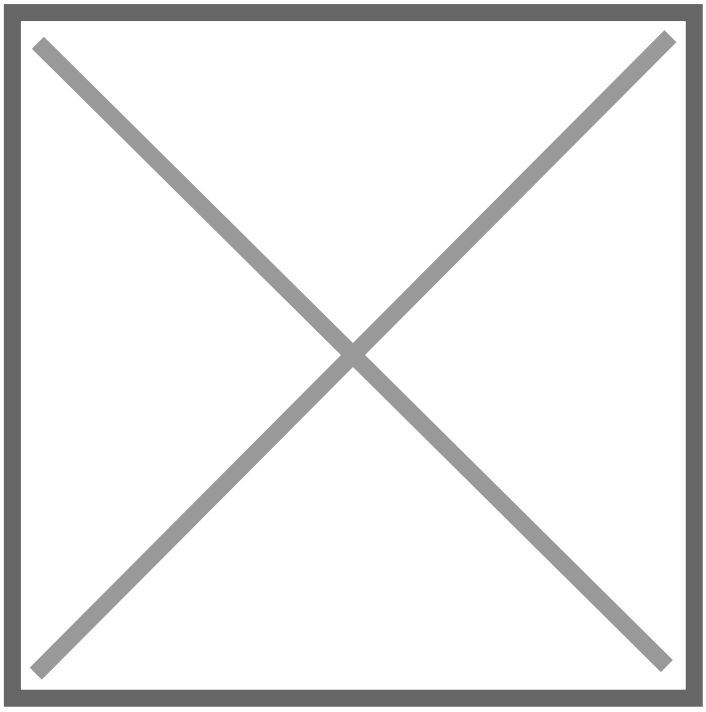
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The Age of Theranostics

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Medical practice is undergoing a radical transformation in the post-Genomic era where disease management is demanding more advanced diagnostics that are designed to work on an individual rather than a population level thus spearheading the age of personalized medicine. Future trends indicate that diagnostics will need to focus on the internal manifestation of the disease i.e. genotypes rather than the outward manifestation of disease which are based on symptoms that physicians refer to as "phenotypes".

The era of pharmaco-genomics

The seeds of personalized medicine were sown in 1998 at Mayo Clinic, Rochester, USA when a team led by Dr Weinshilboum made a groundbreaking discovery that explained why a childhood leukemia drug, Azathioprine, which proved efficacious in most children, caused fatality in some. The fatality was pinned down to a missing enzyme, TPMT (Thiopurine methyltransferase) which led to the build up of the drug and caused acute bone marrow failure. The missing enzyme was attributed to a faulty gene and thus began the era of "pharmaco-genomic medicine". Since then, a large number of commonly used drugs have been known to have variable drug responses thus questioning the "one drug fits all" approach taken by pharmaceutical companies. In the recent past, several drugs have failed on account of extremely variable efficacy which in most cases is attributable to genetic mutations. A good example of this is Astra Zeneca's drug Iressa for Non Small Cell Lung Carcinoma which proved to be efficacious in only 10 percent of patients, eventually linked to a specific gene mutation. Genentech's Herceptin, a monoclonal antibody for breast cancer is likewise dependent on the over expression of the HER 2

gene.

Theranostics

The new medical approach to disease management looks at disease as a process rather than a state, where tracking disease progression will allow for better therapy. Gene regulation and other bio-algorithms will form the core of a new wave of diagnostics that are now being referred to as "theranostics."

Theranostics are designed to diagnose diseases at their stage of progression to enable the careful and accurate selection of a treatment regimen and further to monitor the patient's response to the said therapy. In short, theranostic tests can determine a patient's response to a specific drug therapy, or guide and assist in choosing the correct and most efficacious treatment regime. Companies such as Roche Diagnostics, Millennium Pharmaceuticals and others are investing in this nascent sector. The European Diagnostic Manufacturers Association (EDMA) believes theranostics, pharmacogenomics and genetic testing are the new market drivers for medical intervention and preventative medicine, aimed at providing improved and cost effective healthcare. Bayer Diagnostics forecasts that the theranostics market will grow by 20 percent per year until 2010.

India as the hub for differentiated medicine

India offers, perhaps, one of the most affordable development bases for personalized medicine. Developing well validated personalized therapies will demand extensive clinical data to be generated from well differentiated patient populations. India and China are clearly the two countries with the most desired disease and patient profiles that can enable such studies. Coupled with this is the need for a large number of novel diagnostics based on gene and non-gene based platforms that are both predictive and qualitative in terms of disease status. These are clearly large opportunities for Indian biotech companies to pursue. Personalized drugs also address the affordability factor for expensive therapies such as those that are involved with cancer where early diagnosis and new diagnostics can substantially reduce dosages and even eliminate expensive chemotherapy in certain cases.

IT and new medicine

The advent of personalized medicare will require a strong informatics approach that combines both software and biotech skills in augmenting high-speed data mining of both genotypic and phenotypic information with a view to evolving new forms of medical diagnostics and therapies. Genomics and Proteomics are churning out endless reams of data which need to be statistically evaluated and harnessed for commercial end use. India has a powerful advantage in addressing these emerging opportunities in personalized medicine through its well developed capabilities in information technology. It is envisaged that in the years ahead there will be a number of collaborative initiatives between software, biotech and pharma companies.

The healthcare challenge

Healthcare bills all across the world are mounting. Whilst developing nations are burdened with infectious diseases, AIDS, TB, diabetes, SARS and the like, developed nations like the US, Japan and European countries are seriously addressing the burden of diseases caused by their aging populations. Both types of disease burdens will have to focus on preventative medicare. Developing countries will need to invest in large scale immunization whilst the developed world will need to manage "wellness". Both approaches have to find innovative ways to minimize hospitalization and surgical interventions. Managing "wellness" as opposed to treating "illness" is therefore the new mantra for health care management the world over.

India's window of opportunity

Although India is well positioned to address these emerging opportunities in personalized medicine, government policies are not in place to take full advantage. Investment is inadequate, funding is still scarce, infrastructure is expensive and regulatory regimes are deficient. These trends in modern medicine will not wait for India to get its act together. India has but a narrow window to seize these opportunities. There are hopeful signs in the right direction: There is already a perceptible paradigm shift in the research culture in our scientific institutions which seeks to partner more closely with Indian industry. Added to this is the re-orientation of our hospitals and medical centers from merely delivering medical services to research based disease management. These institutions are rapidly transforming themselves into high quality clinical development hubs for new drugs, new devices, new diagnostics and new therapies.

Gene therapies and stem cell therapies are slowly making visible progress the world over. Given the strong political support that stem cell research receives in India, it is important to make rapid strides in this nascent domain to surge ahead of other more scientifically advanced regions that are mired with political and religious road blocks.

The success of building a global business in personalized medicine is going to depend on the ability of Indian biotechnology to apply its people resource in a knowledge intensive manner to create unique niches in pharamco-geneomics, clinical research and new therapies and for government on its part, to provide an enabling regulatory environment that will make all this possible.