"Data-driven medicine will enable the discovery of new treatment options"

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By : Rahul Koul - February 20, 2019

With rising population and alongside increasing burden of healthcare, the Indian healthcare market is expected to be worth $372 billion by 2022 and the biotechnology industry in India is expected to grow to $100 billion by 2025. In the wake of this, one of the key drivers to fuel growth is the science of genomics which forms the basis of innovation and relevance in the biotech healthcare sector. Studying genetic codes, convergence of technologies for analysis, data processing and modification in the life sciences and biotechnology has significantly helped the industry grow.

Among the companies that are spearheading efforts in this direction is

MedGenome Inc., a global leader in personalized medicine with unique genomic solutions in immuno-oncology, diabetes, ophthalmology, cardiology and other rare

diseases. Headquartered in California, USA, it has a workforce of more than 450 people across the globe with offices in Bangalore, India and Singapore.

In the above backdrop, the BioVoice did an exclusive interaction with Dr VL Ramprasad, Chief Executive Officer, Medgenome Labs to discuss the future of innovation in biotechnology industry. Do read his detailed responses below:

What role would the genomics play in the next wave of healthcare revolution and biotechnological product development?

There has been an increased awareness about genomics in the last few years. Multiple entities and stakeholders seem to be leveraging genomics in varied forms. Pharma companies are leveraging genetic data of large population cohorts to look at developing targeted therapy. There is more evidence and hence doctors are motivated to look at more precise forms of treatment and review the genetic pool of patients to analyse their risks, diseases or conditions. Patients or consumers at large are also becoming informed and asking their doctors for options for better treatment management.

The healthcare industry in general is increasingly getting aligned towards precision medicine where genomics plays an important role. Genomics is changing the future of healthcare and medicine. Proactive consumers, advancing technology in the genomics industry and the progression of precision medicine are the keys to expansion of genetics in healthcare.

The human genome sequencing allows for analysis of huge volumes of data, in turn facilitating pharma drug discovery and biotechnology product research and development. As we refine our understanding of this space and gain more experience, we further simplify our understanding of complex conditions and diseases and help find more personalized disease management solutions.

At present multiple stakeholders in healthcare industry seem to be fragmented and working with some preliminary collaboration in this space. However, the road ahead would involve leveraging techniques, approaches and technology to build an integrated network of care.

MedGenome also believes in the principle of integration and hence as a part of its business portfolio, diagnostics, research and bioinformatics capabilities are aligned and work in tandem to deliver astonishing results. We are also working in the cancer vaccine approach and immunotherapy space as the next logical extension to our comprehensive cancer diagnostic and treatment frameworks.

What is the market size of genomics industry in India and what are its growth drivers?

As per a recent report published by "Executive Summary – Healthcare Delivery Services In India – 2015 by Singhi advisors[1]", the genetic diagnostics market is likely to be growing at a rate of 28% CAGR from US $ 55 Mil in 2012 to US $ 667 Mil by 2020. The report also states that a substantial part of this growth is likely from cross platform switching. Example: Molecular diagnosis of infectious disease will make primitive tests obsolete or less important. Molecular diagnosis of cancers and other non-infectious conditions will supersede histopathology. A large part of the market remains unaddressed due to several factors apart the qualifying criteria of affordability and people at risk. Several psycho-social factors, lack of awareness amongst the doctor and patient community also contributes to lower penetration of the market.

Larger level of awareness combined with acceptance among consumers and clinicians, increasing demand for these tests and trust in test outcomes have driven investments and expansions of medical genomic industry. Leveraging genetics in areas such as cancer, reproductive health, rare diseases is now common. Infact, over time one might also see newer areas such as infectious diseases, chronic lifestyle conditions covered by these tests.

As more collaborations take place between pharmaceuticals and genetic research bodies, the targeted therapy and precise medication concepts will also soar. Constant innovations & technological advancements will lead to cost effectiveness in data generation which in turn will result in affordability for end user & higher user base for genetic testing.

Government has already initiated several genomics R & D facilities and started promoting genetic tests (in prenatal to begin with). With more involvement from government, new policies and possible collaborations with health & science department, more successful ventures could be explored.

How is the big data playing a role in identifying predictive biomarkers by the scientific community? What would be its impact?

Medical and genetic sciences have been highly affected by the generation of large data sets.

The DNA sequencing machine generates piles of data at a much faster rate and due to latest advancements, at a much lower cost. The "big data", which is a by-product of the digital revolution uncovers hidden patterns, unknown correlations, and other insights through examining large-scale data. Use of Big-data to identify biomarker is a new concept to understand genetic mutations and disease pattern across large scale data populations.

Data-driven medicine will enable the discovery of new treatment options for patients and patient care. The integration of diverse genomic data on a Big Data platform helps to identify clinically actionable genetic variants. The generalized patterns derived from big data will lead to personalized therapies though targeted treatments for specific diseases.

How do you look at the way Next Gen Sequencing has evolved in last two decades?

Next Generation Sequencing has evolved significantly in the last 20 years. It started with NGS finding application in non-research settings. A couple of companies entered the space by offering single gene sequencing in clinical settings to over time getting into complex whole genome sequencing. With more visibility, research and investments better technologies were available which allowed for faster processing of the genome and at higher throughput. This also influenced the cost of the tests which are today priced as low as US $200.

With more evidence and higher acceptance of clinical papers, adoption of these tests has increased significantly in areas such as cancer, prenatal and rare diseases. Examples are tests such as NIPT, Germline Cancer Tests, EGFR mutation tests, carrier screening, tests for muscular dystrophy etc.

What are the trends in genomic diagnostics and how is it important in making the precision care a reality?

There is an increase in the acceptance of genomics in several areas. It has found significant prominence in cancer and reproductive health. With more clinical evidence and scientific publications in these segments, there are lower apprehensions among the doctor and consumer community.

Cancer genetic testing is estimated to witness high growth owing to increasing awareness about genetic tests for cancer treatment, increasing alignment for hereditary risk assessment and an alarming high rate of cancer incidence. The market for screening of new-borns, diagnosing rare and fatal disorders will expand as well owing to poor coverage of antenatal care, poor maternal nutritional status, high consanguineous marriage rate, and high carrier rate for hemoglobinopathies etc. With higher incidence rate of hereditary & rare diseases, genomic tests are probably the only means to find disease causing variants as against the traditional methods that yield limited results.

Pharma majors are also looking at this space with great interest and investing in drugs and related companies to provide a more comprehensive portfolio of theranostic solutions With drug resistance to the existing drugs lurking as a big scare, use of human genetics during drug development can help improve the rates of success in trials phase. Example: Use of PARP inhibitors for ovarian cancers with pathogenic *BRCA1* and *BRCA2* mutations, use of 1st generation TKIs for EGFR positive lung cancer cases and so on. Recent news of GSK, 23andMe to apply personal genetics to drug discovery[3]. Recently, Novartis has received European approval for Kymriah, its gene-modifying therapy for blood cancer.

Apart this several other factors such as reduction in cost of these tests over time and possible public private partnership models is giving the usage of these tests a push.

How do you view the challenges as well as opportunities before the industry? What is your outlook for the future?

Even though genomic industry is expanding at a very high rate, there are numerous challenges that need to be addressed. First is Population Diversity and mutations. India has a vast population mix and complexity resulting in a large gap in information on prevalence and mutation profiles.

Second is Limited understanding amongst the physician community. There are very few institutes across the country that are focussed towards genetic training and education. Hence, a majority of doctors are not familiar with the power of genomics. It is important to have CME's, conferences and other awareness programs for clinicians and genetic researchers to come together and bridge this gap

Third is Access to genetic tests. Most of these tests are available at premier facilities in cities and hence India's vast rural population is either unaware or doesn't have access to them.

Fourth is Targeted Therapy. While many pharma majors have research and drug pipelines aligned towards targeted therapy, few of them are first launched in India. As many as 40-50% of the cases may not have actionable treatment for now.

Fifth is Non-reimbursed market. Genetic tests are still expensive and in a market which is non-reimbursed these would be out of pocket expenses. At present, genetic tests are not covered under Insurance..

Sixth is Regulatory Framework and govt support. The genetic diagnostics services framework is presently governed by ICMR's ethics guidelines for biomedical and research companies. Separate standards and frameworks aligning to diagnostics need to be developed. Similarly, it is important that govt support policies that can lead to better investment, expansion, infrastructure, awareness and coverage for both the industry and the end users.

The future requires companies to focus on three major aspects – awareness, availability and exploration. Today 40-50 % of the diagnostic outcomes are actionable from a treatment management perspective. With frequent new research and development in this space this will be higher over time. The key is to ensure that the stakeholders in the ecosystem – physicians, patients, families are aware of these tests and when they can be leveraged. Reach is another factor that will be critical. India as a country is spread out and it is important that this information is not limited to a few hospitals and cities. Accessibility and penetration in tier 2 and 3 cities is also critical.

We will also see more expansion in our portfolio of genetics tests. Tests aligned to infectious diseases (Tuberculosis), chronic lifestyle conditions (diabetes, heart conditions etc.). Collaboration with pharma, hospitals and government to provide a more comprehensive and integrated offering will also be critical.