

Diagnostics shifts focus

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Molecular diagnostics addressing the pharmacogenetics testing segment will make up the lion's share of market growth.

The global outlook for medical diagnostics is very promising for the current decade. Growing at a double-digit rate annually, it is set to be one of the most profitable sectors in the life sciences industry. The multi-billion dollar industry includes in vitro diagnostics (IVD), in vivo diagnostics and medical imaging. The \$10 billion medical imaging segment primarily falls in the monitoring and detection realm as its offers hardware or the physical equipment/devices in diagnostics. Companies that dominate this space are GE, Siemens Medical, Philips and Kodak Healthcare.

As a whole, medical diagnostics has played a crucial role in diagnosing cancer, cardiovascular disease (CVD), infectious diseases, diabetes and age-related neurodegenerative diseases such as Alzheimer's and Parkinson's. The big names in this industry are Roche, Abbott, Bayer, Dade Behring and Beckman Coulter. In 2004, the worldwide IVD market was pegged at \$28.5 billion with Asia Pacific region and Japan contributing nearly 12 percent. Currently, Asia contributes a miniscule percentage to the whole. However, with big companies such as Roche, Bayer and Beckton Dickinson investing in Asia, the region is set to experience a boom in the field of IVD, particularly in the molecular and immuno-based diagnostics solutions segment.

The shifts-in-progess

Medical imaging to aid diagnosis: Imaging will remain a dominant method to diagnose and treat diseases. The outcomes will be more crucial as they form the basis for many clinical decisions to be taken.

Pharmacogenomics to rule the roost: Molecular diagnostics addressing the pharmacogenetics testing segment will make up the lion's share of market growth. Currently, the second largest market sector after diagnostics

for infectious diseases, the pharmacogenomics sector is projected to take-off from its current \$3 plus billion in revenues to more than \$60 billion in 2016.

Companies shift focus: Pharma companies such as Roche and Novartis turn to personalized medicine to help improve the drug development process and speed the approval of new drugs.

Cost and safety: Modern diagnostics from now on will address two key healthcare challenges - cost and safety.

"Asia has a great potential for diagnostics - it's not just about its market size or high growth rate of sales. Owing to the increasing demand for improved medical products and safer, more effective healthcare services, Asian governments are increasing budgets for achieving higher healthcare standards," said Lucy Lu, vice president, Roche Diagnostics, while making a point, at a diagnostic event in Singapore, in 2006.

IVD in cancer and cardiovascular disease

In vitro diagnostics, which essentially mean testing in a lab or in a controlled environment, has led to many breakthroughs in disease detection and treatment. Its greatest contribution however, has been in the field of cancer detection. The innovations in IVD led to the development of new testing technologies in areas of cancer risk assessment, screening, prognosis and treatment monitoring. Global research firm, Frost and Sullivan valued the US cancer in-vitro diagnostics market at \$881.5 million in 2005 and predicts it will touch \$2.3 billion by 2012. According to Nobel Laureate and President of the Fred Hutchinson Cancer Research Center in Seattle, Dr Lee Hartwell, IVD and molecular diagnostics can pave the way for effective cancer management. In 2001, Dr Hartwell received the prestigious Nobel Prize in Physiology for his groundbreaking discovery of the universal mechanism that controls cell division in all nucleated organisms, from yeast to frogs to humans. He used yeast as a model organism to harness the tools of genetics to study how cells function and determined which genes cause cells to divide. He provided important clues to cancer as his discovery gave a new point of departure for many scientists worldwide to explore ways to stop abnormal cells from dividing." Cancer is a unique disease because mutations can distinguish cancer cells from other somatic cells. Today, DNA changes in cancer cells are being used to diagnose the risk of the disease, early detection, prognosis, therapeutic response and disease recurrence. Protein biomarkers combined with the advances in functional imaging can vastly improve the cancer management," Dr Hartford said.

How medical imaging helped cancer detection over decades

- 1950s
- Nuclear medicine was introduced to treat cancer of the thyroid and diagnose thyroid.
- X-ray angiography introduced to understand at what stage the cancer is.
- Evolution of ultrasound that used high frequency sound waves to show internal tissues and organs.
- 1960s
- Nuclear medicine gains more importance as it helped to identify cancer hot spots and blood flow to the lungs.
- 1970s
- Mammography introduced to detect breast cancer. This used x-rays to detect pre-cancerous tumours.
- 1980s
- PET (Positron emission tomography) scanning introduced in 1985 helped in managing cancer better by indicating metabolic changes in tumors.
- Interventional radiology was introduced. This used various imaging technologies to help catheters and miniature tolls through blood vessels to deliver treatment directly to cancer site.
- During this decade medical imaging became an essential cancer therapy. More and more clinicians used imaging to detect tumors and manage cancers.
- 1990s
- Image guided breast biopsy and digital spot-view mammography developed. n Use of MRI and brachytheraphy for cancer gains momentum.
- 3-D imaging was introduced to map the tumors more effectively.
- 2000s
- Clinicians started using intensity-modulated radiation therapy that uses 3-D images from CT scans to map the cancer precisely.
- Computer aided diagnostics (CAD) became a reality. Clinicians started using computer algorithms to verify scans. CAD systems increase cancer detection rate by 33 percent.

After cancer, the next health concern globally is cardiovascular disease. As heart attack and stroke still remain the leading causes of morbidity and mortality worldwide, there is a huge demand for in vitro diagnostic tests that can address issues such as early diagnosis and detection of predisposing factors. Analysts predict a surge in demand for such tests in the future.

Currently, this market has seen a steady growth of 12 percent, from \$14 billion in 2001 to \$2.2 billion in 2006.

Medical imaging

A key market segment of medical diagnostics that has helped tremendously in detection and treatment of cancer and CVD is medical imaging. It involves activities such as X-ray and radiography, mammography, magnetic resonance imaging (MRI), ultrasound, computed tomography (CT) scans and positron emission tomography (PET) scans. In cardiovascular diseases, imaging technologies such as ultrasound and MRI, provide high-resolution images of arteries, the vascular system, and the brain to identify blockages or the thickening of the artery lining. CT scans, diffusion-weighted imaging, and PET help physicians in assessing whether surgery to clear clogged arteries that supply blood to the brain is needed. Imaging tests also provide rapid information about the nature and location of stroke, and the extent of brain injury, thereby allowing physicians to make judgments rapidly about which treatment approach is best.

The Human Genome Project and what it meant for diagnostics

The Human Genome Project, the mapping of our 30,000-50,000 genes and the sequencing of all of our DNA, has a major impact on biomedical research and the whole of therapeutic and preventive health care. The tracing of genetic diseases to their molecular causes is rapidly expanding diagnostic and preventive options. Since most common diseases have been shown to be influenced by inherited variations in our genes, completion of the Human Genome Project and mapping of the human genome single-nucleotide polymorphisms will have a tremendous impact on our approach to medicine. New developments in genotyping techniques and bioinformatics, enabling detection of single-nucleotide polymorphisms, already provide physicians and scientists with tools that change our understanding of human biology. In the near future, studies will relate genetic polymorphisms to features of critical illnesses, increased susceptibility to common diseases, and altered response to therapy.

Source: American Cancer Society

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