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Personalized medicine gathers steam

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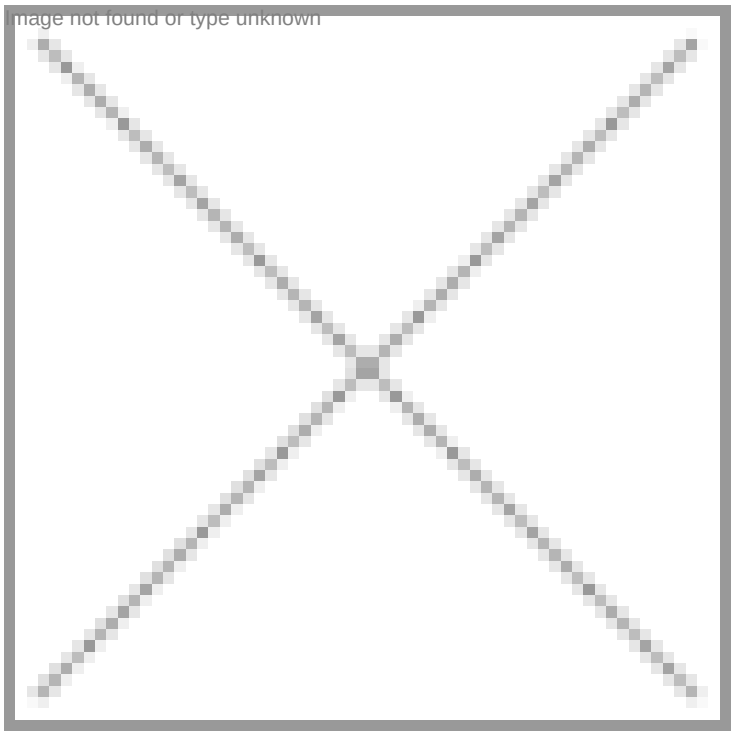
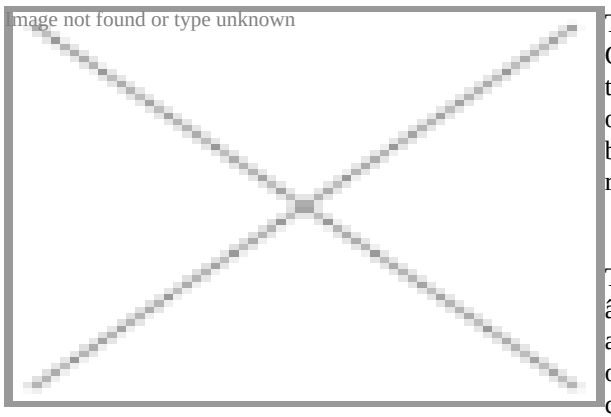


Advances in genomics provides opportunities for researchers to examine the DNA of every individual thereby providing treatment, specific to each patient. The field of pharmacogenomics is evolving at a rapid pace in the country



Thanks to the successful completion of the Human Genome Project, scientists now have a set of tools that can be readily used to understand the complexity of the diseases and its variability in different human beings. These tools can assist the scientists in refining the risk prediction and also in evaluating the

The current healthcare scenario is distinctly more of â€œtrial-and-errorâ€?, which subjects the patients and their physicians to a larger uncertainty of outcome. In the patient's case it often entails greater cost-both physical and financial. Advances in genomics now enable scientists to examine the DNA of each-and-every individual and then predict if the person would be susceptible to a particular disease or will a particular medicine be suitable for that person in case he falls sick. This is where pharmacogenomics comes into play. Pharmacogenomics redefines the way drugs are developed, and the way in which drugs are chosen for patients, based on their individual genetic

make-up. Understanding the underlying genetics behind a patient's response to therapy will allow therapeutic companies to develop safer and more effective drugs. In addition, understanding how individuals are genetically predisposed to risk of disease, may result in new drug targets, thereby leading to new classes of drugs designed to delay, or prevent disease onset.

After the trend of setting up CROs in India, pharmacogenomics-based companies seem to be the new trend. This is because, India has a large population and there are high incidences of genetic disorders in the country. Companies have started investing in pharmacogenomics as it offers several advantages such as elimination of the unpredictable nature of drug development, bring new products to the market and the company could also benefit up to $200-500 million for each drug.

A start-up company, Xcode Lifesciences has come up with the InDNA technology to provide solutions to lifestyle-related diseases such as coronary heart diseases, diabetes and obesity. A person has to order the test online after which a saliva kit will be shipped to the customer. DNA extracted from the saliva will then be used to determine the allelic information of the individual using high-throughput genotyping techniques. Genomic data can then be used to screen for single nucleotide polymorphisms (SNPs) that are associated with the diseases. After screening the genetic information, the company will provide recommendations to individuals that are at a higher risk to certain disease. The price for diabetes, obesity and cardiovascualr services is 6999 each and if a person wants to check the status for all the three diseases, the service will be available for 9999.

In April, this year, NutraGene launched country's first commercial genetic test for type 2 diabetes. NutraGene's type 2 diabetes genetic scan is a DNA testing service that screens DNA variations that have been widely replicated as risk factors for type 2 diabetes. It is based on a buccal (cheek) swab sample, and the methodology of targeted mutation screening (genotyping). NutraGene screens for SNPs that have been widely replicated as risk factors to type 2 diabetes in the Indian population. One of the sequence variants detected by NutraGene's type 2 diabetes genetic test is a SNP (a single base variation in the sequence of the DNA) in the TCF7L2 gene on chromosome 10.

Trend setters in Pharmacogenomics

Company	Product/Service
Acton Biotech	Broad spectrum genetic tests
Avesthagen	AvestaGenome Project
Jai Health	Genomics based tests
NutraGene	Type 2 diabetes genetic scan
Xcode Life Sciences	InDNA technology

Anubha Anusha, managing director, NutraGene commented that, â€œAll our individual tests cost below INR 7,500, and include complimentary genetic counseling. Besides diabetes, we currently are offering genetic screening services for coronary heart disease, hypertension, stroke, obesity, osteoporosis, breast cancer, as well as pharmacogenomic profiling for medications such as metformin, sulfonylureas, clopidogrel, warfarin and more. Our testing service includes complimentary genetic counseling to help customers and their physicians understand their genetic results, as well as complimentary wellness consultations that assess lifestyle and DNA risk and guide customers on diet, nutrition and lifestyle modifications aimed at lowering disease risks.â€?

Avesthagen is another major player focusing on pharmacogenomics field. One of the major projects of the company is the AvestaGenome Project. It is a systems biology-based study of the Parsi population to determine genetic basis of longevity and age-related disorders. This study aims to develop a model for pharmacogenomics-based therapies, development of biomarkers for predictive diagnostics and drug discovery and to enable the archiving of the genome of the community. Avesthagen started this Rs 125 crore project in 2007. The AvestaGenome Project will, thus, lead to generation of a â€œpersonal health mapâ€? of an individual which will enable the goal of personalised medicine to be achieved.

Dr Villoo Morawala-Patell, CEO, Avesthagen remarked, â€œCurrently we have metabolome based signature of a set of biomarkers that would provide early diagnosis for breast cancer. We will soon be testing them in Indian population through a clinical study. The biomarkers discovered from the study on breast cancer, prostate cancer, neurological diseases-Alzheimer's and Parkinson's and metabolic or degenerative conditions

through â€œThe AvestaGenomeProjectâ€? will be used to generate molecular diagnostic tests and kits that could be used to determine the suitability of a drug for the patient in a particular population.â€?

Acton Biotech has been providing these tests for various diseases for the past six years. The company offers genetic tests to predict response from chemotherapy drugs such as gefitinib, cetuximab among many others. Sandeep Saxena, founder and CEO, Acton Biotech believes that, â€œPharmacogenomics is not new in India. We have been offering tests for the last six years. Today, there are many labs offering these tests. It's a routine in cancer clinical and hospitals. We get a lots of support from pharma companies, diagnostic labs and large hospitals. We have lots of highly qualified doctors and most of them are early adopters. Patients also read a lot about the disease and treatment online and are willing to pay a premium for safer, better and faster treatment.â€?

Despite the optimism expressed regarding the impact that this field might have on the health of people, many barriers need to be crossed. Researchers, diagnostic firms and regulatory authorities need to establish methodologies by which to judge their effectiveness. Application of genomic and personalized medicine in healthcare needs a change in regulatory system. For instance, US FDA has embraced genomic and personalized medicine as an important solution to pharma industry model for drug development.

Talking about the challenges in this field, Dr Patell highlighted, â€œThe major challenge is to find a set of robust biomarkers that have been clinically validated across diverse populations. This will need significant amount of resources and time to identify and prove the utility of the biomarker(s) for a particular health condition in the desired population prior to market launch. In addition, the costs of the kit developed for a particular disease-population genotype will need to be competitively priced to enable a large market share. Furthermore, both patient and physician education is required to bring about a change in the practice of medicine towards a targeted, as opposed to a 'one size fits all', therapeutic approach.â€?

The future of pharmacogenomics in India is bright and will be the key in bringing the reality of personalized medicine to the masses in India. â€œIn view of the diversity of the Indian population it is envisaged that pharmacogenomics will play a significant role in the design of therapeutics that minimizes the negative side effects of current drugs and brings individual patient-centric therapy to a large population base. In addition, a significant savings on medical expense and reduction in patient morbidity and mortality will also be evident. This will bring a paradigm shift in the practice of medicine as we know today,â€? concludes Dr Patell.

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