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Time for developing swadeshi kits

07 February 2008 | News

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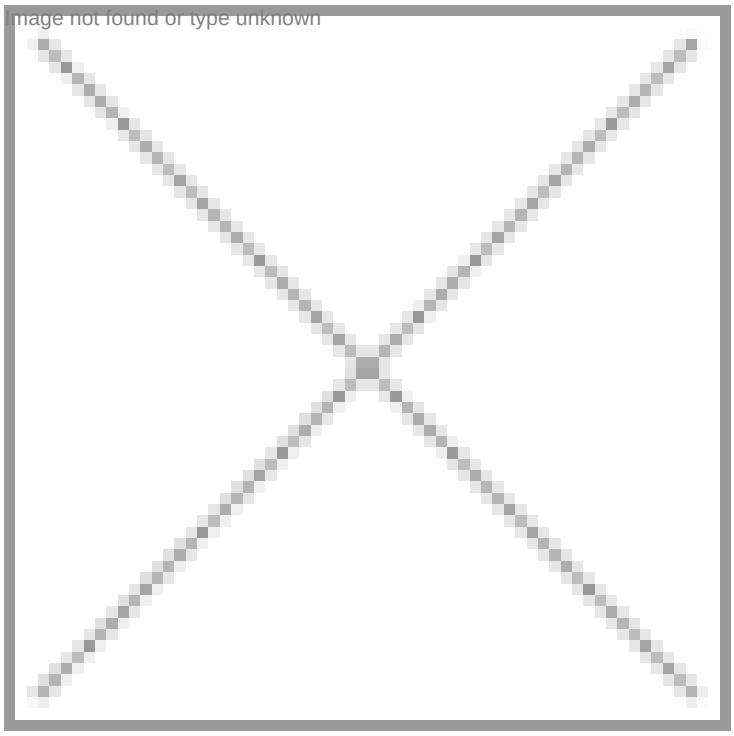

Time for developing swadeshi kits

The biggest driver for molecular diagnostic technologies is the promise of better preventive and therapeutic drugs

India has, in recent years, emerged as a very strong global player in the area of biotechnology. Availability of intellectual capital, skilled manpower, developed infrastructure and the biodiversity in terms of human gene pool are some of the major strengths of the Indian biotechnology industry. It is anticipated that the consumption of biotech products in India will grow to approximately $4.3 billion in another three years. Revenues to the tune of $5 billion are expected to be generated by the biotechnology sector and one million skilled jobs will be created through products and services in the next few years. In wake of this, it is natural that venture capitalists are eyeing biotechnology as one of the thrust areas of investment opportunity. As Dr MK Bhan, secretary, Department of Biotechnology (DBT) said, "the field of biotechnology is not only good business, but it also produces wonderful solutions for our health care, our agriculture, our environment and indeed for creating more environmentally friendly manufacturing technologies". The DBT has invested over Rs 1,000 crore in public research institutions alone since its inception in 1986. There exists several opportunities for venture capitalists in biotechnology such as biopesticides, biofertilizers and diagnostics.

Molecular diagnostics

Dr MK Bhan, secretary, Department of Biotechnology, Government of India, addressing the delegates during the workshop on "Opportunities and Limitations in Developing Diagnostics: Road Map for the Swadeshi Kits" organized by Yashraj Biotechnology, Navi Mumbai.

Diagnosis by employing modern day technological tools is of paramount importance in the clinical management of patients. Over the years, a variety of diagnostic assays have been developed, the availability of which has shown immense potential in therapy. Within the broad umbrella of diagnostics, the traditional methods often become of clinical use after the onset of disease or after the appearance of clinical or subclinical symptoms. On the other hand, with molecular diagnostic tools, it is feasible to detect pathogens even before they manifest their action on body functions, as well as identify the individuals who are at risk of developing a specific disease in their life span. It is also now possible to predict the course of some diseases, evaluate the efficacy of drugs in the form of patient's genome and prescribe alternative and efficacious drugs using gene or non-gene based diagnostic platforms. It is in view of this potential that the biggest driver for molecular diagnostic technologies is the promise of better preventive and therapeutic drugs. The discovery of the human genome and the subsequent expansion of proteomics research combined with other emerging technologies are facilitating the development of need-based personalized technologies as well as therapies.

Another major advantage of most molecular diagnostic testing is that these tests can be performed on very small amounts of tissue and other biological materials obtained using different types of procedures, including small biopsies, fine needle aspirates and also archived material. One of the major areas where molecular diagnostic testing can be of great benefit is oncology. It is now possible to detect small numbers of malignant cells in cytological preparations or biopsies through the clinically validated use of clinical markers. Molecular signatures can help in the detection of minimal residual or recurrent disease and can help distinguish a metastasis from a second primary tumor. Genotyping can effectively detect minimal residual disease and classify lymphoma subtypes. Now it is also possible to detect somatic genetic alterations of solid tumors in clinical settings. Tools are available to provide a molecular fingerprint of tumors that are predictive of the response to specific therapies. It is anticipated that application of molecular pathology and molecular diagnostics will further revolutionize the drug discovery and development process, customize the selection, dosing and route of administration of existing and new therapeutic agents, and truly personalize medical care.

Double-digit growth

It is widely anticipated that during the next five years the molecular diagnostic industry will continue to grow at double-digit pace to meet increasing demand for rising incidence of infectious and vector-borne diseases which account for over 325 million disability-adjusted lost years per year. In addition, India is also becoming a hub for diabetes, cardiovascular diseases and a variety of cancers. Above all an increasing educated public will demand more information about their predisposition for serious diseases and how these potential illnesses can be detected in an early stage when they can be arrested or cured with new therapies custom-designed for their individual clinical status. To respond to this demand, the pharmaceutical companies will have to develop more efficient and less toxic integrated personalized medicine drug and test products.

The global molecular diagnostic industry which was about $3 billion two years back is expected to expand to $12 billion in 2010 and $35 billion in 2015. The in vitro diagnostic market in India is about Rs 800 crore accounting for less than one percent share of the global market. The Indian market is growing by almost 15-20 percent annually. In India most of the molecular diagnostic tests are carried out through kits, which are imported and expensive. For example, the cost of PCR-based assays for different pathogens in India is in the range of Rs 1,300-2,000 per assay, which is beyond the affordability of a common man without any health insurance. These costs can be drastically reduced by developing indigenous assays. Availability of affordable, sensitive and specific diagnostic methods is expected to change the face of medical care in our country. It is therefore essential to focus on technological advances such as in vitro diagnostics, noninvasive diagnostics and point of care diagnostics, which could lead to major improvements in the accurate detection, characterization and diagnosis of human diseases, as well as keep the costs low.

Navi Mumbai-based Yashraj Biotechnology Ltd (YBL) is one of the Indian biotech companies that is focused on molecular diagnostics. YBL uses the proteins purified from human biomedical waste as reagents for the development of indigenous kits.

Thrust on swadeshi kits

In an endeavor to develop cost effective diagnostic kits and indigenize the technologies, YBL and the DBT had recently organized a workshop entitled "Opportunities and Limitations in Developing Diagnostics: Road Map for the "Swadeshi" kits. The meeting identified the unmet needs in the area of diagnostics in the country, debated on whether these technologies be bed-side or laboratory-based, the potential target users of such technologies, and the need for public-private partnership in such ventures. Development of diagnostics on the principles of immunology, DNA detection system and instrumentation were debated at the workshop. Another area of diagnostics of potential future application considered was the use of nano-diagnostics and miniaturization technologies which have been recognized as promising solutions to provide low-cost microchips for diagnostics.

The meeting identified areas pertaining to infectious and vector borne diseases, where development of appropriate diagnostic tools could possibly have a major impact on the global human health. The discussion focused around development of diagnostics for cancers, acute lower respiratory infection, HIV, diarrhoea, malaria, tuberculosis, and sexually transmitted infections. These diseases result in a significant loss of human life.

Indigenization of such technologies will have to factor in several aspects like affordability, wide range of ambient temperature in the country, and availability of minimal essential infrastructure support including water and electricity. The challenge therefore lies not only on the technical front but also on development of an appropriate user interface.

This initiative of YBL and the DBT to bring the industry and the academia together will pave the way for speedier development of diagnostic and therapeutic products. The workshop therefore raised hopes and opportunities to develop "Swadeshi kits" for diagnosis of various diseases. Consortium approach of bringing academic institutions and industry on the same platform, which is mutually beneficial, is essential. While the academic institutions would generate new knowledge and intellectual property, the industry would ensure that the research done is useful, relevant and applicable in real life. In addition, the industry can also augment the meager resources generally available to the academic institutions through government agencies. In fact a tripartite agreement between the three institutions at the conceptual stage of a project would see more dreams turning into reality. To accelerate the development of molecular diagnostics, it is also essential to establish dedicated centers for research, development and evaluation of novel molecular diagnostics and their constituents. The vision of these centers should also be to ensure that the diagnostics are affordable and easily available to the common man.

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