

The year that was!

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Year 2007 can easily be classified as the turning point for the life sciences industry. It saw the completion of the second phase of HapMap Project-created to identify and catalog genetic similarities and differences among populations around the world. Scientists from six countries worked on it. The first phase, completed in 2005, provided data that has led to the development of techniques used in the search for genes associated with common diseases. It has also helped in the identification of 50 such disease-associated genes.

However, the biggest feat is the "designer genome" brought into existence by famed scientist Dr Craig Venter. Using lab-made chemicals, Dr Venter's team stitched together a chromosome that is 381 genes long and contains 580,000 base pairs of genetic code. This has made artificial life a not-so-distant possibility.

Worldwide there were a number of breakthroughs ranging across segments of pharma, biotech and medical technology and a good measure of work happened in APAC countries. While Australian drug discovery company Phylogica focused on finding new Phylomer drugs, the Japanese scientists developed molecular scissors that open and close in response to light and make for a great invention with applications in manipulating genes and other molecules. In Malaysia, scientists developed herbal drug for dengue and scientists in Thailand discovered oral AIDS vaccine while Indian life sciences industry saw the launch of a number of vaccines.

In the ensuing pages BioSpectrum brings to you a recap of some of the breakthroughs, technologies, products and people

who made news in 2007.

Drug-resistant TB genome sequenced, a small win

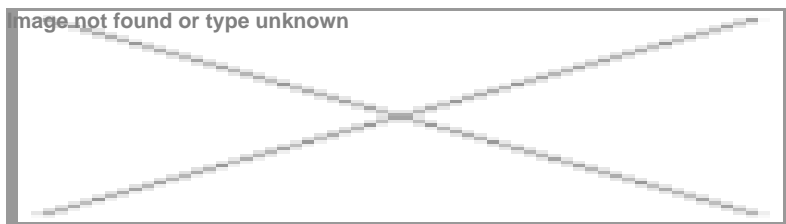
A breakthrough that will help fight the deadly disease of tuberculosis has been achieved in South Africa. The genome of one strain of an extensively drug-resistant tuberculosis (XDR-TB) has been sequenced there, using technology developed in the United States.

"We consider this a breakthrough because it will provide for more analysis of MDR (multi drug-resistant TB) and XDR-TB (extensively drug-resistant TB), and to understand the differences between them," said Dr Carl Montague of LifeLab, a biotechnology project funded by the South African government.

Elsewhere in the world, researchers are on way to develop two highly potent shorter-term tuberculosis drugs. Two anti-TB drugs (Moxifloxacin and PA-824) have reached the advanced stages of clinical trial and could be available worldwide by 2012-2014, raising hopes for shorter-duration treatment and fighting the bacterium that has become immune to the present drugs.

Developed by TB Alliance, Moxifloxacin has reached the phase III stage of clinical trial and 900 patients were given the drug in the three phase II studies conducted on it. While the second drug, PA-824, has entered the phase II trials and will be now given to TB patients to study its short-term potency.

A big leap for Indian enterprises



Year 2007 saw Bharat Biotech International launch BioHib, the first indigenously developed and manufactured Haemophilus Influenza type b (Hib) vaccine in India. It also launched its tetravalent combination vaccine, Comvac4-HB containing Diphtheria, Pertussis, Tetanus and Hepatitis B in one vaccine. These two new vaccines BioHib and Comvac4-HB, enable the deployment of a combination pentavalent vaccine in a single injection.

Serum Institute of India launched its indigenously manufactured low-cost Haemophilus influenza type b conjugate vaccine under the brand name of HibPRO in India. HibPRO has been priced at \$9 (Rs 360) for a monodose vial.

Dr Reddy's Laboratories has launched Reditux, the Dr Reddy's brand of rituximab, a monoclonal antibody (MAb) used in the treatment of Non-Hodgkin's Lymphoma.

Talking about monoclonal antibody-based drugs, Biocon's BIOMAb EGFR for treating solid tumors of epithelial origin has extended applications. BIOMAb-EGFR that was launched in September 2006, has in 2007 seen an increase in the total number of registered patients to almost 1,000 in the country. The drug indicated for head and neck cancer is also being studied in global clinical trials for colorectal, lung cancer, glioma (brain cancer), and pancreatic cancers.

Minicells for cancer drug delivery discovered

Sydney-based biotechnology company, EnGeneIC, has successfully created the world's first nano-sized particle aimed at providing more effective and efficient drug delivery to cancer cells. The new, patented delivery technology is derived from minicells of bacterial origin and is called EnGeneIC Delivery Vehicles (EDVs).

EnGeneIC has achieved results in reducing tumors without toxic side effects in pre-clinical animal models of cancer. The drug delivery technology is applicable for a wide spectrum of cancer types.

Two senior Australian scientists, Dr Jennifer MacDiarmid and Dr Himanshu Brahmbhatt, have led the EngeneIC research

team. They founded the program in 2001 and are joint managing directors of the company. The researchers claim that for the first time it has been proved that this technology could lead to the use of multi-drug combinations and could eventually help in the development of custom-made therapies for cancer patients.

Bharat Biotech launches thimerosal-free vaccines

Bharat Biotech has launched Revac-Bmcf, a thimerosal-free Hepatitis B vaccine. With it, Bharat Biotech joins this elite club of vaccine manufacturers in developing, manufacturing and commercializing thimerosal-free vaccines.

Biocon, Abraxis BioScience announce approval of Abraxane Biocon and Abraxis BioScience, an integrated, global biopharmaceutical company, have announced the approval to market Abraxane for Injectable Suspension--paclitaxel protein-bound particles for injectable suspension (albumin-bound)--in India for the treatment of breast cancer. Commercial introduction of Abraxane in the Indian market is expected in 2008 following the completion of the appropriate importation certifications.

Eli Lilly launches Byetta

Eli Lilly and Company India has launched Byetta (exenatide injection) in India. Byetta is used to improve blood sugar control in patients with Type 2 diabetes. The drug is indicated in combination with metformin and/or sulphonylureas, two common oral diabetes medications. Studies with Byetta found that it not only improved blood sugar control but also resulted in a reduction in body weight.

Indian Immunologicals launches nutraceuticals for animals

Indian Immunologicals, a wholly owned subsidiary of the National Dairy Development Board (NDDB), has made its foray into the animal feeds segment by launching a range of dairy nutrition products. The products include: Calsagar (an animal feed supplement in pellet form, containing calcium, phosphorus and vitamin D3), for improved milk production, improved fat and SNF content in milk; Garbhamin Bolus (contains essential trace minerals in chelated form and coated vitamins) for superior reproductive performance, and Goumix, the first customized mineral supplement in the country for livestock based on regional mineral mapping carried out by NDDB.

Panacea Biotec launched oncology drugs

Panacea launched a suite of products in the oncology sector like Paclitrust, Docetrust, Gemtrust, Zoletrust and Temotrust. It also inaugurated its Vaccine Formulation plant (VFP) in Baddi, Himachal Pradesh and entered into an agreement with Family Vaccines of the Philippines to provide access to value added combination vaccines under the umbrella of "Easy Vaccines" manufactured by Panacea Biotec, to the people in Philippines through a chain of 50 immunization clinics, run by Family Vaccines.

TERI develops biopesticide against cotton bollworm

Scientists at The Energy and Resources Institute (TERI) have developed a biopesticide against cotton bollworm. The product is expected to hit the market this year. Taking up the challenge for developing a biopesticide to tackle the problem of *H. armigera* infestation, TERI scientists began research in this area during the late 1990s with support from the DBT.

The pesticide affects the growth of the bollworm larva resulting in reduction of larval weight up to 88 percent, hence restricting the larvae population, resulting in ultimate death of the larva itself, apart from its mild anti-feedancy thereby preventing the crop damage.

Xcyton launches "Xcyto-Screen" diagnostic kit

Xcyton Diagnostics, the Bangalore based molecular diagnostics company, announced Xcyto-Screen series of products--Xcytoscreen Keratoconjunctivitis, Uveitis, Retinitis and Endophthalmitis. This category of products detect up to 15 key microorganisms that infect both eyes and brain. Based on nucleic acid amplification technology and a macro-chip, this platform has been developed for the first time in the country and as a public-private initiative.

Government approves national biotech policy

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Government of India approved the much-awaited National Biotechnology Development Strategy. The strategy is an outcome of a two-year-long nationwide consultation process with multiple stakeholders including ministries concerned, universities, research institutes, private sector, civil society, consumer groups, non-government and voluntary organizations and international bodies.

The strategy addresses the formation a National Biotechnology Regulatory Authority to provide a single window mechanism for biosafety clearance of genetically modified products and a high-powered Inter-ministerial Committee to effectively coordinate the development of the sector by addressing cross cutting issues. The policy also focuses on public-private partnership programs, Biotechnology Industry Partnership Programme (BIPP) for Advanced Technology. Approval has also been accorded for the expansion of SBIRI during the 11th Plan.

Nano science initiatives take off

The Bangalore Nano 2007 Convention, a two-day event on nanoscience and technology and the first major event of its kind in the country was held on December 6-7, 2007, organised by the Department of Science and Technology in association with Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR). The government has made a budgetary provision of Rs 1,000 crore to promote the sector. The Nano Science and Technology Initiative (NSTI) has funded around 100 basic science projects worth Rs 60 crore.

A Nobel Prize for gene targeting

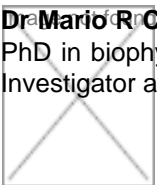
Dr Mario R Capecchi, Dr Martin J Evans and Dr Oliver Smithies were honoured with this year's Nobel Prize for medicine for their discoveries of "principles for introducing specific gene modifications in mice by the use of embryonic stem cells".

These Nobel Laureates have made a series of ground-breaking discoveries concerning embryonic stem cells and DNA recombination in mammals. Their discoveries led to the creation of an immensely powerful technology referred to as gene targeting in mice. It is now being applied to virtually all areas of biomedicine-from basic research to the development of new therapies.

Gene targeting is often used to inactivate single genes. Such gene "knockout" experiments have elucidated the roles of numerous genes in embryonic development, adult physiology, aging and disease. To date, more than 10,000 mouse genes (approximately half of the genes in the mammalian genome) have been knocked out. Ongoing international efforts will make "knockout mice" for all genes available within the near future.

With gene targeting it is now possible to produce almost any type of DNA modification in the mouse genome, allowing scientists to establish the roles of individual genes in health and disease. Gene targeting has already produced more than five hundred different mouse models of human disorders, including cardiovascular and neuro-degenerative diseases, diabetes and cancer.

Dr Mario R Capecchi: Born in 1937 in Italy, he didn't know how to read and write until he was 9. Later he continued to do his PhD in biophysics in 1967 from Harvard University, Cambridge, MA, USA. Currently he is Howard Hughes Medical Institute Investigator and Distinguished Professor of Human Genetics and Biology at the University of Utah, Salt Lake City, UT, USA.



Dr Oliver Smithies: Born in 1925 in Great Britain he did his PhD in Biochemistry 1951, Oxford University, UK. Currently he is Excellence Professor of Pathology and Laboratory Medicine, University of North Carolina at Chapel Hill, NC, USA.

Dr Sir Martin J Evans: Born in 1941 in Great Britain he did his PhD in Anatomy and Embryology 1969, University College, London, UK. Currently he is Director of the School of Biosciences and Professor of Mammalian Genetics, Cardiff University, UK.

Top Invention Prize for Dr Sidhu

Indian-Australian stem cell scientist, Dr Kuldip Sidhu has won the 2007 Top Invention Prize for his pioneering work in stem cells.

Dr Sidhu, an Associate Professor at University of New South Wales, was acknowledged for the work on the derivation of a new human embryonic stem cell line, Endeavour-1.

The prize is awarded by BioMed North Limited, a not-for-profit agency for the management and commercialization of intellectual property generated within the state of New South Wales (NSW).

Dr Sidhu has produced a human embryonic stem cell line without the use of any animal product. This breakthrough eliminates the risk of animal-to-human contamination in potential stem cell therapy treatments. Dr Sidhu's work could eventually lead to safer treatments for conditions such as diabetes, Parkinson's disease, spinal cord injury and even breast cancer.

Novozymes acquires Biocon's enzyme business

Biocon Ltd sold its enzymes activity to Novozymes, for a total consideration of \$115 million. The acquisition of Biocon's enzyme activities provides an important step for Novozymes in strengthening its position in the Indian market.

RFCL acquires Wipro BioMed

RFCL signed a definitive agreement to acquire Wipro BioMed, a leading provider of biomedical solutions. The acquisition of Wipro BioMed is a part of RFCL's multi-pronged inorganic growth strategy to emerge as a globally respected company in the field of life sciences solutions. The business operations of Wipro BioMed will be integrated with RFCL's diagnostics division--Diagnova.

Avesthagen acquires Renaissance Herbs

Avesthagen acquired Renaissance Herbs Inc., a fully-integrated supplier of proprietary nutritional products. The acquisition supports Avesthagen's bio-nutritional business strategy through vertical integration and access to key markets.

Malaysian scientists develop herbal drug for dengue

A group of Malaysian scientists have discovered a breakthrough antiviral drug from an herbal extract for the treatment of dengue. This could be the world's first dengue antiviral drug based on herbal extracts. Dengue is an acute infectious, eruptive, febrile disease caused by four antigenically related but distinct serotypes of the Dengue virus. It is transmitted by the bite of infected Aedes mosquitoes, especially A. aegypti.

Scientists at the Medical Department of Universiti Malaya and the Universiti Malaya Medical Centre have developed the antiviral drug, known as Dengimm2, from extracts of Artemisia and eight other local herbs. Dengimm2 was proved safe when tested on infected cells and in mice.

