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ASIA EDITION

Personalized medicine picks up pace in India

23 August 2012 | Analysis | By BioSpectrum Bureau

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Thanks to the successful completion of the Human Genome Project, scientists now have a set of tools that can be readily used by them in order to understand the complexity of diseases and their variability in different human beings. These tools assist scientists in refining risk prediction and also in evaluating the response to therapies with greater precision.

The current healthcare scenario is distinctly more of 'trial-and-error', which subjects the patients and their physicians to a larger uncertainty of outcome. In the patient's case it often entails greater physical and financial burden. 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 whether a particular medicine be suitable for that person in case he falls sick. This is where pharmacogenomics comes into play.

After the trend of setting up CROs in India, pharmacogenomics-based company 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-to-$500 million for each drug.

A start-up company called Xcode Lifesciences has come up with the InDNA technology to provide solutions to lifestyle-related diseases such as coronary, diabetes and obesity. A person has to order the test online after which a saliva kit will be

shipped to the customer. This saliva kit is completely non-invasive and safe. DNA extracted from the saliva will then be used to determine the allelic information of the individual using high-throughput genotyping techniques.

In April this year, NutraGene launched the 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).

Mr Anubhav Anusha, MD, NutraGene, comments that, "All our individual tests cost below Rs7,500, and include complimentary genetic counseling. 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."

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 Rs125 crore project in 2007.

Dr Villoo Morawala-Patell, CEO, Avesthagen, says that, "Currently, 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 / degenerative conditions through The AVESTAGENOME Project will be used to generate molecular diagnostic tests/kits that could be used to determine the suitability of a drug for the patient in a particular population."

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. Mr Sandeep Saxena, founder CEO, Acton Biotech believes "Pharmacogenomics is not new in India. We have been offering tests for the last 6 years. Today, there are many labs offering these tests. It's a routine in cancer clinical and hospitals."

Bright future lies ahead

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, the 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 highlights that, "the major challenge is to find a set of robust biomarkers that have been clinically validated across diverse populations. 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."

The future of pharmacogenomics in India is bright and will be key in bringing the reality of personalized medicine to the masses in India. "In 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," concludes Dr Patell.