



## GLOBAL PHARMA

### Novartis invests in China

Novartis is investing \$250m (€170m) to construct a facility in China focused on research, development and manufacture of APIs and has earmarked a further \$1bn to expand its R&D activities in the country.

The investment is a significant expansion of Novartis' activities in China, which will become the big pharma's third largest R&D region, as it attempts to capitalise on the cost-effectiveness, expertise and rapid market growth the country offers.

A \$250m global technical centre will be constructed in Changshu, in east China which will focus on the R&D and manufacture of active pharmaceutical ingredients (API). By co-locating API R&D and manufacture Novartis believes it can realise synergies which will significantly improve pharmaceutical processes and operational efficiencies. Novartis predicts the centre will become a "critical part" of its global production and supply chain network. The company already operates a facility in Changshu, which focuses on the process and analytical research and development of drugs and their manufacturing technologies, and the new centre will double the number of high quality jobs Novartis provides at the site.

### Novartis Biological Drug Ilaris Approved In EU to Treat Children and Adults

#### With CAPS, A Rare Debilitating Auto-Inflammatory Disease

The new biological medicine Ilaris® (canakinumab) has been approved in the European Union (EU) to treat adults and children as young as four years old with cryopyrin-associated periodic syndrome (CAPS), a rare life-long auto-inflammatory disease with debilitating symptoms and few treatment options. The accelerated EU decision follows approvals in the US and Switzerland, where Ilaris was granted priority review in view of the significant unmet medical need. Ilaris is the only medicine approved in the EU for CAPS patients as young as four years old, and for patients with the most debilitating form of CAPS, neonatal-onset multisystem inflammatory disease (NOMID)[4]. It is a fully human monoclonal antibody given by injection under the skin once every two months - the longest dosing interval of any available treatment [2],[5],[6]. "We are excited by the latest approval because Ilaris represents a significant therapeutic advance for patients with this debilitating and sometimes fatal disease," said Joe Jimenez, CEO of the Novartis Pharmaceuticals Division. "Ilaris is the outcome of our pathways-driven search for innovative medicines that are tailored to the needs of patients. Initially we studied Ilaris in a very rare disease with a well-understood genetic profile, and now that its efficacy has been proven, we are able to move ahead rapidly with development in other diseases characterized by the same inflammatory process." The regulatory submission was supported by data showing that Ilaris produced rapid and sustained remission of symptoms in up to 97% of CAPS patients, with most of them responding within hours of the first injection.



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### **Pfizer chief hopes for US health reform by end of 2009**

Pfizer's chief executive Jeffrey Kindler has said he expects plans for healthcare reform in the

USA to be approved by the end of this year and has supported the moves despite the additional costs that the pharmaceutical industry will have to bear. In an interview with the *Financial Times*, Mr Kindler praised the US Senate Finance Committee's latest draft, saying that it was "balanced and thoughtful". He has given his backing to the the \$80 billion, 10-year cost savings deal agreed in June between the Pharmaceutical Research and Manufacturers of America and SFC chairman Senator Max Baucus, despite the fact that it would "certainly cost the industry" money. Mr Kindler also rejected criticism that there would be "an enormous offsetting windfall from new customers" as a result of additional cover being proposed for uninsured Americans, and told the newspaper that "we think these are the right things to do for patients". His comments come at a time when the US House of Representatives' (as opposed to the Senate's) version of the Affordable Health Care for America Act (HR 3962) included requiring firms to provide drug rebates for people enrolled in both Medicare and Medicaid. Observers believe the House plan could cost the industry \$150 billion over a decade.

### **Lundbeck says expands stroke drug candidate trials**

Danish pharmaceutical group Lundbeck (LUN.CO: Quote, Profile, Research, Stock Buzz) said on Monday it had started phase IIa clinical trials on a candidate drug it is developing for stroke patients to expand its range to another nervous system disorder. Lundbeck said it began trials with its Lu AA24493 drug candidate in Friedreich's ataxia, a rare inherited disease that causes damage to the nervous system resulting in symptoms ranging from gait disturbance and speech problems to heart disease. "The primary objective of the study is to evaluate the safety and tolerability of two weeks treatment with a fixed dose Lu AA24493 in patients with Friedreich's ataxia," Lundbeck said.

Lu AA24493 is currently being developed for acute ischaemic stroke, the firm said. Lundbeck generates most of its revenue from antidepressant Cipralext, sold in the United States as Lexapro. The patents on the drug expire in major markets in 2012 to 2014, so the firm is trying to replace it with new products.



### **World's largest malaria vaccine trial now underway in 7 African countries**

Pivotal testing of RTS,S is on track for target enrolment of 16,000 children

A pivotal efficacy trial of RTS, S, the world's most clinically advanced malaria vaccine candidate, is now underway in seven African countries: Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique and Tanzania. The trial, which is expected to involve up to 16,000 children, is on schedule, with more than 5,000 children already enrolled, researchers announced Tuesday at the 5th Multilateral Initiative on Malaria Pan-African Malaria Conference. Developing a vaccine against malaria, a scientific challenge for decades, is critical to defeating the disease. A vaccine would complement existing interventions, such as bed nets and effective drug therapies. GlaxoSmithKline Biologicals' (GSK Bio) RTS,S is the first malaria vaccine candidate to demonstrate significant efficacy during early development to warrant Phase III testing. It is the leading vaccine candidate in the global effort by the PATH Malaria Vaccine Initiative (MVI) to develop a malaria vaccine.

### **NEWSMAKERS**

**Bristol-Myers Squibb and ZymoGenetics Present Final Phase 1b Results for PEGInterferon Lambda in Hepatitis C**

Bristol-Myers Squibb Company (NYSE: BMY) and ZymoGenetics, Inc. (NASDAQ: ZGEN) today presented final results from a Phase 1b clinical trial of PEGInterferon lambda administered with ribavirin in relapsed and treatment-naïve hepatitis C virus (HCV) patients. The poster included data on 56 patients in the study. Antiviral activity was observed at all dose levels tested. The results will be presented at the American Association for the Study of the Liver Diseases annual meeting in Boston on November 3. Interim results were previously presented at the European Association for the Study of the Liver annual meeting in April 2009. "There is a strong need for additional options for hepatitis C patients," said Brian Daniels, M.D., senior vice president, Global Development & Medical Affairs, Bristol-Myers Squibb. "We are pursuing this investigational pathway to address the fact that although current interferons have been the backbone of therapy with meaningful efficacy, they are often poorly tolerated, leading to dose reductions, poor compliance and avoidance of treatment." "We are excited about the prospects for PEG-Interferon lambda as a potential HCV treatment," said Eleanor L. Ramos, M.D., senior vice president and chief medical officer of ZymoGenetics. "There is a clear unmet medical need for an interferon with improved safety and tolerability. We look forward to obtaining additional clinical data on this promising investigational medicine." The Phase 1b clinical trial was designed to evaluate the safety and antiviral activity of PEG-Interferon lambda when given as a single agent or in combination with ribavirin in genotype 1 HCV patients with relapsed disease and in treatment-naïve patients.



### Industry must stop complaining and 'reinvent innovation' – Lilly CEO

The chief executive of Eli Lilly has been speaking about the need to fix the “broken” engine of biopharma innovation and reverse the “loss of trust in product safety and in the honesty of pharmaceutical businesses”. Speaking a day after opening the Lilly Biotechnology Center-San Diego, John Lechleiter said there is a need to “reinvent innovation”. He added that “at a time when the world desperately needs more new medicines - for everything from H1N1 to Alzheimer’s disease – we’re taking too long, spending too much and producing far too little”. Dr Lechleiter went on to say that “repowering pharmaceutical innovation is an urgent need not only for our company and our industry but for our nation”, saying that “we remain dependent on a society that welcomes and values new ideas, and public policy that enables innovation to be rewarded for the value it creates. But we also know that we need to change”. He claimed that despite its value, the biopharma industry “is losing its advantage and wasting its potential”. Noting the problem of a lack in trust in drugmakers, the Lilly chief also bemoaned a “risk-averse policy and regulatory environment that has led to high hurdles for new medicines” and the pressures of the healthcare system, “where the industry has become an attractive target for policy makers looking for cost savings”.

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### Increasing with the time



The African countries hold the potential to an increasing number of HIV positive patients which are rising at a rapid pace. The rising pace of disease spread is in millions of people in countries like Mozambique. The people of the African countries affording population are a less affording population for treating their “detectable” and “undetectable” diseases prevailing in their countries. The people of these countries are dependent on subsidized government supplies of anti retroviral drugs which are imported from countries which manufacture the same at subsidized rates. The anti retro viral sent to these countries are sent on a large scale are manufactured by prominent Indian Pharmaceuticals companies and are predominantly generics. The generic anti retroviral drugs are tested for their bio equivalence criterion before they are sent out for export to African nations. More at---  
<http://blogs.veedacr.com/Lists/Posts/Post.aspx?ID=92>





### The Right Choice



The recent trends in the industry particularly Global Pharma indicates heavy scouting by Big Pharma for smaller players in emerging markets particularly in Generic drugs. The trends indicate the "dire" need of Big Pharma to develop and work towards targeting the generic drug market with a "reinforced" approach. Coupled with the intentions of acquisitions, Big Pharma faces challenges to sustain its growth with the sales of its existing brands and simultaneously develop newer drugs as well. Both the factors and in today's' recession decelerate the growth of Big Pharma in terms of profitability. To sustain growth in the recession, Big Pharma wants to move towards "potential" areas of growth like targeting M &A in emerging markets and hence move towards the tackling the pressures on the sales of their branded drugs from generics. The nature of outsourcing of Bio equivalence studies for generic drugs has taken a completely different look with the changing activities of Big Pharma.

More at-

<http://blogs.veedacr.com/Lists/Posts/Post.aspx?ID=89>

### **NOXXON Announces Initiation of First-in-Human Clinical Trial with Hematopoietic-Stem Cell Mobilizing Spiegelmer® NOXA12**

NOXXON Pharma AG, the biopharmaceutical company focusing on the development of novel drugs based on its unique proprietary Spiegelmer® technology, announced the successful initial dosing of healthy volunteers in a first-in-human clinical trial with Spiegelmer® NOX-A12. NOX-A12 is NOXXON's second drug candidate entering the clinical stage of development within only five months. The Phase I program is currently being conducted in Germany following review and approval of the Clinical Trial Application by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). This single center study is designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics in up to 42 individuals, following intravenous administration of the hematopoietic stem cell (HSC) mobilizing Spiegelmer® NOX-A12. Further information about this clinical trial is available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (ID: NCT00976378). Dr. Frank Morich, Chief Executive Officer of NOXXON, commented: "Based on exceptionally positive pre-clinical data, we strongly believe that, NOX-A12 has the potential to become an improved alternative for hematopoietic stem cell mobilization. Our goal is to have NOX-A12 approved by 2014. In this ongoing trial we are expecting to see a good safety profile and to gain initial efficacy data that will further validate the value of the Spiegelmer® technology for the drug development in areas with high unmet medical need."



## OPTIONS FOR GROWTH PATHS

**Funny that some U.S. pharma companies are eyeing Japan as a growth market, considering that Japanese drugmakers are looking to grow everywhere but home**

As the Financial Times points out today, the Japanese health ministry has been pushing drug prices downward for some 20 years now. Every other year, drug makers are required not just to minimize price increases--or even to keep prices constant--but to cut them. Plus, the government has grown notorious for its zealous promotion of generic meds. The result? Japan's share of the global pharma market is now 10 percent, down from 22 percent in the 1990s

Japanese pharma has been snapping up companies outside its home base, including Millennium Pharmaceuticals (bought by Takeda) and Ranbaxy Laboratories (bought by Daiichi Sankyo). And Japanese drug makers have been inking development deals outside Japan as well; just think of this week's obesity-drug pact with Amylin Pharmaceuticals.

But meanwhile, Western drug makers have been working their way into Japan's drug market. The most recent example: Eli Lilly plans to staff up in Japan even as it lays off thousands in the U.S.

**Plenty of options** ---The clinical research industry is vast and is dominated with many experienced people across the globe. The drug industry is today is faced with many challenges as to having while developing new and complex drugs. During the development of the drugs, clinical research is outsourced in major way to CRO's. For mega projects of Big Pharma, one CRO is certainly not sufficient. However, large processing units are not the most suitable environments for true innovation and it is not surprising that big pharmaceutical companies constantly scout for new alliances in the biotechnology and CRO industry. For large trails with subjects/volunteers ranging in numbers greater than double digits and the trials covering multiple geographical regions, CRO's with proven capacity to handle large "chunks" of data for data management are preferred. If the quantum of targeted data is less than double digits then smaller CRO's are preferred because of their ability to adapt to new challenges quickly and deliver true innovation. Newer players will continue to enter this market because of the sheer growth potential as an attracting factor.

More at-

<http://blogs.veedacr.com/Lists/Posts/Post.aspx?ID=80>



## **POLICY UPDATES ON BIO SIMILARS-USA**

United States: Bio similars Provision Included In House Health Care Reform Bill - The Time Has Finally Come

On October 29, 2009, the Democratic leadership of the House of Representatives released the Affordable Health Care for America Act, H.R. 3962. The proposed legislation contains provisions that, if enacted, would result in numerous changes in the way that health care insurance is provided and paid for in the United States. H.R. 3962 includes section 2575 entitled, "Licensure Pathway for Biosimilar Biological Products," which is intended to give the U.S. Food and Drug Administration (FDA) the authority to approve biosimilar versions of biotech drugs.

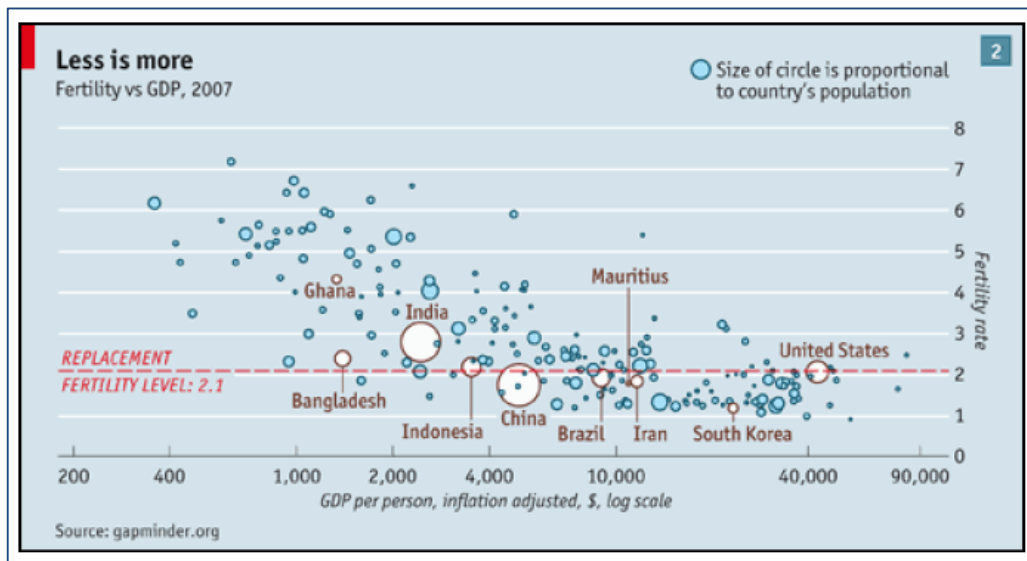
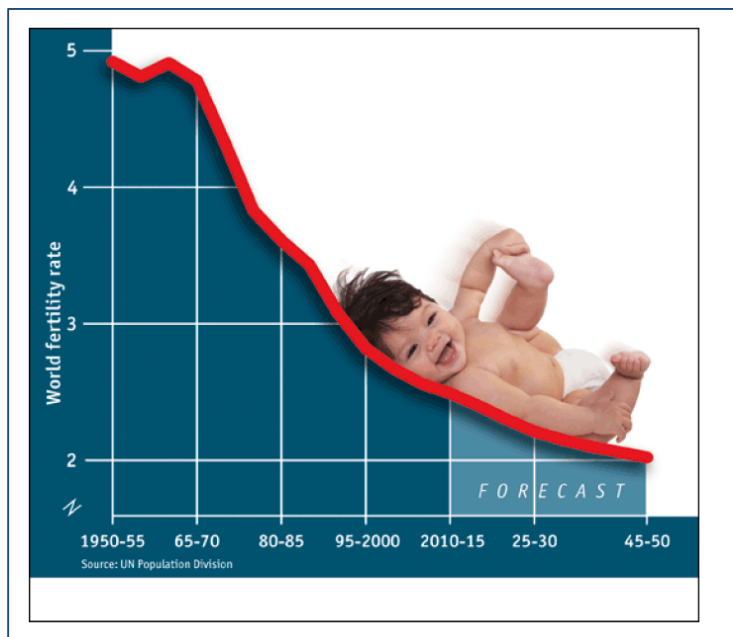
Similar to previous bills, H.R. 3962 provides for the approval of biosimilar products, defined as those " ... being highly similar to the reference product, [i.e., the brand name biologic that is referenced by the biosimilar product], notwithstanding minor differences in clinically inactive components" and "no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency of the product." H.R. 3962 also includes a section allowing for, but not mandating, "interchangeable" biosimilars, defined as a product that meets certain standards and can be "substituted for the reference product without the intervention of the health care prescriber who prescribed the reference product." There also are exclusivity provisions for the first interchangeable biological product. The biosimilar product would be required to bear a name that distinguishes it from the reference product. The bill also permits the FDA to issue guidance documents concerning the licensure of biologic products; however, such issuance, or non-issuance, of any such guidance cannot preclude the review or action on any application.

The bill also strikes a balance by providing incentives for brand companies to develop new therapies. The bill provides a 12-year period of market exclusivity from the date of approval of the reference product. The length of this period of market exclusivity has been the subject of much debate. An application for a biosimilar cannot be submitted for four years from the date of approval of the reference product. There also is a six-month pediatric exclusivity period. There is no period of exclusivity for supplements providing for changes to the reference product, if the change (other than a modification to the structure of the biological product) results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength, or if the modification of the structure of the biological product does not result in a change in safety, purity, or potency. This is quite different from the current exclusivity scheme under Hatch-Waxman for approved drugs. [http://www.mondaq.com/article.asp?articleid=88672&email\\_access=on](http://www.mondaq.com/article.asp?articleid=88672&email_access=on)



WEEKLY STATISTICAL CLIPS-I

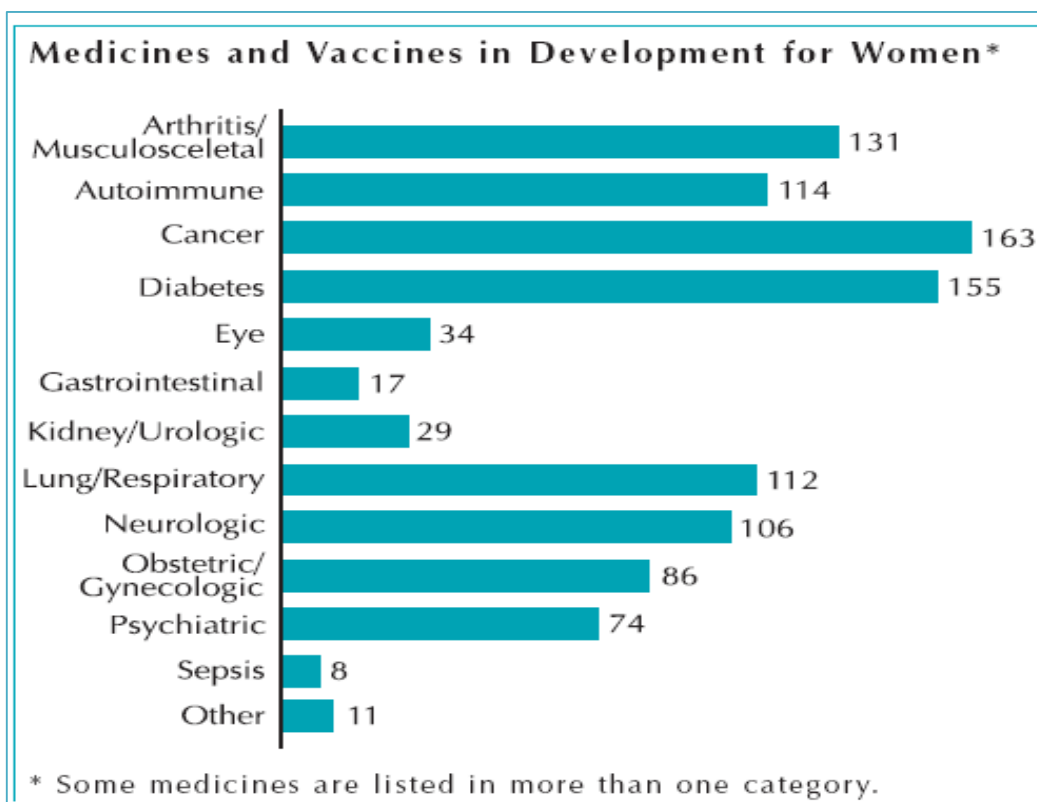
POPULATION STATISTICS----Lower fertility is changing the world for the better





**WEEKLY STATISTICAL CLIPS-II**

Nearly 1,000 Medicines Are in Testing for Diseases of Major Concern to American Women





### Survey Suggests More Pain than Gain for INVESTIGATIVE SITES

A survey conducted in conjunction with the Fourth Annual Site Solutions Summit (SSS) in Clearwater Beach, Fla. suggests that investigative sites are collectively feeling the pain of lengthening study delays, aging accounts receivables, and slipping profit margins. Routinely meeting enrollment targets offers no shelter from the financial storm.

1. The survey represents the experience of 84 sites, predominantly freestanding, private practices, and site management organizations (SMOs) that do phase II-IV clinical research. Less than half, inclusive of all seven hospitals surveyed, conduct phase I studies. One-fourth of the sites have five or more years of research experience; 12%, two to four years; and 62%, one year.
2. The average site did 22 studies in 2008, with SMOs doing the most (30) and private practices the least (11).
3. Study delays were more common in 2008 (12 months) than 2007 (four months), which SSS attendees attributed to the economy, mergers among sponsor companies, and uncertainties about health care reform.
4. Hospitals are far less likely than all other types of investigative sites to utilize a clinical trial management system (CTMS)—34% versus 50% or more elsewhere. The chief downsides are the time investment for initial setup, lengthy learning curve, ongoing re-training due to staff turnover, and the technology's failure to adequately capture screen failures and interface with a site's financial system. Pierre notes that Rx Trials ran a legacy CTMS in parallel with a new one for a "good year" as a matter of due diligence.
5. Nearly all of the sites (95%) have standard operating procedures and the majority also ensure compliance via an in-house quality assurance(QA)/auditing process (ranging from 66.7% among hospitals to 90% among SMOs). Top performers in this arena include a site with a QA and compliance committee (pronounced "quack") that treats every monitoring visit like an FDA audit—including responses in CAPA (Corrective and Prevention Action) format.
6. In 2008, nearly 34% of sites were audited by the FDA and close to 29% received a 483 citing inspectional observations. That's up from about 38% and 25%, respectively, in 2007. Sites are highly inconsistent when it comes to requesting and receiving compensation for an FDA audit, which tends to interrupt enrollment. Overall, 35% of sites say they "always" ask for compensation and 68% say they "never" get paid, compared to 48% and 43%, respectively, in 2008. Pierre speculates that some sites "quit asking because they've heard 'no' so often." The experience of several attendees suggests large pharmaceutical companies are more flexible than smaller biotechs about re-negotiating budgets once a study begins.
7. The majority of sites assess the feasibility of a new study before accepting it, with hospital-based sites doing so most often (80% of the time). Surprisingly, only 68% of sites considered per subject payment "critical to know." The study start date was accorded "nice to know" status by just 57% of sites, presumably a reflection of how routine study delays have become.
8. More than half of all sites, except the freestanding ones, "sometimes" conduct a post mortem on studies to compare expectations with reality. The freestanding sites were the most likely, at 17%, to "always" do so. In the 2008 survey, 12.5% of sites overall reported that they always conduct a post mortem and over two-thirds rarely if ever did.



GMD, Mr Apurva Shah interviewed OUTLOOK 360 MAGAZINE IN THEIR NOVEMBER 2009 edition.

THE TITLE OF THE CLIP IS “DEVELOPING THE DRUGS OF TOMORROW”.



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## VEEDA IN THE NEWS



### APURVA SHAH

Co-Group Managing  
Director and co-founder,  
Veeda CR



Veeda CR, an Ahmedabad-based CRO, won this year's Frost and Sullivan Award for the best clinical research company. Apurva Shah talks about what it takes to be a part of this industry.

**Q. How does your company hire clinical research professionals?**

**A.** Earlier, we would go through regular channels like academic institutions, pharmaceutical colleges and placement agencies. But in the last two years, because of our reputation in the clinical research fraternity, people approach us directly. Most of our employees recommend Veeda as a workplace to their friends.

**Q. What is your view on the quality of professionals trained by universities and institutes in clinical research?**

**A.** From our experience we can say that most of the time, freshers from training institutes are not exposed to the nitty-gritty of a real-time clinical research environment. We realised that they must be exposed to different facets of the business and client expectations, and must imbibe the spirit of good clinical practices, which is why we at Veeda have our own intensive training programme to train our people as per the international industry requirements. We also send groups of our people from India to our units in the West for on-the-job training for up to six months.

**Q. What should a student keep in mind before thinking of a career in the field?**

**A.** You must be passionate about science and believe in being a partner in the discovery and development of drugs to preserve and improve the quality of human life.

**Q. Tips on choosing a company...**

**A.** Turn the interview process around. Interview the company to understand its growth path. Look for excellent work environment, a good team to work with, one that could give you a rich research experience. A good salary package would be yours in the years to come. But if you start pursuing a salary then you will soon realise it's a mirage!