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Can predictive genomics take-off in India?

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"The market value for predictive genomics is considered to be about Rs 100 crore," says Dr Raja Mugasimangalam, founder and CEO, Genotypic Technology. Also, an approximate estimate can be drawn based on the US market size which is predicted to grow to as much as $452 billion by 2015.

This includes not only the healthcare and pharma markets but also the nutrition and wellness market opportunities that use predictive genomics.

Current research in predictive genomics in India is primarily about identifying specific genetic variations and their association to diseases. However, what is needed is to follow up on these initial studies to validate the targets by doing follow-up studies. It is important to find out if the association is indeed clinically relevant.

One of the applications of predictive genomics is in the field of personalized medicine where each individual is treated based on his or her unique genetic makeup.

"This will have an impact on how the biotech, pharma and healthcare industries operate. Raw genomic data and its interpretations will eventually come to be seen as an indispensable part of health and wellness," said Dr Saleem Mohammed, founder and CEO, Xcode Life Sciences.

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For example, several individuals metabolize different drugs in various fashion. Widely prescribed drugs like Clopidogrel, Warfarin and Statins have different efficacies in different individuals based on their genetic makeup. If this is determined early, then the number of dosages can be altered to prevent complications.

According to Dr Kalyanasundaram Subramanian, CSO, Strand Life Sciences, for pharma and biotech companies the opportunity here is to develop drugs paired with companion diagnostics that will clearly help identify responders to their treatments.

Over the last couple of years, Indian start-up landscape has seen a handful of genomic companies that have begun to address the initial needs of the Indian market. Each of these tend to offer a range of services that include sample collection, sequencing, primary analysis and finding variants in a dataset.

Of these activities only 'variant calling' falls in the purview of predictive genomics. However the real potential of predictive genomics lies in the interpretation of data. Metaome is building products and technologies to address this need.

A lot of biomarker panel based genetic testing companies have evolved rapidly in India in the recent past. The use of genomics tool at clinical level has already started in India. However, according to experts, the future lies in whole Exome or whole genome sequencing (WGS).

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Currently, there are no companies in India making Next Generation Sequencing (NGS) instruments. They are imported from the US. There are three major players in NGS namely Illumina, Life Technologies and Pacific Biosciences.

Among the sequencing providers Illumina has almost 90 percent market share, owing to their superior data quality and throughput. Since, data quality is the most important factor, especially for the diagnostic applications, most of the service providers choose Illumina's platform.

The existing major challenge now is the lack of awareness among the medical community and general public. "Another challenge is the availability of genomic data. We have had to rely on studies based on global populations that have a different genetic makeup compared to the Indian population. Importantly, both these challenges present opportunities to first movers to take predictive genomics to the next level in India," opined Dr Saleem.

While the cost of sequencing a genome has come down rapidly in the past few years, the technology is still expensive to use. But this situation is changing fast as costs are being lowered at a faster than exponential rate, and will no longer be as big a barrier as it is currently.

Also, the industry suffers with the issue of 'no' regulation. "This is an ethically fraught situation since a genetic diagnosis potentially affects the whole family and hence needs to be performed in manner that is considered ethical, and with the

consumer and clinician clearly understanding the parameters of the test and the risks that various types of diagnosis may provide," he stated.

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On the pharma side, these tests have the potential to make drugs more applicable by being able to provide them to patients who are most likely to benefit.

The other challenges comes from a poor understanding of the Indian genome. Indian genomes are poorly represented in worldwide consortia attempts such as the 'HapMap' and the '1000 genomes project'. There is a need for government agencies and private players to develop strategies to share data and create an Indian genome.

The social and ethical implications of genomic testing pose a major challenge. Confusing regulatory guidelines or the absence of any guidelines in India is a major threat.

Not to mention, the lack of infrastructure, and the consequent cost of tests, makes it difficult for this technology to penetrate the existing disease testing market. Mr Sam Santhosh, CEO, SciGenom, justifies by saying, "Cost is a major bottleneck. The technology required to bring predictive medicine to the bedside today is primarily imported from vendors in the US and Europe."

India is yet to realize the significance of predictive genomics. "The size of our population makes it such that we can derive a lot of valuable information from large scale genomic studies. The potential for such information to have an impact on public health is also much more," predicted Dr Saleem.

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Predictive Genomics industry is changing at the breath taking pace globally but India is in its early stages, and people have started accepting it recently.

"In India the major focus is on sequence analytic methods, whole exome analysis, integration of systems biology modeling, large scale mutational analysis, Evolutionary connection studies to Genetic disorders," opined Dr Amit Kumar, CEO and CSO, BioAxis DNA Research Centre.

While genomics industry in the US has an economic output of $65 billion per annum, Indian genomic industry is less than one-fourth the amount.
Investments are huge in the US, and the government is also actively participating in boosting this industry with clear guidelines.