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India steps closer to personalized medicine

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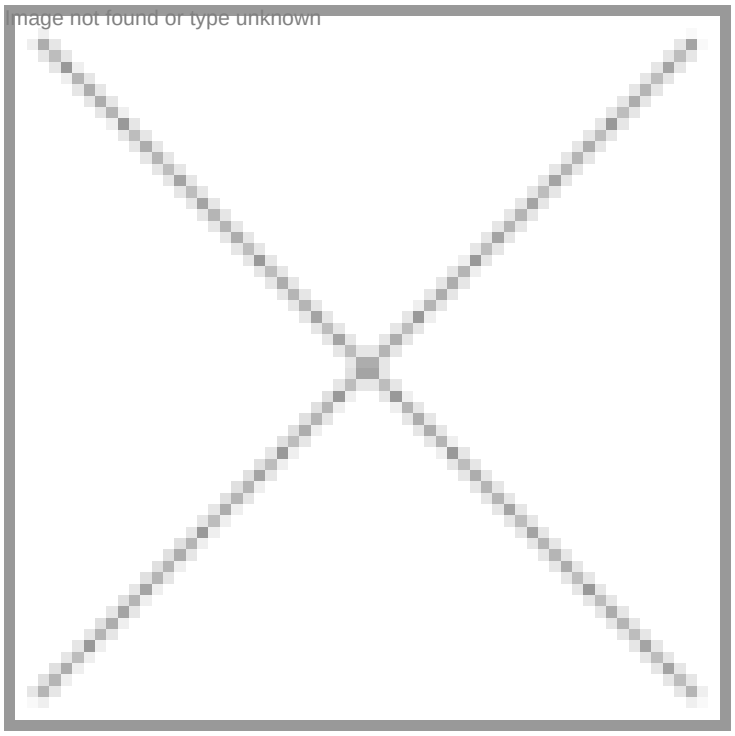
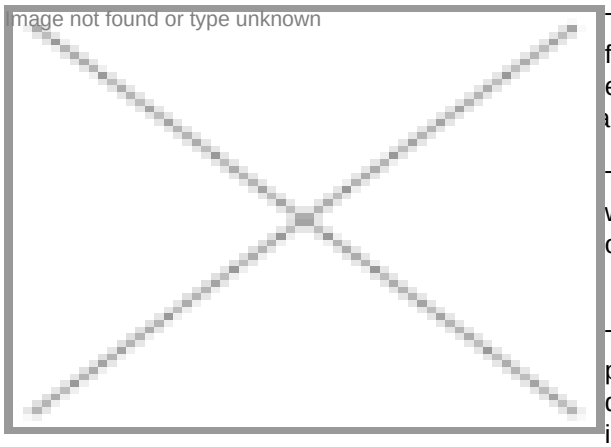


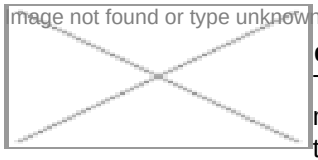
As the knowledge of genetics and genomics rapidly expand, a personalized approach to health care is becoming increasingly important. India is fast becoming a promising contender in the global healthcare arena



The majority of the global healthcare industry is ready to offer solutions for the masses. The rapidly advancing field of pharmacogenomics enables diagnostics and subsequent treatment to be 'tailor-made' for akeup.

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 cost - both physical

The lessons from several spectacular drug withdrawals including Fen-phen, Rezulin and Baycol have improved the ways to test prospective drugs, for toxicity. The role of customized therapy is becoming more important in healthcare and diagnostic industry. 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, is said to allow therapeutic companies 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.



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The existence of a large and diverse population, coupled with a high incidence of genetic disorders makes India, an ideal setting for pharmacogenomics research. Growing interest in individualized therapy to improve drug efficacy has attracted huge investments in pharmacogenomics research. India's growing capabilities in research, clinical development and bio-manufacturing, give it a decisive edge in the development of personalized medicine.

An offshoot of personalized medicine is the emergence of new age diagnostics, based on genetic and protein markers, as well as other metabolite-based bio-markers. Today's diagnostic techniques track disease progression, drug response; and are designed to customize therapy in a differentiated manner.

Many pharmaceutical companies have made significant investments in pharmacogenomics, with the expectation that it will help to eliminate the unpredictable nature of drug development, bring new products to market, aimed at preventing common diseases, and create premium pricing for their products. It is estimated that by using pharmacogenomics-enhanced drugs and diagnostics, pharmaceutical companies could benefit up t 90; 2,258 crore ($200-$500 million) in extra revenue for each drug.

Indian scientists are eagerly undertaking pharmacogenomic studies, and many companies are also shifting their focus towards this field. The notable players include Avesthagen, OncQuest Laboratories, Acton Biotech, TCG Life Sciences, Advinus Therapeutics and Jubilant Biosys.

Currently, Mumbai-based diagnostic company Acton Biotech, offers pharmacogenomics tests, to identify effective treatment for chemotherapy patients who can benefit from anti-cancer drugs like Cetuximab, Gefitinib, 5 Fluorouracil, Capecitabine, Tamoxifen, Cisplatin and Oxaliplatin. This test makes sure that patients recover effectively. Acton has tested 2,000 cancer samples for 30 genes and 10 drugs. The company is currently working on cardio-pharmacogenomics drug section; and plans to increase its range of pharmacogenomic test as the market grows.

Oncquest Laboratories, another important company in pharmacogenomics field brought to the market, Imatinib Resistance Mutation Analysis (IRMA) for chronic myeloid leukemia (CML). â€œThe success of IRMA has been resounding. Many of the prescribing physicians are showing confidence and acceptance of our experience with the assay; and have hence, helped many patients get appropriate therapy for their disease,â€? says Aditya C Burman, managing director of Oncquest Laboratories, New Delhi.

â€œThe many years of Oncquest's experience in the field of molecular diagnostics in oncology, has allowed the company to foray into pharmacogenomics, several years ago. With the launch of IRMA, the company has an in-depth look at the potential of the pharmacogenomics market in India,â€? adds Burman.

The company has subsequently launched several pharmacogenetic tests including Irinotecan toxicity, Warfarin dosing, Clopidogrel dosing, and have many more in the pipeline. Oncquest is currently working with several companies in this area, and sees many avenues for collaborative work in the future. Burman believes that pharmacogenomics is the future of medicine; and India, which is fast becoming a serious contender in the global healthcare arena, could well be at the epicentre of future breakthroughs.

Apart from private companies, public research institutions too, are actively involved in pharmacogenomic research. The Department of Biotechnology (DBT) has been receiving many proposals for funding such studies.

The recent completion of the first-ever human genome sequencing as part of Human Genome (HUGO) project in India, by scientists at the Institute of Genomics and Integrative Biology (IGIB), New Delhi, is being seen as a step closer towards personalized medicine. The Council of Scientific and Industrial Research (CSIR)-led Indian Genome Variation (IGV) project, studied 1,000 biomedically important and pharmaco-genetically relevant genes, in populations representing the genetic spectrum of India. The IGV database has information on over 1,000 genes which are involved in diseases such as asthma, diabetes, neuropsychiatric disorders, cancer, coronary artery disease, clotting disorders, high altitude disorders, retinitis pigmentosa, predisposition to malaria and other infections.

A team of researchers at IGIB is studying the pharmacogenomics of anti-psychotics, anti-depressant and anti-epileptic drugs, including their pharmacokinetics and pharmacodynamics. The functional consequence of genetic polymorphisms involved in drug response is also being studied by the IGIB team.

Another CSIR-led institute, Center for Drug and Research Institute (CDRI) has been leading the pharmacogenomics studies

in various areas of research, including the cancer biology.

The Indian Council of Medical
Research (ICMR) has recently set up a new task force on pharmocogenomics to focus on specific research topics in the field of pharmacogenomics. The task force will focus on various topics of research, including identification of genes and pathways involved in pharmacokinetics and pharmacodynamics of common drugs, and validation of human single nucleotide polymorphisms (SNP) haplotypes of short-listed genes in Indian population. The task force is also intending to conduct research on the development of an 'Indian pharmacogenomics chip'.

The ICMR center in Puducherry, an Advanced Center for Pharmacogenomics at the Department of Pharmacology in Jawaharlal Institute of PostGraduate Medical Research (JIPMER) is doing research in this field, and a team of researchers are studying the influence of genetic variation on drug response in patients.

Challenges ahead
The majority of pharmocogenomic work being conducted in India and globally, are very basic in nature; and so are the end results. Yet, this lays a foundation for many future revelations to come.

Burman adds, â€œPharmacogenomics is a combination of various scientific disciplines that gives a clear picture of individual and general population trends. Such a deep understanding of any subject would throw light on problems its practitioners face; and that holds true for healthcare as well.â€?

â€œAs more work is done in pharmacogenomics, the industry is able to introduce newer and better pharmaceuticals and companion diagnostic products. The governing bodies have acknowledged the utility of such products; and have, in many cases, guided industry to follow this path in specific instances. Globally, the pharmacogenomics-driven diagnostics and therapies have gained acceptance at a much faster rate, than its predecessors,â€? says Burman.

Aravind K Tripathi, senior researcher, Cancer Profiling & Pharmacogenomics Division, Acton Biotech, says, â€œThe field of pharmacogenomics is not immature, and it involves complex processes. Complexity in finding gene variations that affect drug response is tough, because of our limited knowledge of single nucleotide polymorphisms (SNPs). Finding the variations that occur when a single nucleotide in the genome sequence is altered, is more complex, when the three-billion-base human genome can give the possibility of finding such SNPs in millions, which plays a direct role in drug response.â€?

Tripathi, however, agrees that the field of pharmacogenomics has not gained enough popularity. He attributes it to the lack of exposure of molecular biology among doctors; high costs of these tests compared to cost of treatment; longer turnaround times and lack of bedside technologies; lack of skilled manpower and smaller market size; and hence lack of investment in marketing these tests.

Introducing multiple pharmacogenomics products to treat the same condition for different population subsets, is undoubtedly, a complicated process, in terms of prescribing and dispensing drugs. Apart from these, inherent problems regarding the time and cost associated with the development of diagnostic tests, remain a major restraint for market growth. Moreover, obtaining intellectual property for pharmacogenomic tests pose significant challenges for companies. Therefore, it is essential that the Indian governments' patent systems offer protection for innovations related to personalized medicine.

Among different countries, the European pharmacogenomics market is the largest revenue generator, primarily due to the high level of awareness about pharmacogenomics among medical professionals as well as the public. Following the European market is the US, which has radically changed the emphasis on disease management uniformity; focusing more on individual patient management and personalized medicine.

Burman of OncQuest believes that there are two main driving factors for this industry. The first is the aforementioned R&D being conducted by pharmaceutical and molecular diagnostic companies. He says, â€œThis is imperative to set the groundwork for a robust pipeline of products that will target several disease segments. In addition to this, efforts need to be given to reducing costs for such tests and treatments, without which it would remain out of the majority of the global population.â€?

The second, and perhaps the most important driver, he mentions, is educating the healthcare providers to the proper use of these products; and to facilitate them in formulating appropriate treatment plans for their patients. Without the explicit involvement of treating physicians, these products would stay primarily in the research laboratories, and would rarely make it to the mainstream.

Sandeep Saxena, founder & CEO of Acton Biotech, Mumbai, says, â€œThe driving forces for the Indian pharmacogenomics market will be the development of cost-effective and rapid methods, equipment, and kits for the diagnostic tests. With prices

coming down, pharmacogenomic tests will find a larger market, and hence attract investments. Significant investments are needed in educating doctors about the basics of molecular biology, clinical significance of these tests; and publish papers relating to drug response and Indian patient genetics.â€?

According to Sandeep Saxena, extending partnerships with pharmaceutical companies, medical device companies, large hospital chains and teaching hospitals is vital for growing pharmacogenomics market in India.

Jahanara Parveen (with inputs from Rahul Koul)