/pharmacy/fda-approving-generic-drugs-at-record-pace-report-finds.html

DCGI approves specialized centre for derma clinical trials

In a first, the Drug Controller General of India (DCGI) have given approval to a chain of dermatology and plastic surgery centres— The Esthetic Clinics, for conducting clinical trials and drug development for skin, hair and other plastic surgery medications, cosmetology and cosmetic surgery devices in India.

Read More: https://biospectrumindia.com/news/22/11913/dcgi-approves-specialized-centre-for-derma-clinical-trials.html

Infographic: Record year for ANDA approvals in US

While over the past five years, ANDA (abbreviated new drug application) approvals have slowly increased, the industry has observed a spike within the past two years. Each year the approval rate reaches a record level, and 2018 is no different - with generics continuing to lead the pack.

Read More: https://www.biopharma-reporter.com/Article/2018/10/26/Infographic-Record-year-for-ANDA-approvals-in-US

USFDA generic guidance to help local pharma formulators with ANDA approvals

The recent guidance from the US Food & Drug Administration (USFDA) on complex generics is expected to provide more clarity to US-focused Indian pharmaceutical formulators in preparing and submitting abbreviated new drug applications (ANDAs), says a report.

Read More: https://www.business-standard.com/article/companies/usfda-generic-guidance-to-help-local-pharma-formulators-with-anda-approvals-118102800130_1.html

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CLINICAL RESEARCH

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Cedar Rapids cardiac provider among first in international clinical trial of 'groundbreaking' device

A Cedar Rapids hospital's Heart and Vascular Institute has successfully performed the first surgical implant in an international clinical trial to test a new therapy for chronic heart failure.

Read More: https://www.thegazette.com/subject/news/health/cedar-rapids-cardiac-provider-among-first-in-international-clinical-trial-of-groundbreaking-device-20181010

Clinical Trial Supplies Market To Grow at a CAGR of +7% by 2026 According To New Research

The analysts of Healthcare Intelligence Markets have thoroughly examined the Global Clinical Trial Supplies Market and have anticipated that the market will grow at a CAGR of +7% during the forecast period.

Read More: https://www.medgadget.com/2018/10/clinical-trial-supplies-market-to-grow-at-a-cagr-of-7-by-2026-according-to-new-research.html

Review Finds Better Efficacy of Biologics in Trials Without Placebo

A review was recently conducted among 2 different types of randomized clinical trials in the treatment of rheumatoid arthritis (RA): those comparing reference biologics' efficacy versus placebo, and those comparing reference biologics' efficacy versus biosimilars.

Read More: https://www.centerforbiosimilars.com/conferences/acr-2018/review-finds-better-efficacy-of-biologics-in-trials-without-placebo

NEW GENERIC DRUG REPORT SHOWS PROMISING SAVINGS

The report from the Association for Accessible Medicines, an industry trade group, states generic drugs saved Medicare and Medicaid $82.7 billion and $40.6 billion, respectively, in 2017.

Read More: https://www.heartland.org/news-opinion/news/new-generic-drug-report-shows-promising-savings

New Clinical Research Shows the Safety, Tolerability and Efficacy of the Epitomee Capsule

Research led by Prof. Shirin, and conducted by a group of physicians from the Kamila Gonczarowski Institute of Gastroenterology,

Read More: https://www.prnewswire.com/news-releases/new-clinical-research-shows-the-safety-tolerability-and-efficacy-of-the-epitomee-capsule-300736053.html

Blockchain Key to Enhancing Clinical Research, Patient Data Sharing

Blockchain may be the key to accelerating clinical research, according to a new report by Deloitte, due to the technology's potential to streamline data sharing and enhance interoperability.

Read more: https://healthitanalytics.com/news/blockchain-key-to-enhancing-clinical-research-patient-data-sharing

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FINANCIAL NEWS

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Cambrex Invests c.$3 Million to Upgrade Generic API Manufacturing Facilities at Milan, Italy Site

Cambrex Corporation (NYSE: CBM), the leading manufacturer of small molecule innovator and generic Active Pharmaceutical Ingredients (APIs), and finished dosage forms.

Read More: https://markets.businessinsider.com/news/stocks/cambrex-invests-c-3-million-to-upgrade-generic-api-manufacturing-facilities-at-milan-italy-site-1027597054

Janssen and R-Pharm to compete for $45 million contract in Russia

Russian drugmaker R-Pharm plans to compete with Janssen Pharmaceuticals, part of US healthcare giant

Read More: https://www.thepharmaletter.com/article/janssen-and-r-pharm-to-compete-for-45-million-contract-in-russia

Ireland's largest generics maker invests €86m, targets US market

As part of the investment, Chanelle Pharma will build a €11m manufacturing facility for liquid generic products in Galway, for export to the US.

Read More: HTTPS://WWW.IN-PHARMATECHNOLOGIST.COM/ARTICLE/2018/10/11/IRELAND-S-LARGEST-GENERICS-MAKER-INVESTS-86M-TARGETS-US-MARKET

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/

SCHOTT Tubing India to further invest 20 million euros

Jambusar: SCHOTT AG, manufacturers of pharmaceutical glass and packaging, has announced the launch of a new glass tank in its Indian manufacturing plant at Jambusar, Gujarat.

Read More: https://health.economictimes.indiatimes.com/news/pharma/schott-tubing-india-to-further-invest-20-million-euros/66270607

India, Vietnam identify biotechnology, super-computing to take bilateral trade to $15 bn

India and Vietnam have identified biotechnology in agriculture and healthcare, super-computing and remote sensing, among other areas to drive bilateral trade to $15 billion by 2020, the government said on Wednesday.

Read more : http://economictimes.indiatimes.com/articleshow/66348367.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

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MERGER & AQUISITION

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BioIVT Acquires UK-based Clinical Trials Laboratory Services

BioIVT, a leading provider of research models and services for drug development, today announced that it has acquired Clinical Trials Laboratory Services (CTLS), a donor center and laboratory based in London, UK. **Read More:** https://www.prnewswire.com/news-releases/bioivt-acquires-uk-based-clinical-trials-laboratory-services-300725538.html

Allergan Joins TriNetX to Access Network of Real-World Data for Clinical Research

Allergan, a leading global pharmaceutical company, has joined the TriNetX global health research network for real-time access to patient populations, driven and refreshed by clinical data, to determine protocol feasibility, cohort analysis and site identification.
Read More: https://www.prnewswire.com/news-releases/allergan-joins-trinetx-to-access-network-of-real-world-data-for-clinical-research-300728264.html

Mundipharma buys Spanish biosimilars firm Cinfa Biotech

The deal will see Mundipharma, which includes NAPP Pharmaceuticals in the UK, gain access to a biosimilar to Amgen's Neulasta (pegfilgrastim).
Read More: https://pharmaphorum.com/news/mundipharma-buys-spanish-biosimilars-firm-cinfa-biotech/

Telix and ANMI Expand PSMA Imaging Partnership

Telix Pharmaceuticals Limited (ASX.TLX) ("Telix", the "Company"), a clinical-stage biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or "molecularly-targeted radiation" (MTR),
Read More: http://www.ptcommunity.com/wire/telix-and-anmi-expand-psma-imaging-partnership

Daiichi Sankyo signs clinical trial collaboration deal with Merck and Pfizer

Daiichi Sankyo has entered into a clinical trial collaboration agreement with Merck and Pfizer to evaluate the combination of its [fam-] trastuzumab deruxtecan (DS-8201)
Read More: https://www.pharmaceutical-business-review.com/news/daiichi-sankyo-signs-clinical-trial-collaboration-deal-with-merck-and-pfizer/

Indian pharma players Cipla, Aurobindo buy assets abroad

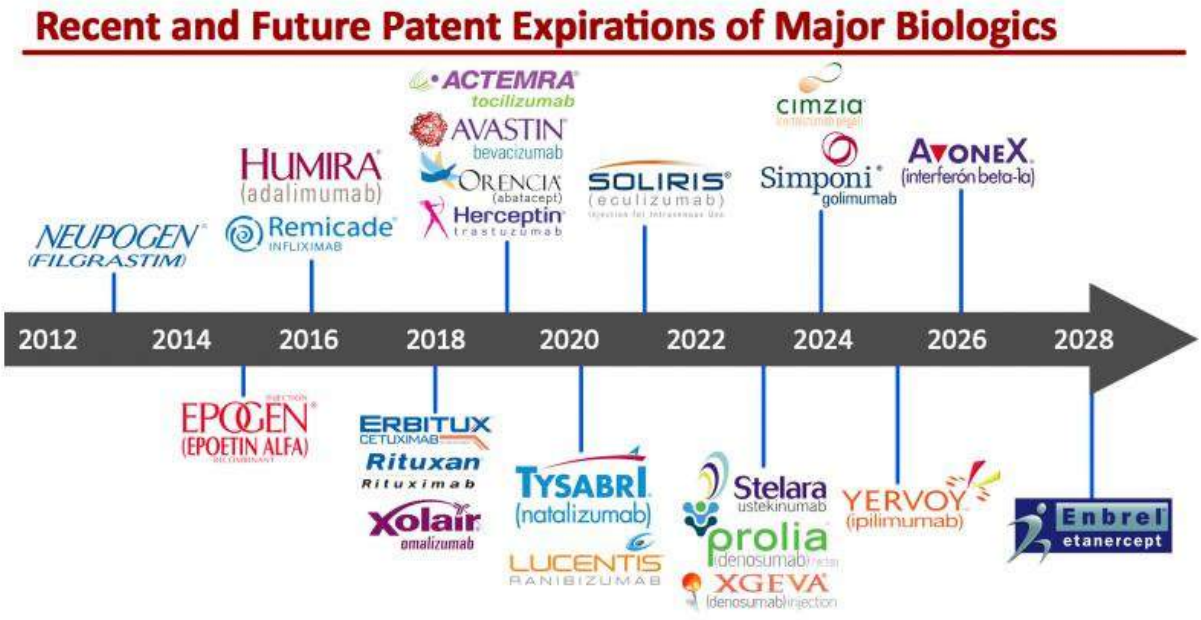
Pharma major Cipla's subsidiary InvaGen Pharmaceuticals Inc is acquiring US-based specialty business firm Avenue Therapeutics for up to $215 million while Aurobindo Pharma Ltd agreed to buy a product under development and related assets from Australia-based Advent Pharmaceuticals Pty. Ltd for $12.5 million in an all-cash deal.
Read more: https://www.dealstreetasia.com/stories/indian-pharma-players-cipla-aurobindo-buy-assets-abroad-111048/

Next Generation of Biosimilars and Biobetters: Challenges and Opportunities

The biopharmaceutical market is a rapidly growing class of therapeutics, showing significant potential in oncology, diabetes and other disease areas. Unlike conventional chemically synthesized pharmaceuticals, biopharmaceuticals—also known as biologics—are derived from living organisms, typically using biotechnology.Examples of biologics include hormones, blood products, cytokines, monoclonal antibodies (mAbs), and vaccines, as well as gene transfer, cell therapy and tissue engineered products.

There are more than 300 mAbs, more than 250 vaccines, and more than 100 other biologics—including cell and gene therapies—currently in clinical development. The global biologics market is expected to reach around $291 billion in 2020 and by 2022, 50 percent of the pharmaceutical market share is expected to be in biologics. But the future of biologics won't be focused solely on the discovery of new therapeutics. There is also a significant market for biosimilars, biologic drugs that demonstrate high similarity to an already approved biologic reference drug, and can in turn serve as an alternative to it. Biosimilars are different than generics, which are synthetic chemical copies of their reference drugs and are identical in active ingredients, strength, dosage form and route of administration.

Because biologics are made with living cells and no two molecules can be exactly the same, making a copy of a biologic is a much more involved and expensive process than creating a generic drug. There will always be very subtle differences between the biosimilar and its reference biologic.



Read more: https://www.rdmag.com/article/2018/10/next-generation-biosimilars-and-biobetters-challenges-and-opportunities

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UPCOMING CONFERENCE

1. **17th-Pharmacovigilance-2018**
   Mumbai, India
   15th Nov 2018

2. **CPhI India 2018**
   New Delhi, INDIA
   12th Dec - 14th Dec 2018

3. **13th-Biosimilars-Congregation-2018**
   Mumbai, India
   13th Dec 2018

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

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