Sustaining Malaysia's Future

The Mega Science Agenda

AKADEMI SAINS MALAYSIA

Health

A MEGA-SCIENCE FRAMEWORK FOR SUSTAINED NATIONAL DEVELOPMENT (2011 – 2050)

EPILOGUE

1. Introduction

Science has been universally touted as the main engine of economic growth and national development. Science from its Latin name 'scienta' means knowledge. A knowledge-based economy is essentially a science-based economy. New knowledge i.e. "science" is generated by undertaking research, experiments and strategic studies or R&D. R & D and strategic studies provide the means to fulfill market needs and find solutions to various problems. The results and findings are delivered in the form of new or enhanced knowledge, technology and products or services. This results in productive economic activities which contribute to wealth creation and economic growth.

Malaysia, as a country, should adopt the concept of a Mega-Science Framework as a comprehensive vehicle to drive the use of science, technology and innovation (STI) to contribute towards economic growth. Mega essentially means big, therefore the discipline of Mega-Science implies a pervasive (broad-based), intensive (in-depth), and extensive (long period of engagement) use of science or knowledge to produce technologies, products and services for all sectors of the economy to derive economic growth and development. It also calls for extensive investment in research activities to enhance the knowledge base for the targeted sectors. Since knowledge in marketing and finance is equally important in promoting the success of a commercial venture as compared to technical needs, it is envisaged that the Mega-Science approach will require research to be conducted both in non-technical sectors as well as in traditional scientific sectors.

2. A need for national knowledge generating mechanism

As we are aware, national economies are classified into 5 sectors namely: agriculture, mining, manufacturing, construction and services (Table 1). Efforts to generate knowledge by establishing research institutions and universities and centers of excellence to support agricultural, mining and manufacturing sectors are well established. The construction and services sectors are also dependent on new knowledge and technology in order to progress and remain competitive.

R & D and strategic studies are also necessary to drive the development of these two sectors.

Table 1 NATIONAL ECONOMIC SECTORS (% OF GDP)

SECTOR	2010*	2015**
SERVICES	58.5	61.1
AGRICULTURE	7.6	6.6
MINING	7.9	5.9
MANUFACTURING	26.2	26.3
CONSTRUCTION	3.2	2.9

*Source:*Economic Report 2009/2010 (MoF)*
***RMK10 Report (EPU)*

The Mega-Science approach would emphasize the need to strengthen R & D and strategic studies to be undertaken in these non- traditional sectors. For example, to enhance the development of the tourism industry (service sector), dedicated R&D and strategic studies should be undertaken to generate new knowledge that will lead to the delivery of new tourism products, services and innovative strategies which will improve competitiveness of the industry. Similarly, research studies, market surveys and financial models are proposed especially for the services sector as the knowledge created will fulfill a need or solve a problem which eventually will generate revenue and contribute to economic growth. The Mega Science approach therefore identifies R&D and strategic studies as the key enablers to economic growth in all targeted sectors of the economy.

3. A need to invest sufficiently in knowledge creation: R & D and knowledge acquisition

To become a high income developed economy, Malaysia as a country has to intensify knowledge generating capacity by investing in R&D and strategic studies. The expenditure in R & D must reflect the norm usually associated with countries having a developed economy. While past

expenditure in R & D for Malaysia as a developing country has hovered at 0.5% of the national GDP, the present and future rate of spending should be increased to above 2.0% as benchmarked against the rate of spending for countries with developed economies (Figure 1). Towards achieving this goal, it is proposed that the Government formalize the rate of spending of 2% and above through the promulgation of a Science and Technology Act ("S&T Act"), which is long overdue.

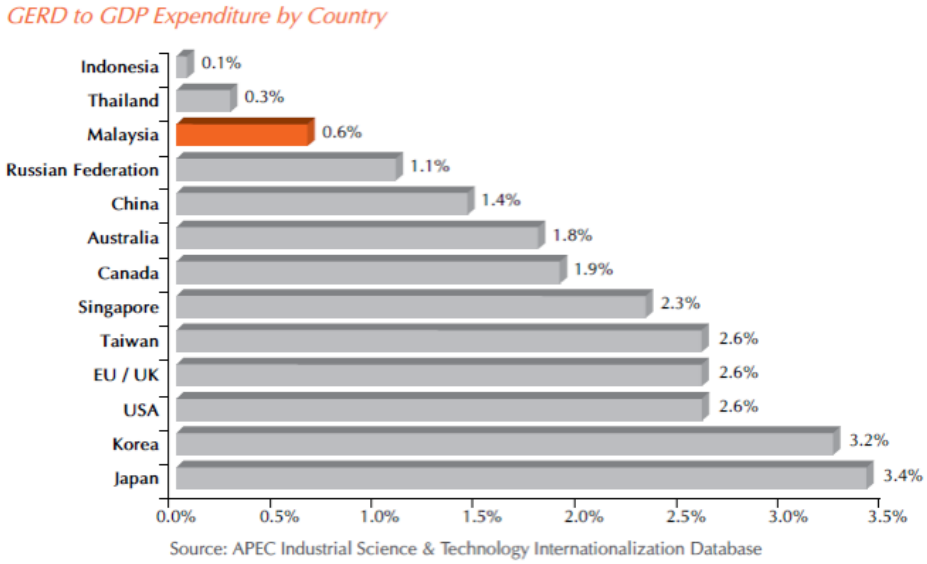

Figure 1 Malaysia's Low R&D Investment

R&D needs a long lead time before beneficial results can be harnessed to contribute to the economy through commercialization of research results and development of expertise (Figure 2). To fulfill the need to have pervasive, intensive and extensive R&D activities and satisfy the long lead time needed for R&D to mature, bold up front investments in R&D spending will be necessary. While this is financially difficult to reconcile, extensive and expensive upfront investment in R & D is necessary and forms a critical dimension of the Mega-Science Framework approach. These long lead times from R&D to Commercialization are amply demonstrated in Malaysia in the rubber and palm oil sectors of agriculture. In rubber, we took some 50 years to see Malaysia "topping the world" in rubber technology since initiating R&D in rubber. Similarly, in palm oil, Malaysia took about 40 years to "top the world".

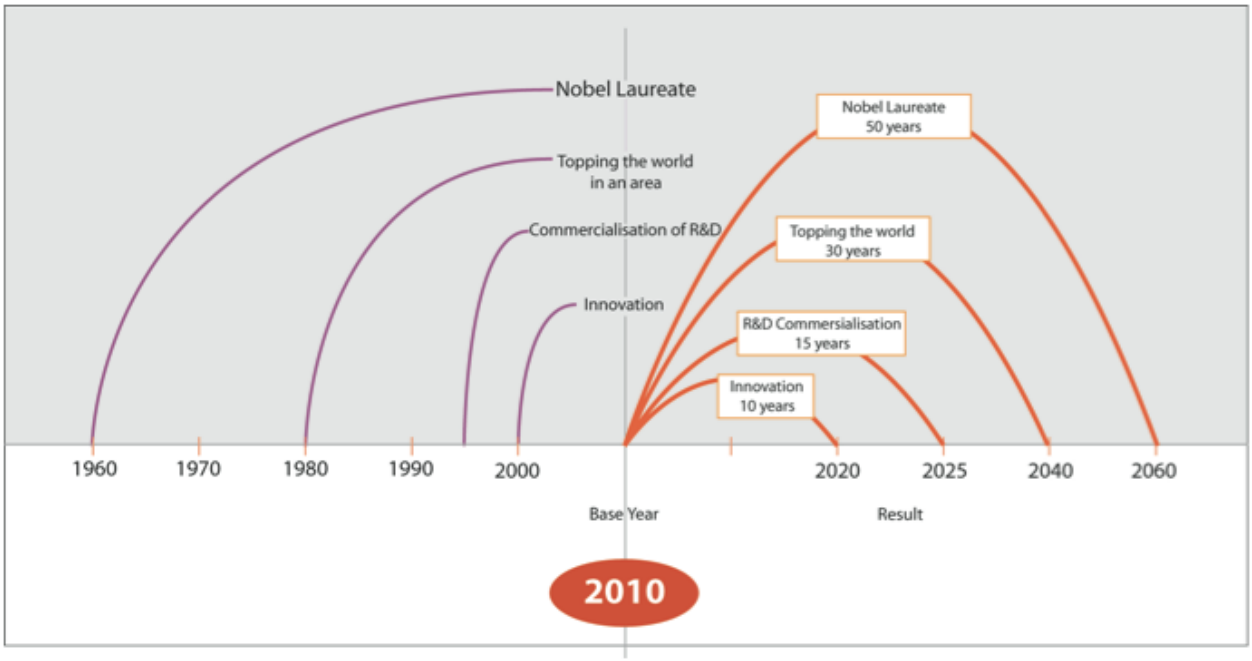

Figure 2 Time Lag on Increase in HR and R&D Investments and the Resultant Key Indicators Stimulating Economic Growth

Although a certain amount of knowledge, technology and research inputs may be imported especially through FDI activities, these are often out-dated or out-of-sync with business and economic needs. Therefore, the process of knowledge renewal and enhancement must continue to be undertaken for the country to remain competitive.

4. A need to manage knowledge generation and acquisition nationally through private and public sector participation

The Mega-Science Framework looks at national efforts in generating new knowledge and STI deliverables. The country's science infrastructure must exist to help deliver the desired results. The science infrastructure should also ensure the evolution of more R&D to be undertaken by the private sector vis-à-vis the public sector as is typically found in a developed country economy.

The present proposal to establish the National Research Council (NRC) and the National Innovation Unit (UNIK) should be encouraged as these provide the management function of ensuring that funding and management for R & D and strategic studies will be maximized. A significant role of ensuring the timely development and availability of STI deliverables for economic growth must be emphasized. In this respect, the role of MIGHT and other Technology Development Corporations in technology foresight scoping, development and acquisition are highly crucial especially bearing in

mind that some technologies can be obtained through offset programmes of government international tenders.

5. Knowledge gaps in various economic sectors

In the past, economic growth was a function of knowledge (technology) and capital accumulation. Past investments in R&D in the relevant sectors would have generated knowledge to stimulate economic growth. Continuous knowledge enhancement (training) or accumulation of human capital development (expertise) adds to facilitate and accelerate economic growth. The serious lack of researchers in basic and applied sciences has to be urgently addressed such that it does not hamper the generation of knowledge and hamper sustained economic growth of the nation (Figure 3).

Future economic growth may be limited by natural limits to growth effected by population growth and excessive demand for non-sustainable and non-renewable resources. There is the possibility of reaching limits of environmental carrying capacity. Therefore, future economic development may not only depend on accumulation of capital and technology, but also on natural resources including energy and land, and the carrying capacity of the environment. These additional factors of economic growth must be factored in to the future development of the country's economy.

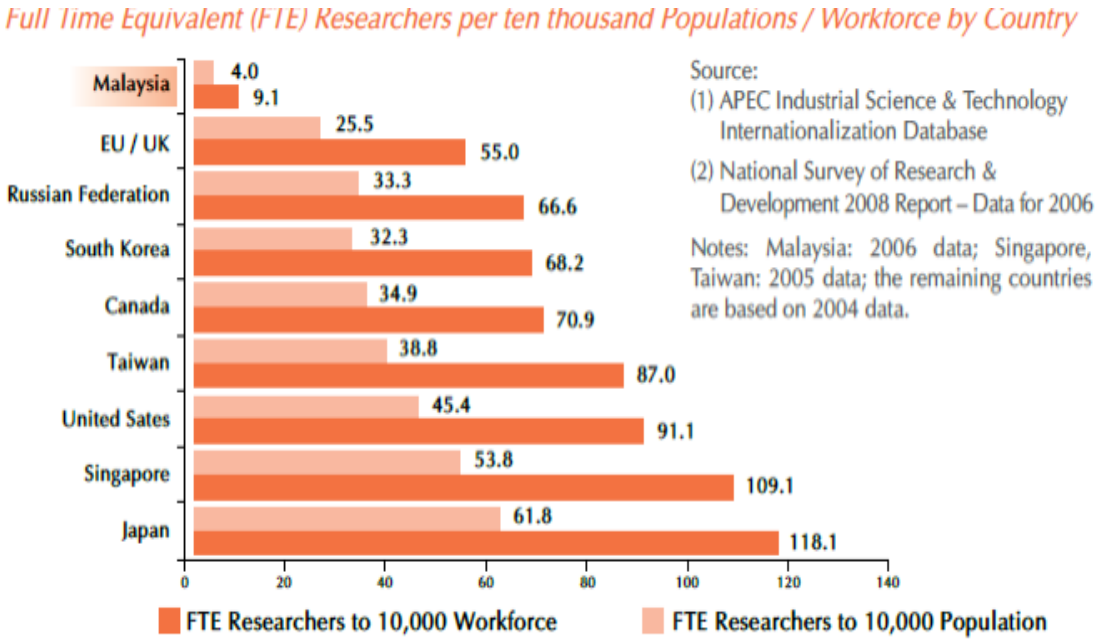

Figure 3 Low FTE Researchers – A Barrier to Sustained Economic Growth

To sustain future economic growth in Malaysia, investment in knowledge creation must be continued or enlarged. The knowledge creation (R&D) function of the Mega-Science Framework will rightly identify and address these needs.

6. Malaysia needs to intensify knowledge generation in niche sectors

Part of the Mega-Science Framework calls for pervasive, intensive and extensive use of science to identify and develop competitive knowledge and STI opportunities for commercialization in various sectors of the economy. Subsequently, another part of the Mega-Science Framework will require prioritizing of sub-sectors so that returns to strategic R&D investments are maximized. This will naturally lead to more efforts being devoted to developing of niche key sectors where Malaysia has certain competitive advantages.

Identification of the niche sub-sectors may employ the process of consultation and short term evaluation of opportunities such as the "laboratory retreats" studies undertaken by the Malaysian government recently. In addition, long term development of niche areas at the national level and the private sector will be necessary. The process is iterative. The more the investment in knowledge (R&D and STI development) the more will be the discovery of niche areas for commercial exploitation where Malaysia has the competitive advantage. But in-depth knowledge developed through the Mega-Science Framework is firstly needed to identify the niche areas.

7. Sectoral knowledge gaps and STI requirements

Studies of various economic sectors have identified the need to invest in knowledge gaps to sustain current and future needs, maintain competitiveness and contribute to the country's economic development. Firstly, cost must be kept optimally low and secondly revenue must be maximized. Ideally, the sector will generate enough commercial revenue to cross-subsidise the need to maintain the sector at minimal cost. For example, in the health and medical sector, knowledge enhancement is continuously needed to maintain the capacity of the sector to provide a high standard of health service. Efforts include promotion of preventive activities which will reduce health treatment in the long run. But there are also opportunities to generate revenue by supplying and exporting competitive health services and products such as health tourism which can contribute directly to economic growth. Similarly, in the Water Sector, ASM's Mega Science Study has identified opportunities in S&T in various niche areas.

In the biodiversity, energy and agricultural sectors which have been subjected to the Mega-Science Framework Studies undertaken by the Academy of Sciences Malaysia (ASM), it was found that the knowledge creation and STI application opportunities and gaps exist in both the home consumption

and exportable components of each sector. The defense sector could similarly fall into the two categories of development, and as more economic sub-sectors are evaluated in the future under the Mega-Science Framework Studies, the pattern will probably be the same: the need to develop both the home consumption and exportable components of the sector in order to improve the country's standard of living directly and to generate revenue for increased income.

Examples of gaps in STI adequacy and niche opportunities have been identified during the Mega-Science Framework Studies undertaken by the ASM recently. The examples clearly show that Malaysia has many niche areas for STI development for commercial exploitation especially for the export component. It is also noted that a sector with well developed export component will also provide for adequate home consumption needs. It implies that developing the export component of a sector should be given greater focus and priority as this will serve to also develop the home consumption sector to bring about improved standard of living while increasing revenue and income.

8. Lubricating the Engine of Growth

The Mega-Science Framework advocates the pervasive use of knowledge and proposes the use of STI as the main engine of economic growth and national development. An engine does not function without lubrication. To facilitate the smooth or lubricated functioning of STI, human resource expertise must be adequately available. Fortunately, the enhancement of expertise of human resource is achieved through the same engagement in knowledge creation process (R&D) and other forms of knowledge enhancement process (training) at universities, research institutes and training centers. The more people are involved in R&D and STI development; the better will be the available expertise of the country. R&D investments therefore contribute to expertise and knowledge enhancement of human resource.

Another dimension of the lubrication process to the engine of growth is the level of income itself. There exists an iterative cycle in the relationship between intensity in investment in R&D and the level of income of the country. The higher the R&D expenditure the higher will be the income level. The higher the income level, the higher will be the R&D expenditure. To break this vicious cycle, it is necessary to adopt a strategy of a high income economy, similar to what the country is currently attempting to do. In the past, Malaysia has adopted a low income and low cost economy with a reasonably high purchasing power parity index compared to other countries. It was found that the low income and low cost economy has severe limitations to promote further growth and consequently, Malaysia was led into the middle income trap. Low income strategies do not attract talents and retention of expertise in the country. Low income strategies also under-exploit the services sector which now becomes a major sector of the economy. Services provided in Malaysia

earn much lower revenue compared to similar services provided by the developed economy countries.

High income economy means high salary which means high costs. Malaysia must be prepared to adopt a high income and high cost economy as this is the norm seen in other developed countries. High cost is inevitable because when looked from the income side, high income means high salary, but the same high salary will mean high cost when looked at from the cost perspective. The big advantage of high income and high cost (salary) economy is that expertise is easier to obtain and retain, and in addition, the services sector such as hotels, tourism, banking, airlines, etc will be charging internationally competitive prices to maximize revenue and income for the country. Furthermore, efficiency will automatically be enhanced when an economy operates on a high income and high cost strategy. Such an economy will also be able to pay international prices and avoid most subsidies. The billions of Ringgit of subsidy money currently provided in the government budget can instead be distributed to increase salary. Leaving it to the high income individuals to buy the unsubsidized goods and services will further improve efficiency and reduce wastages which are often encountered in a subsidized economy.

9. S&T Governance

In Malaysia, Science, Technology and Innovation are being given very high priority. However, Academics and Researchers need to play a very strong role in evidence- and data-based decision-making, while bureaucrats should continue to play a supporting role.

In the Korean example, a high-level National S&T Council, chaired by the President with the Minister of Environment, Science and Technology as the Vice-Chair and the Ministry of Environment, Science and Technology as the Secretariat, has 5 Committees (Figure 4) on Key Industrial Technologies, Large-Scale Technologies, State-led Technologies, Cutting Edge and Convergence Interdisciplinary Technologies and Infrastructure Technologies.

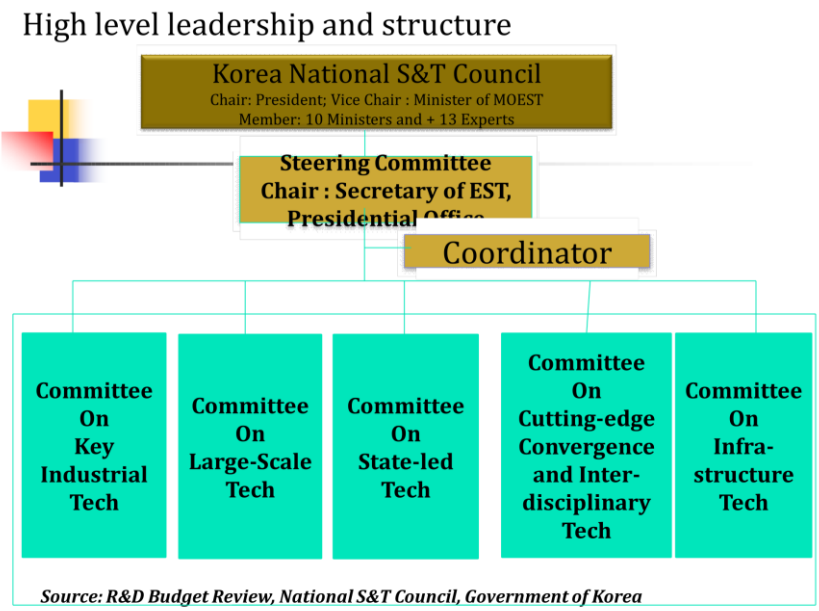

Figure 4 Korean National S&T Council

10. Funding

Malaysia is in the process of improving its science infrastructure to help improve the capacity of the country to use science (STI) as the main engine of growth for its future development. Funding and investment in R&D and strategic studies in all sectors of the economy remain underdeveloped. Such funding is both important and urgent because of the long lead time needed to provide future STI deliverables.

It is proposed that Malaysia makes a 'jump start' and allocates RM 20 billion for an accelerated development of its science industry between now and the year 2020. This fund should be managed by the responsible agencies to ensure both priorities in R&D and strategic studies and the intensification of R&D especially in the private sector can be implemented. Such funding should be increased if necessary during the period of implementation. Commitment to fund the science industry with a RM 20 billion grant would greatly contribute to the achievement of the high income economy strategy as proposed by the government. In comparison, many other countries, both developed and developing, are already providing such mega science grants to invest for their sustained growth in the future. As an example, the Korean Government gave an allocation amounting to US$16 billion to facilitate the R&D programme in the country. UNIK can be authorized to manage, coordinate, distribute and monitor the RM20 billion grant.

As a second option, part of the RM20 billion grant can be created from taxing corporate profits, amounting from ½% to 2%. The corporations will however be exempted from this taxation if they

can show that they are undertaking R&D. UNIK can be authorized to verify and certify that the R&D is being carried out. The exemption will be given to corporations able to show that they are undertaking R&D, Strategic Studies and/or undertaking technological acquisitions to further their R&D capacity and capability. In this way, more R&D, of at least 75%, will be carried out by the private sector.

In essence, the following actions are proposed as part of the functions of UNIK which will be authorized to manage, coordinate, distribute and monitor the grant:

(i) Raise R&D funding, amounting to 2% and above of GDP, through the Government initially giving a "launching grant" amounting to RM 20 billion. The grant can be sustained through taxing corporate profits, amounting from ½% to 2% with the necessary tax exemptions given as described above;

(ii) Prioritise R&D areas with advice from the National Science Research Council; and

(iii) Migrate to improving the R&D activities to be mainly private-sector driven with the ratio being private sector: public sector at 75%:25%.

11. Conclusion

A Mega-Science Framework can be the national vehicle to promote the application of knowledge (science) through STI commercialization to generate better standard of living and new sources of revenue and income to achieve economic growth and national development. The advocacy of science (STI) as an engine of growth can be reinforced through the strong recognition given via the Mega-Science Approach on the need to have extensive investment in R&D and other strategic studies in both traditional 'scientific' sectors and the newly-emphasized services sector.

The scientific STI system as an engine of growth can be further 'lubricated' to deliver the end objectives by the adoption of knowledge enhancement strategies through R&D and training, as well as the adoption of a high income and high cost economic system as practiced by other developed economy countries. By systematically evaluating the knowledge and technology gaps in various sectors and sub-sectors of the economy, it is possible to provide the country with a road map of future opportunities in STI implementation for economic growth and national development. Present studies show many fertile areas of future opportunities exist for the sectors evaluated.

Malaysia's rate of knowledge generation is falling far behind the desired target. It can be concluded that science has not be given the needed funding and urgency to enable it to be truly the engine for sustained national growth for the future. It is hoped that the adoption of a Mega-Science Framework approach will help resolve these limitations and assist in the development of the science industry in the country.

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22nd December 2010

PREFACE

One of the most frequently asked questions by decision-makers and scientists themselves is “How can Science, Technology and Innovations (S, T and I) contribute more effectively to economic development and wellness in a sustained manner without compromising the environment’s sustainability”. There are good reasons to turn to S, T and I because they have a track record to meet critical challenges posed primarily by the growth of human population and their wants. The eradication of small pox by 1979 saved millions of life, the green revolution in the 1960's staved off global famine, nuclear power help to supplement increasing energy demand and the computer enhanced the dissemination of information for education, research and business. Antibiotics and vaccines dramatically increased life spans and improved health all through S, T & I.

Unfortunately, during the past 30 years, the anthropocentric S, T & I approach changed food production, transportation, communications, education, health and even culture (consumption society) which resulted in unsustainable environments including climate change. Designed for efficiency and driven by profit, S, T & I innovated and produced non-biodegradable plastics, toxic DDT, CFC, harmful nuclear wastes and encouraged a new generation of consumption society through automation and mass production - not to mention sophisticated weapons of mass destruction. Today we face the results of "destructive creation" because the innovators failed to factor in the impact on sustainability and wellness.

Once again no doubt, S, T & I will rise to meet the new challenges in response to the national and global demand to factor towards enhancing quality of life in all products, processes, services and development projects. It is now known that there is no positive co-relationship between the rise in GDP and wellness or quality of life. The new awakening of the global community towards a more ecocentric paradigm will change innovations and business. There are already instruments in place such as "eco-labeling" for tropical timber, traceability for food products in EC and green building index in Malaysia.

The biggest challenge to all scientists is how to use the fixed earth resources (especially water, land and minerals) to produce food, water and goods for human needs without depriving habitats for the millions of other species and destroying the ecosystems. Proven existing technologies must continuously be improved to be eco-friendly whilst the emerging one such as renewable energy, genomics, stem cells, nanotechnology, biotechnology and the novo-ICT must conform to the new order of sustainability, ethical and moral obligations whilst contributing to the economic development of the nation.

Malaysia, with its biodiverse wealth, can turn to nature for many of the answers for a developing innovatively (and of course, sustainably) our economy. Scientists only need to uncover them. We need to turn to the sun - a natural nuclear fusion reactor for all our energy needs and to water (rivers and oceans) to provide the additional food needs to begin our new journey towards a sustainable world for all. This journey for Malaysia must begin now.

At the same time, there are vast opportunities in various sectors of the national economy which can be leveraged upon in an attempt to resolve challenges and problems faced by the populace through innovative approaches in the application of Science, Engineering and Technology (SET). Through identifying and developing various tools through SET, it will go towards ensuring that our economy is not only sustained but sustained in a sustainable manner.

The Academy recognizes the importance of cross disciplines linkages that must be integrated during planning, implementation and monitoring of national programs and projects. Social engineering must be designed to match the rapid technical advances to minimize their negative impacts.

In this series, of the Mega Science Framework Studies for Sustained National Development (2011-2050), undertaken by the Academy of Sciences Malaysia, S, T and I opportunities have been identified and roadmaps provided for the short- to long-terms applications of Science, Engineering and Technology in the critical and overarching sectors such as water, energy, health, agriculture and biodiversity.

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ABBREVIATION

UNU-IIGH	United Nations University-International Institute for Global Health
ASM	Academy of Sciences Malaysia
MOSTI	Ministry of Science, Technology and Innovation
STI	Science, Technology and Innovation
R&D	Research and Development
T&CM	Traditional and Complementary Medicine
ICT	Information and Communication Technology
GDP	Gross Domestic Product
FGD	Focus Group Discussion
UM	University of Malaya
UKM	Universiti Kebangsaan Malaysia
USM	Universiti Sains Malaysia
UPM	Universiti Putra Malaysia
MMA	Malaysia Medical Association
OECD	Organization For Economic Co-Operation And Development
WHO	World Health Organization
SARS	Severe Acute Respiratory Syndrome
DALYs	Disability-Adjusted Life Years
MOH	Ministry Of Health
NHMS	National Health And Morbidity Survey
NGO	Non-governmental Organization
CNCDs	Chronic Non-Communicable Diseases
HDI	Human Development Index
GNP	Gross National Product
UNDP	United Nations Development Programme
HIV	Human Immunodeficiency Virus
AIDS	Acquired Immunodeficiency Syndrome
GERD	Gross Expenditure on Research and Development
WDI	World Development Indicators
KRW	South Korean Won
RSE	Research Scientists and Engineers
FTE	Full-Time Equivalent
USA	United State of America
IMR	Infant Mortality Rate
MMR	Maternal Mortality Ratio/

TB	Tuberculosis
NCD	Non-Communicable Diseases
PPP	Purchasing Power Parity
AMMI	Association of Malaysian Medical Industries
MRI	Magnetic Resonance Imaging
GMP	Good Manufacturing Practice
GLP	Good Laboratory Practice
CABG	Coronary Artery Bypass Grafting
TURP	Trans-Urethral Resection Of The Prostate
UK	United Kingdom
CAGR	Compound Annual Growth Rate
IMR	Institute for Medical Research
IRB	Institutional Review Board
NBBnet	National Biotechnology and Bioinformatics Network
HR	Human Resource
NMR	Nuclear Magnetic Resonance
TARRC	Tun Abdul Razak Research Centre
FRIM	Forest Research Institute Malaysia
ITTO	International Tropical Timber Organization
INTI	International University College, Nilai
CUCMS	Cyberjaya University College Of Medical Sciences
MSU	Management and Science University
IMU	International Medical University
NUS	National University of Singapore
IRPA	Intensification of Research In Priority Areas
MNI:	Malaysian Nanotechnology Initiatives
TRIPS	Trade Related Intellectual Property Rights
HPRI	Halal Products Research Institute
HDC	Halal Industry Development Corporation
GAVI	Global Alliance For Vaccines And Immunisation
JE	Japanese Encephalitis
EPI	Expanded Programme On Immunization
HPV	Human Papillomavirus
MLSCF	Malaysian Life Science Capital Fund
LHP	Lifetime Health Plan
CME	Continuing Medical Education
GDS	Group Data Services
HIMSS	Healthcare Information Management And Support System
CSS	Clinical Support System
DRG	Diagnosis-Related Group
HIS	Health Information System
NNC	National Nanotechnology Centre
NSRC	National Science and Research Council
INEE	Institute of Nano Electronic Engineering

EXECUTIVE SUMMARY

BACKGROUND

Fifty-three years after its independence, Malaysia is now a successful and economically prosperous middle-income country. It has transformed itself from a producer of raw materials in the 1970s into a multi-sector economy. The country invested in science, technology and innovation (STI) to drive its economy and development. Malaysia's success story is driven by forward thinking policies and strategies, and complemented by long-term plans. This, coupled with an enabling policy environment, is becoming increasingly crucial for the country given the globalization trend and strong competition in all sectors of development. It is in this context that the Government continues to explore scenarios for Malaysia's development in the next 40 years. Related, its search for innovations remains a priority.

ABOUT THE STUDY

In the interest of informing the government about application of science, technology and innovation (STI) to achieve greater health and economic outcomes for the country by 2050, the Academy of Sciences Malaysia commissioned the United Nations University-International Institute for Global Health to conduct an independent analysis to answer three core questions that focus primarily on STI and health: (1) Where is the country at?, (2) Where does the country want to be?, and (3) How does the country get there? These questions are answered through reviews, synthesis, and analysis of secondary data, policies, legislation, strategies, and plans, as well as information gathered from national and international experts. The outcome of the study is a roadmap towards achieving greater wellbeing of Malaysians and sustainable economic outcomes for Malaysia by 2050.

FINDINGS

Where is the country at? Malaysia has an effective health care system which contributes significantly towards the health and wellbeing of Malaysians. The system and health status have a favourable standing globally, but the country is in the shadows of developed countries such as Sweden and South Korea, and neighbouring countries including Singapore and Brunei. While Malaysia's socioeconomic achievements are above the global average, it has yet to be at par, or in a better standing, than Singapore, South Korea and Sweden. On STI in health, the promotion and support for STI on the part of the government led to growing utilization of advance science and technology for management and detection of health issues, which led to positive health outcomes. At the same time, increasingly there are local initiatives to research and develop advances in the use of STI in

health. Similarly, a growing number of local companies are investing in and commercializing STI and health; thus contributing to the Malaysian economy.

Where does the country want to be? By 2050, Malaysia envisions to be a nation where its population enjoy the highest level of health and wellbeing. It will also have a health sector that is highly efficient and offers widely and easily accessible health care services of the highest quality and cost-effectiveness. By then, Malaysia will have become a high income country. Several enablers are in place to transform this Vision into a tangible reality: a strong healthcare system; supportive policy and regulatory framework that centres around strengthening research and development capacity and human resources, enhancing investments, and fully exploiting locally available natural products; ongoing health and STI-related research and development initiatives for greater health outcomes; political, social and economic stability; and good infrastructure in all sectors. On the other hand, Malaysia needs to overcome formidable challenges that include: unfocused priorities; lack of strong leadership and coordination in policy implementation and R&D efforts; insufficient investments in R&D and commercialization; weak innovative system; and shortage of highly skilled researchers, scientists and professionals in R&D and commercialization in health related STI areas.

How does the country get there? The Study acknowledges the critical roles of the health system as well as other systems in achieving greater health outcomes and capitalizing the health sector to generate revenues for the country. However, the recommendations for how the country will achieve its vision for greater health and economic gains will be limited to the areas of health-related STIs, as per the purpose of the Study.

1. Focus on priority STI strategies

Based on an analysis of 11 health related STI areas and ratings by experts, the Study concludes that priority should be given to the following five areas: Natural Products, Health Tourism, Pharmaceuticals, Medical Devices, and Traditional and Complementary Medicine (TCM). The products and services within these priority areas should focus on five diseases that carry the highest burden (diabetes, cancer, cardiovascular diseases, dengue and health problems related to ageing) and tropical diseases.

2. Other Areas for Consideration

The other areas for consideration are Medical Diagnostics, Vaccines, Information, Communication and Technology (ICT) in Health, Stem Cells, Genomics and Nanotechnology. However, investments in these areas should not jeopardise the focus and investments for the recommended priority STI areas.

3. Key Strategies/Cross-cutting Recommendations

In order for Malaysia to be a strong player in the five priority STI strategies, it has to strengthen responses in research and development (R&D), human resources and policy.

1. Research and development (R&D)

   Malaysia must significantly enhance its research and development initiatives if it is to compete favourably in the area of STI in health. Toward this objective, it must:

   - Increase the level of investment from the current 0.6 percent to a minimum of 3 percent of the GDP.
   - Increase the allocation of funds for health R&D from 2.14 percent to 20 percent of total R&D by 2050.
   - Develop a master R&D plan.
   - Establish R&D structure and improve coordination.
   - Improve legal and regulatory framework.
   - Strengthen commercialization of research outputs.

2. Human Resources

   Generally, Malaysia has to promptly strengthen its competency in STI. In particular, as research and development is fundamental in the development of STI, the ratio of researchers to total employment must be increased from 9.1 per 10,000 total employment to 150 researchers per 10,000 total employment. Specifically, there should be 30 researchers working on health issues per 10,000 total employment. These objectives are achievable through implementation of:

   - Long-term comprehensive education and human resources development plan that gives emphasis on STI, especially in the five priority areas. Specific actions will include (a) intensive training for qualified professionals to enhance their STI competencies, (b) post-doctoral programmes, and (c) research management skills for senior professionals involved in managing and coordinating research activities.
   - Short-term strategies including (a) recruitment of foreign experts and partnerships with international science based collaborators, (b) greater incentives and attractive benefits packages for national professionals who are already engaged in STI areas, (c) enhanced incentives to lure skilled

Malaysians who are working abroad, and (d) attractive career pathways and recognition to promote engagement in STI in health.

3. Policy

Two key challenges or actions must be heeded to operationalise the recommendations set out for R&D and human resources. These are:

- Strong leadership and coordination at all levels, particularly the highest level.

- Full implementation of existing relevant policies that support STI development.

CHAPTER 1

INTRODUCTION

Fifty-three years after its independence, Malaysia is now a successful and economically prosperous middle-income country. It has transformed itself from a producer of raw materials in the 1970s into a multi-sector economy. The country invested in science, technology and innovation (STI) to drive its economy and development.

Malaysia's success story is driven by forward thinking policies and strategies, and complemented by long-term plans. This, coupled with an enabling policy environment, is becoming increasingly crucial for the country given the globalization trend and strong competition in all sectors of development. It is in this context that the Government continues to explore scenarios for Malaysia's development in the next 40 years. Related, its search for innovative and effective means remains a priority.

The Mega Science Framework for Sustained National Development (2011-2050)

The Mega Science Framework for Sustained National Development (2011-2050) is a national effort to guide Malaysia's long-term development. It focuses on policies, strategies and plans of action that will promote the development and application of scientific knowledge and technological innovations for sustained economic prosperity and societal well being. The Framework will determine the STI areas and level of investments in order to enhance Malaysia's economic expansion. In a nutshell, this Framework aims to have STI as a key driver to an even more prosperous, progressive and healthier Malaysia by 2050.

This is an initiative of the Ministry of Science, Technology and Innovation (MOSTI) that is managed by the Academy of Sciences Malaysia (ASM). It aims to inform an over-arching framework to mainstream innovative scientific, engineering and technological inputs into national development strategies and plans for the period 2011-2050. In a nutshell, this initiative addresses three core questions related to STI:

- Where is the country at?
- Where does the country want to be?
- How does the country get there?

The Framework covers five sectors, one of which is the Health and Medicine Sector.

Mega Science Framework: Health and Medicine Sector

In March 2010, the Academy of Sciences Malaysia and the United Nations University-International Institute for Global Health (UNU-IIGH) signed a Memorandum of Understanding for the Mega Science Framework for Sustained National Development: Health and Medicine Sector Study. Against the background of shaping the future of health and medicine in Malaysia, the main purpose of the Study is to establish a roadmap for achieving health outcomes that will contribute to the wellbeing of Malaysians and sustainable economic growth of the country by 2050. The objective is to fully exploit science, technology and innovation opportunities for generating new knowledge and to translate it into applications.

Box 1.1 Examples of health benefits of STI

- Angiography for diagnosing coronary heart diseases.
- A simple biotechnology based blood test can detect ovarian and prostate cancer without the need for expensive and invasive surgery.
- An MRI scan can be used as an extremely accurate method of disease detection throughout the body.

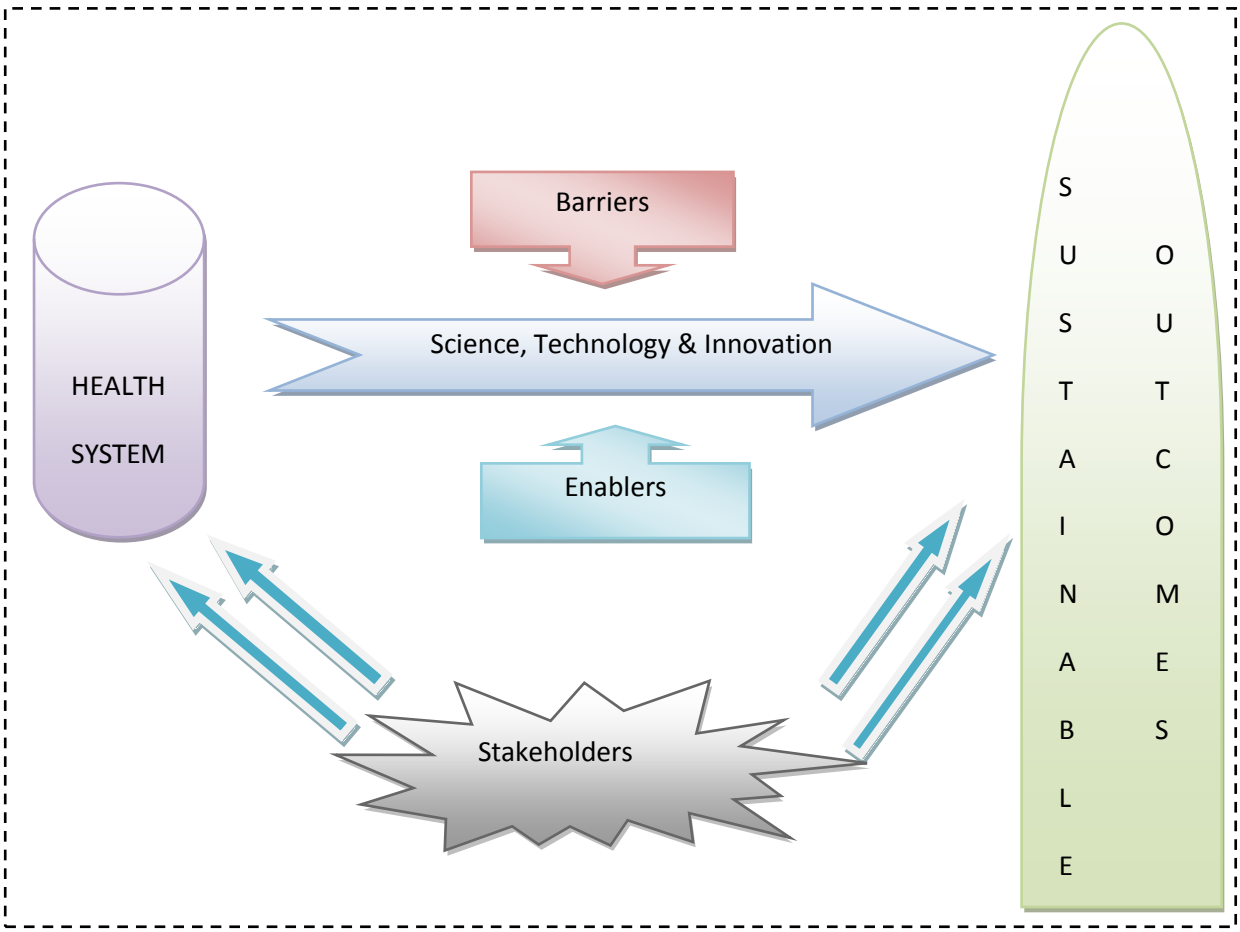


Figure 1.1: Conceptual framework

Conceptually, as summarized in Figure 1.1, the Study builds upon the current health system as the building block towards achieving long-term sustainable health outcomes and economic growth. Science[1], Technology[2] and Innovation[3] are the drivers for this transformation. STI are vital in a growing globalized, open, knowledge-driven and market-based economy. In the past 50 years, progress in medicine and treatment has been significantly affected by technological advancements made possible by combining the principles and techniques in engineering, biology and medicine to develop new devices and innovative approaches and systems. Exploitation of diagnostic and therapeutic modalities of medical technology, such as molecular biology techniques giving rise to new vaccines and diagnostics, communications technology simplifying information flow and promoting the concept of e-health, and innovations in management sciences and quality processes that affect how health systems are managed, have contributed to (1) prevention, diagnosis and treatment of diseases, (2) patient care and rehabilitation, and (3) improving medical practice and healthcare delivery. Beyond the biomedical boundaries, social sciences facilitate addressing diseases and health issues from a societal and systems perspective. Advances in, and use of these technologies and sciences have significantly reduced mortality rates, improved patient quality of life and reduced healthcare expenditure by reducing frequency and length of hospitalization. At the same time, some related products have generated significant revenue for the country. For example, Malaysia is the largest medical rubber glove manufacturer worldwide, which brought revenue of RM1.53 billion in 2009.

The conceptual framework is also based on the relationship between health and economic growth. Empirical evidence from both developing and developed countries demonstrates that economic growth improves health, while improved health significantly enhances economic productivity and growth (World Bank 2008). The World Health Organization's Commission on Macroeconomics and Health (Commission on Macroeconomics and Health 2001) outlined in its report that health inputs contribute to economic growth through three channels:

- Returns to individual health through labour market outcomes, a demographic dividend[4], and increased savings.

- The net value of increased income from household investment in human capital.

- Societal returns to health, through economic activity such as the agricultural industries.

[1] Science is defined as any systematic field of study or the knowledge gained from it.
[2] Technology is defined as the usage and knowledge of tools, techniques, systems or methods of organization.
[3] Innovation is defined as the introduction of a new concept, idea, service, process, or product aimed at improving treatment, diagnosis, education, outreach, prevention and research, and with the long term goals of improving quality, safety, outcomes, efficiency and costs.
[4] A rise in the rate of economic growth due to a rising share of working aged people in a population.

Related, a statistical estimate suggests that one extra year of life expectancy at birth add to a GDP per capita of about four percent (Bloom et al 2004). Hattar-Pollara (2009) estimated that reductions in adult mortality rates can account for up to 11 percent economic growth. These improvements in health may increase output through labour productivity and the accumulation of capital. Healthier workers are physically and mentally more productive and earn higher salaries. They are also less likely to be absent from work because of illness (Bloom et al 2004; Bloom and Canning 2005). In conclusion, health is a productive economic factor in terms of employment, innovation and sustainable development and growth.

Malaysia's own dramatic improvements in health status over the past 50 years, most obvious from the declines in mortality and increases in life expectancy, can be charted against the economic growth and health inter-relationship. As the country paved its economic growth course, it invested in public health which afforded greater access to health care for the population. At the same time, the population had the means to access food which resulted in better nutrition. The education sector also flourished thus generating better educated Malaysians which influence the predisposition to illness and the ability to prevent and manage illnesses. It is important to note, in a nutshell, that health status is also affected by food and nutrition, health care, education, and other complementary investments as shown in Figure 1.2 (Commission on Macroeconomics and Health - WHO 2001). As such, the country must continue to give emphasis and to invest in these areas.

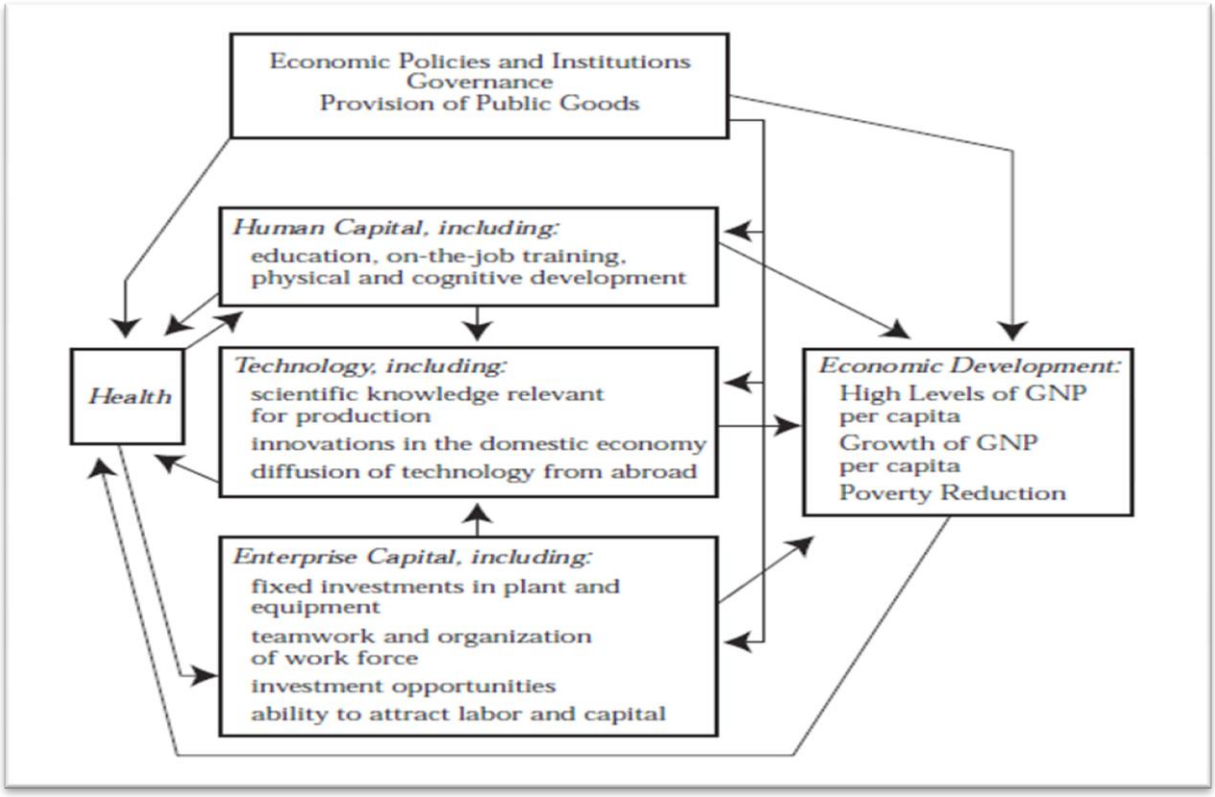


Figure 1.2: Inter-relationship of factors that affect health status
Source: CMH-WHO 2001

Objectives

The objectives of the Study are to:

- Define and establish the desired health outcomes for Malaysia, and the corresponding monitoring indicators and milestones.

- Identify gaps in STI knowledge and development in the health and medicine sector, and propose appropriate measures, including research and development needs to achieve the desired health outcomes.

- Undertake comparative studies with developed countries that will allow the local health sector to grow, including the identification and/or development of policies necessary to sustain this growth.

- Identify and propose areas in research, development and commercialization in the health and medicine sector where Malaysia has a competitive edge and can contribute to the country's sustainable economic growth.

- Identify sources of future growth opportunities in the various areas of health and medicine.

- Conduct a review of international best practices in STI Policies and Plans for sustainable development in the Health and Medicine sector.

- Review and analyze the Government's various policies, strategies and plans towards identifying educational (capacity building), technological, scientific and governance (institutional framework) in the health and medicine sector, identify gaps and recommend appropriate remedial measures in line with best practices.

- Propose an Action Plan for implementation.

The purpose and objectives of the Study, as outlined by the ASM, focus exclusively on STI as a means to achieve the desired health and economic outcomes for Malaysia. Thus, while this Study recognizes the critical roles of other elements such as quality of health delivery and health financing towards achieving greater health and wellness, the core discussion and recommendations are devoted to health-related STIs.

Methodology

The scope of the Study is national. It systematically reviews, synthesizes, and analyzes existing data, policies, legislation, strategies, and plans. Secondary data is a primary source of information for the Study. The initial months of the Study were devoted to collecting secondary data and relevant literature. In addition to online

search, the Study teams approached various government and professional institutions for data, documents and materials. The materials collected were reviewed and analyzed to create a preliminary knowledge base, thus providing a good starting point for discussions with select national experts through focus group discussions and in-depth interviews which expanded the knowledge base, and identified knowledge gaps.

New information is gathered through focus group discussions and interviews with experts and academicians. In total, three focus group discussions (FGDs) on the themes associated with the objectives of the Study were conducted to add more details as well as gather professional perspectives and practical experiences that would complement the secondary data. The participants of the FGDs are national experts with extensive knowledge and experience in their respective areas of professional activity or academic subjects (The list of experts is provided in Annex 1). The following paragraphs describe details of the FGDs.

FGD on *desired health outcomes for Malaysia in 2050*. Experts discussed the health scenario and outcomes for Malaysia in the next 40 years. Although the focus of discussion was on the domains for the future health outcomes, the group also identified gaps in the current health system and proposed strategies to overcome them. The context in which the proposed domains for health outcomes can be achieved was explored.

FGD on *areas for research and development and commercialization.* The themes for this FGD were: (a) Contributions of health and medicine sector to national economic growth; (b) Potential niche areas of STI and health which include biotechnology, natural product, genomics and stem cell, *halal* medicine, nanotechnology, health tourism, telemedicine, traditional and complementary medicine; (c) Strengths, opportunities, challenges and barriers related to utility or commercialization of research findings in the health sector; and (d) ways to address the challenges and overcome the barriers.

FGD on *enablers and barriers for promoting and applying STI in the health sector*. This FGD focused on key enablers that may promote, and barriers that may hinder STI in the health sector.

In-depth interviews with select academicians, health professionals, and heads of private and government-linked companies were conducted to expand upon the information from secondary data and FGDs. The interviews were helpful in soliciting opinions about the successes and setbacks in the development and application of STI in the health sector.

Sweden and South Korea were referred as models for success in using STI to drive the countries' health development and economies. These countries were selected based on the following best practices criteria:

- Availability of proven programmes, strategies, policies and cutting edge research in the health and medicine sector including telemedicine, health tourism, health products (vaccines and natural products), biotechnology, and nanotechnology.

- Implementation of programmes and policies for at least the last 10 years and has shown positive results.

- Successful programmes are initiated either by the government or private sector or both.

- Fully or partially home-grown programmes, with local practitioners who are well-known internationally.

- Acquired international or regional recognition and reputation for its best practice.

- Recognized by the national government as an innovative sector for the country, either through specific government policy, implementation plan, funding initiative(s), infrastructure provision, regulatory body, or legislative facilitation.

Review of the literature, coupled with discussions with international experts[5], enabled the Study to construct case studies on how South Korea and Sweden had used STI to improve their health status. These case studies are presented in Annex 2 and 3 respectively. The case studies facilitated the Study to refer to the achievements and lessons learned from South Korea and Sweden for potential adaptation in the context of Malaysia. They thus serve as benchmarks. Additionally, best practices related to select health areas from several Asian countries were also reviewed to draw lessons learnt as well as comparison with Malaysia.

Structure

This Study is structured around the tasks agreed upon in discussions with the Academy Sciences Malaysia. These tasks, listed below, correspond to the specific objectives of the Study:

- Establishing the current status of health and medicine in Malaysia.

- Setting the desired outcomes in health and medicine and identifying suitable health indicators and milestones which will serve as measurable targets for monitoring progress and achieving objectives.

[5] Prof Bong-Min Yang of South Korea and Prof Bengt Jonsson of Sweden visited Malaysia to share the experience and lessons learned from their respective countries and international best practices, as well as to provide their inputs towards the Study recommendations.

- Undertaking case-studies of developed countries to establish how they employed STI in achieving their health outcomes.

- Identifying current gaps in STI knowledge and development in the health and medicine sector and how these gaps may be bridged in order to achieve the desired outcomes.

- Identifying and proposing research, development and commercialization in the health and medicine sector where Malaysia has a competitive edge and can contribute to overall sustained economic growth of the country. Related, identifying sources of future growth opportunities in the various areas in the health and medicine sector.

- Conducting a review of international best practices in STI Policies and Plans for sustained national development in the health and medicine sector. Related, reviewing and analyzing existing government policies, strategies and plans pertaining to STI in the same sector, as well as identifying gaps and recommending appropriate remedial measures in line with international best practices.

- Preparing a Plan of Action and Roadmap for implementation of the Plan of Action.

The tasks above are managed by three teams of researchers from UNU-IIGH, Universiti Kebangsaan Malaysia (UKM), and Universiti Sains Malaysia (USM). These tasks are closely related, and thus where necessary, the teams work collaboratively to address common themes. International consultants, one each from South Korea and Sweden, provided the teams with information, experiences and lessons learned related to STI in their respective countries. Additionally, they offered expert advice on the Study.

Recognizing the efforts of various other agencies working in the health and medicine sector, the Study collaborated with government agencies, national universities, and professional institutions, and built upon existing body of knowledge and experiences. Inputs from these partners were gathered through focus group discussions and in-depth interviews (refer to the Methodology Section above).

The UNU-IIGH formed an Expert Advisory Group, to provide overall guidance to the Study. The members consist of high level experts and professionals whose names were identified in consultation with the ASM (see Annex 4 for list of members). The main functions of this group are to: (1) Provide critical review of the Study findings and recommendations; and (2) Review draft report of the Study. Members of the Group performed their roles through participation in meetings at ASM where findings of the Study were presented, and in a Stakeholders' Consultation Workshop. The two-day stakeholders' consultation workshop, co-organized by ASM

and UNU, was conducted on October 26-27, 2010. The objectives of the workshop were to:

1. Present findings of the Study.
2. Seek the views of the stakeholders before finalizing the Study Report.
3. Review recommendations based on the Study findings.
4. Identify potential R&D areas, policy and STI areas in the health (and medicine) sector.

Representatives from the various government ministries, private sector and the academic participated in the workshop. Outputs of the workshop provided valuable inputs towards strengthening the Study (see Annex 5 for the list of participants).

CHAPTER 2

WHERE ARE WE NOW?

Health Status

Malaysia has a favourable health status, where Malaysians are living healthier and longer lives. This is achieved through a universal[6], equitable[7], efficient[8] and cost effective[9] health care system that provides quality services. The infant mortality rate in 2007, at 6 per 1000 live births, is a strong indication of the overall effectiveness of healthcare in this country (Ministry of Health 2007). In 2008, the life expectancy at birth was 73 years; another indicator of a successful health system. Several other enablers contributed to the achievements of the health sector, as discussed in the following paragraphs.

Vision and Mission

The health sector is led by the Ministry of Health, which has a clearly defined vision (see box 2.1) and mission. The latter is to lead and work in partnership to:

a. Facilitate and support the people to attain fully their potential in health, appreciate health as a valuable asset, and take individual responsibility and positive action for their health.

b. Ensure a high quality health system that is: (1) customer centred; (2) equitable; (3) affordable; (4) efficient; (5) technologically appropriate; (6) environmentally adaptable; and (7) innovative.

Box 2.1: MOH Vision

Malaysia will become a nation composed of individuals, families and healthy communities through health system that is fair and equitable, efficient, able to make appropriate technology available, compatible and appropriate to the customer environment. This system will also satisfy the quality, innovation, health promotion, respect for human dignity and promote individual and community participation towards improving the quality of life.

Ministry of Health

The mission is to be achieved through professionalism, caring and teamwork value, as well as respect for human dignity and community participation.

Skilled health professionals

Malaysia boasts high numbers of locally and internationally trained professionals in the various health areas (see Table 2.1). The distribution of doctors is skewed towards a concentration in urban areas. As an example, the ratio of doctors to

[6] Universal coverage of health care means that everyone in the population has access to appropriate promotive, preventive, curative and rehabilitative health care when they need it and at an affordable cost.

[7] Equitable access is the distribution of health services determined by social, economic and demographic characteristics and need. Effective access is the use of health services that improve the health status or satisfaction.

[8] Efficiency refers to the use of health services that minimizes the cost of health services and maximizes the health status or satisfaction.

[9] Cost effective ensures activities and programmes are implemented using the lowest cost albeit high quality positive outcomes.

population in Kuala Lumpur is 1:353. In East Malaysia, the ratio inflates dramatically to 1 doctor per 2,524 Sabahans (MOH Health Report 2007).

Table 2.1: Health human resources in Malaysia, 2009

	Public	**Private**	**Total**	**Profession: Population**
Doctors	20,192[a]	10,344	30,536	1: 927
Dentists	1,858	1,709	3,567	1: 7,936
Pharmacists	3,877	2,907	6,784	1: 4,137
Opticians	-	2,720	2,720	1: 10,407
Optometrists	204	573	777	1: 36,431
Asst. medical officers	8,648	766	9,414	1: 3,007
Asst. pharmacy officers	2,949[b]	n.a	2,949[b]	-
Asst. environmental health officers	2,715[b]	n.a	2,715[b]	-
Medical laboratory technologists	4,450[b]	n.a	4,450[b]	-
Occupational Therapists	489[b]	n.a	489[b]	-
Physiotherapists	664[b]	n.a	664[b]	-
Radiographers	1,619[b]	n.a	1,619[b]	-
Nurses	45,060	14,315	59,375	1: 477
Dental nurses	2,447[b]	-	2,447[b]	-
Community nurses	18,851	1,312	20,163	-
Dental technologists	737[b]	n.a	737[b]	-
Dental surgery assistants	2,820[b]	n.a	2,820[b]	-
Traditional & complementary medicine practitioners	n.a	n.a	11,691[d]	1: 2,421

Note: n.a: not available, [a]: Includes Houseman (House Officers), [b]: MoH only, [c]: Includes Midwives (Division II), [d]: Refers to voluntary registration by local practitioners & application for professional visa by foreign practitioners.
Source: MOH Health Facts 2009

Despite these numbers, data on health care personnel depicts a gap in the required number of physicians, nurses and midwives, pharmacists and dentists. The current numbers are below the global ratio, and much lower compared to some high income and neighbouring countries as shown in Table 2.2.

Table 2.2: Health workforce ratio globally and in select countries

Health personnel (per 10,000 population) (2000-2009)	**Malaysia**	**Global**	**Sweden**	**South Korea**	**Singapore**	**Brunei**
Physicians	**7**	14	36	17	15	11
Nursing and midwifery personnel	**18**	28	116	44	44	61
Dentistry personnel	**1**	3	8	14	3	2
Pharmaceutical personnel	**1**	4	7	11	3	1

Source: World Health Statistics 2010

Malaysia had planned to increase the health professional per population ratio by 2010. However the availability of health professionals in 2009 falls short of the expected targets:

- Doctors: The national requirement is about 48, 000, based on an optimal ratio of 1 doctor per 600 population. Yet, availability of a total of 30,536 doctors shows a staggering shortage of nearly 18,000 doctors.

- Dentists: The number of available dentists was just over 3,567 when the required dentists are 5,162 (based on a norm of 1 dentist per 4,000 population).

- Pharmacists: The national requirement is 14,454 while the actual number of pharmacists was a mere 6,784 (based on a norm of 1 pharmacist per 2,000 population).

Currently, Malaysia has 26 universities which offer medical training, of which 10 are public universities and 16 private universities and medical colleges (see Annex 6 for a listing). Together, these schools produce approximately 1,200 doctors annually (MMA website), which will lead to an increasing the number of doctors in the near future. Many doctors choose to enrol in programmes to be trained as specialists in their chosen areas although the top five specialties are internal medicine, paediatrics, general surgery, obstetrics and gynaecology, and anaesthesiology as these are highly demanded skills that offer greater salary especially in the private sector. In order to ensure sufficient numbers of health professionals to serve in the public sector, the government needs to put in place

attractive incentive packages to doctors to discourage them from serving in the private sector.

Utilization of STI

Over the last 50 years, Malaysia has kept abreast with scientific advances and the utilization of medical technologies, which has played an important role in enhancing health care and delivery, thus resulting in greater health outcomes. The health sector has applied technologies and innovations that include among others medical devices, nanotechnology, vaccines, nuclear medicine, imaging technologies, stem cells therapy, and information, communication and technology in health.

Despite the impressive achievements, a review of key health indicators shows that Malaysia trails behind high income countries such as Sweden and South Korea, as well as neighbouring Singapore and Brunei, for a number of indicators. The following Table presents comparison for a select set of key indicators, while Annex 7 offers a larger number of indicators and countries.

Table 2.3: Comparison of some key indicators for Malaysia, global and four developed countries

Country	**Life expectancy at birth**	**Infant mortality rate**	**Mortality rates (communicable)**	**Mortality rates (non-communicable)**
Malaysia	**73**	**6**	**161**	**623**
Global	68	45	275	612
Sweden	81	2	22	372
Korea	80	5	32	470
Singapore	81	2	79	345
Brunei	76	5	37	473

Source: World Health Statistics 2010

A number of barriers are identified to explain gaps in the health sector.

Health care resources

In 2008, the total expenditure on health was 4.75 percent of the Gross Domestic Product (GDP) and 7 percent of the total government expenditure (THE) (MOH Health Facts 2009). This is five percentage points lower than the global standard of 9.7 percent, and also trail behind that of Sweden and South Korea where the investments in health was 9.1 percent and 6.4 percent of the GDP respectively

(WHO 2009). In OECD countries, more than 5 percent of GDP is apportioned to finance the health system (OECD 2009). The low government expenditure in Malaysia is compensated by high out-of-pocket expenditure; 73.2 percent of private expenditure on health. This pattern has high financial risk to individuals and families upon unexpected and/or catastrophic health events. While those with greater economic means can bypass the public system and seek private care, the poorer members of the community have no choice but to rely on the government system and face long waiting time for treatment. This has resulted in problems of equity as the people in higher income groups have better access through the private healthcare system (Karol 2007).

The current health financing system will be unable to sustain the growing demands from the public. To address this issue, a National Health Financing Scheme was proposed in early 2000 to replace the existing taxation-based system. The proposed scheme aims to pool together funds from multiple sources including taxation and contribution from employers and employees. It will facilitate the integration of health services at primary, secondary and tertiary levels, within the public sector, and between the public and private sectors to achieve equitable access to healthcare, hence offer protection to specific groups of people including the poor and those living in rural areas (WHO 2010). The proposal recommended that an agency directly under the Prime Minister Department manages the scheme, while the MOH's role is to regulate the Scheme.

Approximately 61 percent of the health budget is allocated for medical and curative services, with emphasis on treatment and less on cost effective interventions and screening in primary care (Ministry of Health Report 2007). A budget allocation of 21 percent is an indication of the low priority given to health prevention and promotion. The remaining 18 percent of the budget are shared amongst management of programmes, new policies, research and technical support, and one-off development programmes.

Disparity in access to healthcare

Despite a near universal access to health care, there is disparity especially among the marginalized populations (Mat Zin 2007). Over the last several decades, Malaysia has moved towards greater industrialization and socioeconomic development, and urban migration. Along with this transition was the marginalization of urban poor, migrant workers especially those who reside and work illegally in this country, and populations that engage in drug use and sex work (WHO 2007; WHO 2005). They are challenged in accessing health services. Geographically, concentration of specialized care as well as the provision of highly skilled health providers is in the urban areas. This reality leaves tertiary care out of easy reach for the rural population. Unfortunately, there is no routine monitoring of equitable access to health care while reimbursement to clinics and hospitals are through global budget and experience from previous years. Thus, the inefficient clinics or hospitals are also receiving the same amount of resources year after year.

Insufficient evidence based programming

There are numerous research institutions that have generated a substantial amount of health-related information and data. Unfortunately, it is not easy to access the wealth of information and data. Where data is available, they are often not fully analyzed and/or utilized. It is noted that there is a need for a robust database system to store the data. This database should be easily accessible to relevant stakeholders. Furthermore, a well coordinated forum is needed for interactive reviews, analysis and discussion of data and research findings. Researchers should also heighten publication of their research findings in local and international journals.

On a related issue, many health programmes and interventions are not guided by local evidence which tend to fail in achieving the desired health outcomes (Findings from Expert Group Discussion 2010). The use of strong evidence based programming, using local data preferably by local researchers, should be the foundation for programming and evaluation.

Lack of public involvement in decision making

There is very little space for consulting the public in health related policy-making and decision-making. Despite a number of well-informed and well-organized civil society organizations, the demand for and acceptance of their participation in policy-making and decision-making processes are silent. As a right holder, the public should be given the space to contribute to decisions that affect their health and wellbeing. Appropriate mechanisms need to be established to allow public participation, and meeting a 'win-win' outcome for all stakeholders.

Poor public-private integration

Linkages and coordination between the public and private health services are weak. This is compounded by heavy bureaucracy and unhealthy competitiveness that dampens the spirit of cooperation and good will among the sectors. The lack of integration hampers patients' treatment, delay referral and interventions that could have been provided efficiently given strong public-private integration (Redhwan et al. 2008). The need to consolidate partnerships between public and private sectors is evident.

The Study notes that the barriers related to health system are discussed in the context of analysing the status of the health system. However, the Study does not make specific recommendations to address the barriers given that its aim is to focus on health-related STI recommendations (see Study objectives on page 10).

Epidemiological Transition

Malaysia is experiencing a challenging epidemiological transition where both communicable and non-communicable diseases are high disease burdens. A number of communicable diseases including dengue (see case study below), malaria, tuberculosis, and filariasis remain a challenge. In the last decade, the world has seen numerous life-threatening diseases such as Avian Influenza, Severe Acute Respiratory Syndrome (SARS), and Nipah Encephalitis. Malaysia was at the centre of these diseases, which left a dent in the economy although the country has since recovered from the impact. While Malaysia responded adequately to manage the outbreaks, experiences showed the need to strengthen disease surveillance and early warning systems, to develop effective rapid response mechanisms and pandemic preparedness, and to strengthen international and regional collaboration (Shah et al. 2007).

Case study 1: Dengue

Case Study on Dengue

At present, there are nearly 50,000 cases of dengue annually. The percentage of deaths due to dengue fever increased by 53 percent in 2010, with 107 deaths in October compared to 70 deaths for the same period in 2009. The current national target for reduction of dengue cases is 10 percent annually, bringing the annual cases down to 558 by 2050. In order to attain this target, Malaysia has to strengthen efforts within the following components recommended by the WHO Strategic Plan for Dengue Control:

1. Monitor trends and reduce dengue transmission. Despite a good surveillance system, Malaysia needs to further improve its capacity in this area.
2. Integrated vector management. Review the effectiveness and efficiency of space spraying and coverage area, and consider the use of insecticide in disrupting dengue transmission. Related it needs to develop an appropriate monitoring system, and conduct regular testing for insecticide resistance.
3. Increase the capacity of health workers to diagnose, treat and refer patients which will lead to improved case management.
4. Enhance effective health promotion activities and community involvement for vector control.
5. Increase research on dengue prevention, management and control.

The government has turned to STI in an attempt to tackle the growing epidemic. At the end of 2010, the government plans to release genetically modified male mosquitoes that carry 'killer' genes which would kill larvae of the female when they mate. This is expected to reduce the population of Aedes mosquitoes. However, this plan has been put on hold.

Lifestyles have changed in Malaysia and so have disease patterns. Nowadays, lack of exercise, poor eating habits, obesity, and risky behaviours resulted in the following leading disease burden based on disability-adjusted life years (DALYs) (MOH Health Report 2004): (1) among males: ischaemic heart disease, road traffic accidents, cerebrovascular diseases, septicaemia, and acute low respiratory tract infections; and (2) among females: ischaemic heart disease, cerebrovascular disease, unipolar major depression, septicaemia and diabetes.

Diabetes has developed into a major medical problem. The prevalence rate has been increasing over the last two decades. A prevalence of 6.3 percent was recorded in 1986. A decade later, the prevalence stood at 8.2 percent. There was yet another jump to 14.9 percent by 2006 (NHMS 1986, 1996 and 2006) which translates into an estimated 1.4 million or one in six Malaysians above 30 years of age suffering from diabetes. This figure may be underestimated given that a high number of diabetes cases are undiagnosed due to late detection and low screening uptake.

The rise in diabetes is parallel to the growing prevalence of overweight and obesity. WHO has estimated that in 2030, Malaysia is likely to have 2.5 million cases of diabetes. Without effective interventions and behavioural changes, this upward trend will continue into 2050. The rising number of patients and complications are bound to raise healthcare costs, which will be very challenging for the government to manage.

Case study 2: Diabetes Mellitus

Case Study on Diabetes Mellitus

Worldwide, in the year 2025, 300 million people are expected to have diabetes. WHO has estimated that in 2030, Malaysia is likely to have 2.5 million diabetics compared to 0.94 million in 2000; an astounding 164 percent increase. Several factors contribute to the upward trend of diabetes: lack of health promotion policies and regulations, poor inter-sectoral coordination among the relevant agencies, unhealthy behaviours of the population, and weak NGO and community involvement especially on prevention of diabetes. Without effective interventions and behavioural changes, this trend will continue into 2050. The complications due to diabetes, namely cardiovascular diseases, end stage renal failure, blindness and limb amputations, are also expected to increase. The rising number of patients and complications are bound to raise healthcare costs. Already, there is a huge mismatch between needs and actual expenditure. A macro-economic study estimated that the cost to treat 650,000 patients in 2007 was approximately RM 12.2 billion, yet the actual expenditure was a mere RM 2.2 billion.

Four key strategies are proposed: (1) Adequate allocation of resources for prevention, treatment, and community based programmes. Related, increase patients' compliance by increasing their knowledge, awareness and self-monitoring skills; (2) Increase the participation of NGOs, pharmaceutical industries, food production, agricultural agencies, sports association, and others in managing the disease; (3) Enhance research especially on the prevention and early treatment of diabetes and the risk factors; and (4) Strengthen human resource development of paramedics and allied health professionals such as dietician, counsellor, physiotherapist and laboratory technologist. In 2050, Malaysia should utilize genetic engineering for treating and managing diabetes. Treatment regimes should include transplantation of pancreas for insulin dependent diabetes mellitus, introduction of diabetic markers test and clinical prevention by using oral hypoglycaemic agents. Equally important, vaccines could be made available for prevention of diabetes mellitus.

As life expectancy rises, Malaysia is becoming an ageing nation. In 2009, there were 2.1 million people over the age of 60 years or 7.1 percent of the total population. WHO predicted that the percentage will rise to 23 percent by 2050 (WHO 2006). Related, there will be an increase in the prevalence of disabilities and age-related diseases such as arthritis, osteoporosis and pathological fractures. Today, records show that nearly 20 percent of elderly patients seek help for chronic diseases. Yet, only four hospitals have geriatric ward, along with some 600 health clinics, facilities of the Community Welfare Department and NGOs that offer similar range of services. The dependency ratio[10] will rise from the current 8 percent to a projected 25 percent in the year 2050. The increasing ageing population and dependency ratio will be a challenge for health and welfare systems as well as pension and social security systems to provide care and services for an older, less healthy and non-working population. Thus new technologies and innovative health interventions to manage a range of diseases related to the process of ageing become critical.

Epidemiological literature suggests that chronic non-communicable diseases (CNCDs) including cardiovascular diseases (mainly heart disease and stroke), some cancers, chronic respiratory conditions and type 2 diabetes accounts for around 60 percent of all deaths worldwide, and 44 percent of premature deaths worldwide (Daar et al. 2007). If the global community fails to put in place effective preventive and curative interventions, we could expect some 388 million deaths from one or more CNCDs in the next decade. As shown in Table 2.4, these deaths will contribute to a substantial economic impact in the next decade, partly as a result of reduced economic productivity. Malaysia could experience the same fate if our healthcare system and relevant other actors fail to respond appropriately.

Table 2.4: Economic impact of CNCDs

	CNCD Billion (US$)	**GDP Billion (US$)**	**Percentage of GDP**
China	558	4,300	12.9
India	237	1,600	14.8
United Kingdom	33	2,600	1.2
Malaysia[11]	**27.7**	**221.7**	**12.5**

Source: Daar et al. 2007

[10] Dependency ratio is a measure of the portion of a population which is composed of dependents (people who are too young or too old to work).

[11] The projection for Malaysia is derived from a crude calculation based on the projection for China, India and the United Kingdom.

Socioeconomic Status

The following table shows that Malaysia's socioeconomic achievements are above the global average. In the ASEAN region, its standing is superior compared to Thailand and Indonesia. On the other hand, the country's human development index (HDI) value and GNP per capita is far behind Singapore, Sweden and South Korea.

Table 2.5: Socioeconomic status of Malaysia against global standard and select countries

	Global	Malaysia	Singapore	Thailand	Indonesia	Sweden	South Korea
Adult literacy rate (2000-2007)	81	**92**	94	94	92	NA	NA
Human development index (2007 value)*	0.73	**0.82**	0.94	0.78	0.73	0.96	0.93
GNP per capita (PPP int.$)	10,290	**13,740**	47,940	5,990	3,830	38,180	28,120

*Source: World Health Statistics, WHO 2010; * UNDP Human Development Report 2009*

STI in Health

The following paragraphs give a broad overview of the STI status. It discusses the enablers and barriers while drawing upon the lessons learned from South Korea and Sweden for Malaysia to improve its performance in health-related STI. A detailed discussion on STI in health is provided in Chapter 4 of this report.

Enablers

Key enablers to the promotion of STI include supportive policies, ongoing R&D initiatives, and success stories in the commercialization of medical devices and diagnostics, pharmaceuticals, and health tourism, as well as good infrastructure.

Policy. More and more, as stipulated in the Vision and Mission of the MOH, the health sector is utilizing appropriate STI for detection and management of health issues. At the same time, government policies and plans promote discovery and application of health-related STI not only to meet health outcomes but also economic outcomes (see Box 2.2).

At the core of the National Science and Technology Policy for the 21st Century is the intention to 'Maximize the utilization and advancement of science and technology as a tool for sustaining economic development, and improvement of quality of life and national security'. Specifically in the health sector, the government aims to place Malaysia as a leader in biotechnology, advanced materials, pharmaceuticals, nanotechnology and photonic.

Box 2.2: Policies related to STI and health

Vision 2020

1Malaysia (2009)

New Economic Model

National Science and Technology Policy for the 21st Century

National Biotechnology Policy

National Telehealth Policy

3rd National Agricultural Policy (1998-2010): Policy of Specialty Natural Products

National Forestry Policy 1978 (Revised 1993)

National Policy on Biological Diversity 1998

Success stories. The promotion of STI in health by the government, and the growing market for new technologies and innovations globally resulted in an increasing number of local initiatives and companies that develop, manufacture and market products and services as sampled below:

Pharmaceuticals: Development, manufacturing and marketing of a range of pharmaceutical products targeted at both overseas and local market (e.g. Pharmaniaga, Chemical Company Malaysia Bhd, Hovid Sdn Bhd).

Medical devices: Development and production of medical devices for fluid and blood management such as infusion and transfusion sets, catheters and syringes; basic respiratory products; latex examination and surgical gloves (e.g. German-Malaysian Medical Industries Sdn Bhd; Foresight Industries Sdn Bhd; Top Glove).

Diagnostics: For typhoid fever, tuberculosis, malaria, HIV, paratyphoid, Nipah virus and dengue; test kits for pregnancy, drug abuse, and brugian filariasis (e.g. Malaysian Bio-Diagnostics Research Sdn Bhd, Geneflux Biosciences Sdn Bhd).

Vaccines: Research and development and planned commercialization of novel prophylactic vaccines against dengue, Japanese encephalitis and EV71 (e.g. Ninebio Sdn Bhd, Sentinext Therapeutics Sdn Bhd)

Natural products: Research and manufacture of herbal and health supplements through extracting and processing novel biologically active compounds from natural resources and developing premium health formulations (e.g. Caroetech Inc)

The initiatives are mostly concentrated on medical devices, pharmaceuticals and test kits. Stem cells and genomics are new areas that are currently limited to research and development activities.

Ongoing research and development. The universities and research institutes conduct research and development activities in various areas of health and medicine. These efforts are funded by government funding, the private sector and through collaboration with foreign partners. Some of these efforts have produced valuable results and discoveries that have contributed to improving healthcare (refer to Chapter 4 for examples).

Good infrastructure. Malaysia's persistent drive to develop and upgrade its infrastructure has resulted in an impressive array of infrastructure that allows for social and economic growth. Specific to STI in health, the availability of research institutions, R&D facilities and laboratories, technology parks and good ICT facilities supports growth in this area.

Barriers

While a number of enablers provide a supportive environment for growth in STI, Malaysia has yet to expedite major breakthroughs and achievements which will put Malaysia on the same level as STI giants like Sweden and South Korea. A discussion on the barriers and comparison with these two countries, and select Asian countries, explains some of the reasons why Malaysia is at a disadvantage in its STI endeavours.

Insufficient investment in R&D. The knowledge-based economy master plan shows that the Malaysian government has the political will to ensure that R&D is a prominent feature of the national agenda. The government has supported R&D in the form of tax incentives, funds, and grants for both the public and private sectors. Under the national biotechnology policy for example, several strategic thrusts had been laid out such as creating an enabling environment with a supportive institutional, regulatory and financial framework. In the 9th Malaysia Plan, 1.5 percent of Malaysia's GDP was allocated to fund research initiatives. While these are strong support for R&D as a means to stimulate innovations and economic growth, low expenditure in R&D shows that more of the intentions need to be translated into actions.

Data in 2006 suggested that the R&D expenditure in Malaysia was 0.6 percent of the GDP. This level of funding is significantly lower than the 3.7 percent and 3.2 percent of the GDP for Sweden and South Korea (see box 2.3) respectively,

Box 2.3: Research and development in South Korea

R&D is a key element in South Korea's success. Recognizing its critical importance, the government enacted the Research and Development Promotion Act and introduced R&D tax credits as early as in 1970s. This Act prompted an increase in R&D funding from just 0.31 percent of GDP in early 1970s to 3.2 percent in R&D initiatives in 2007 (equivalent to US$313 billion); the 5th country globally with the highest R&D investment (OECD, 2009). In general, more than 75 percent of R&D investments are derived from private and foreign sector contributions, with the remaining 25 percent from the government and the public sector (Deok, 2006), which is used to support basic research.

as well as several other countries (see Figure 2.1). It also falls short of the targeted 1.5 percent of the GDP under the 9th Malaysia Plan.

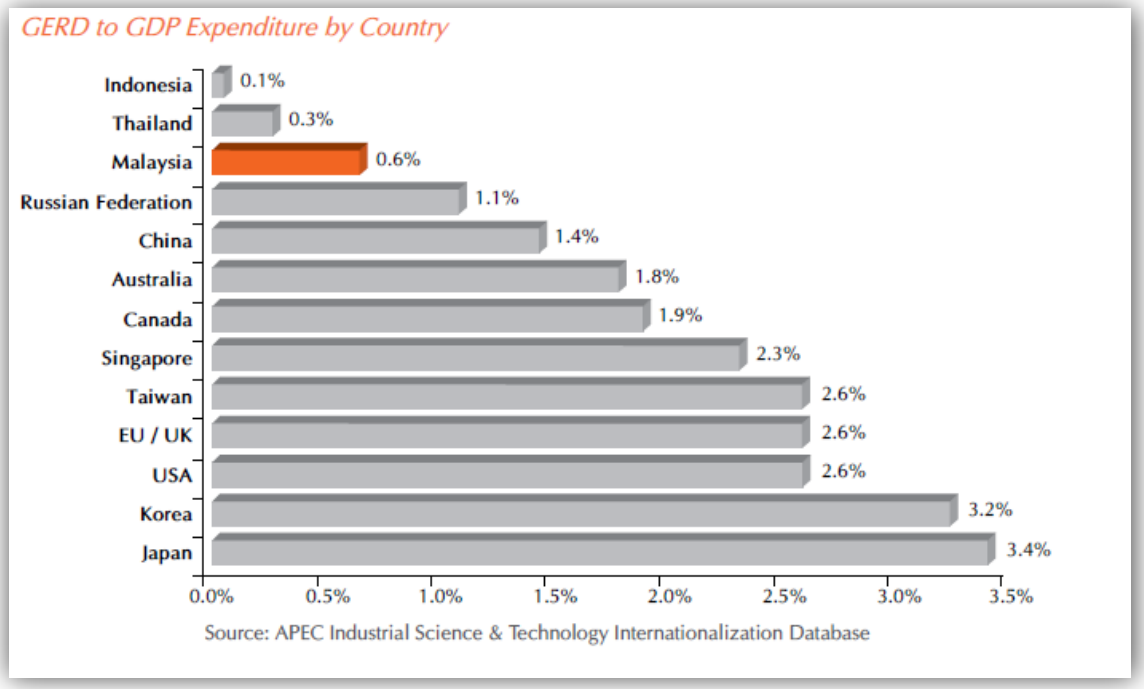


Figure 2.1: GERD to GDP expenditure by country
Source: APEC Industrial Science & Technology Internationalization Databse

Figure 2.2. shows the GERD/GDP ratio for groups of countries by level of income. The average GERD to GDP ratio for high income countries was 2.38 percent, the ratio for the middle income countries was 0.85 percent, and for the low income countries the ratio was 0.57 percent. This means that Malaysia's GERD/GDP ratio of 0.64 percent was lower than the middle income countries but closer to the low income countries.

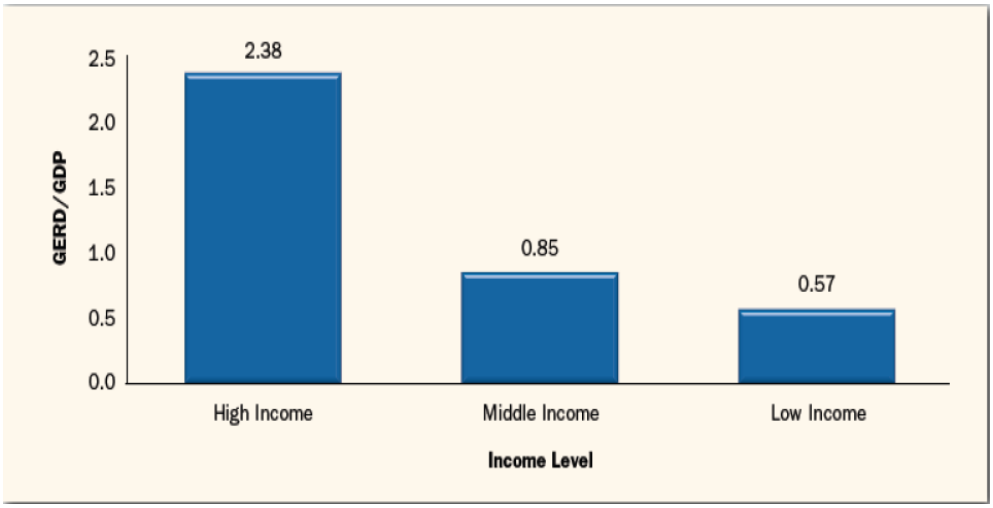


Figure 2.2: GERD/GDP by level of income
Source: World Bank, World Development Indicators (WDI)

Similarly, the investment in health-related R&D is low at only 2.14 percent of the total R&D; an equivalent of RM78 million spent in 2006 (MOSTI 2008). Comparison with South Korea (see Table 2.6) shows that nearly six percent of the total R&D funds (3.2 percent of the GDP) are allocated for the health industry at the amount of US$5.3 billion.

Table 2.6: Health R&D investment in South Korea (Unit, 100M KRW)

	2003	**2004**	**2005**	**2006**
Total R&D	65,154	70,827	77,996	89,096
Health R&D	3,131	3,633	4,189	5,324
Percentage	4.8	5.1	5.4	6.0

Source: 2008 Health Industry Annual KHIDI

Citing South Korean's example for R&D in biotechnology, the country has a strong and specific policy to support R&D activities (i.e. the Bio-vision, see page 35 for details). Under the national biotechnology policy, developments were charted according to definite phases or plans. The country's first biotechnology plan 2000 (1994-2006) aimed to establish the R&D infrastructure and system, and the government spent a total of US$3.6 billion (RM11.3 billion) with an average annual growth rate of 23 percent through this period. With that accomplishment, the Bio-vision 2016 (2007-2016) or the second phase of biotechnology plan was introduced to develop high level technology and establish infrastructure for industrialisation. There is clearly a marked difference between what had been spent for Korea to develop the first phase of the biotechnology plans compared to RM6 billion that Malaysia allocated for the first phase of capacity building in the Malaysian national biotechnology policy. Furthermore, the capacity building period planned for Malaysia which is five years is much shorter than the 12-year period in South Korea.

Exclusiveness of research efforts. In general, collaboration among researchers and research institutions is poor in this country. Most research efforts lack sharing of expertise, research and resource materials, equipment and facilities. The reluctance to share ideas and resources may be influenced by high competition between institutions aspiring to excel in particular niche areas. The competition for grants and the importance of being recognised as experts in the various niche areas do not encourage partnerships amongst and between universities and research institutes. Unfortunately, this reality limits the capacity to provide high quality research outputs, and extensive use of research findings.

Any technology in health must be relevant to the pathological and clinical needs. This makes partnerships between researchers who work in areas such as biomedical engineering and nanotechnology with the medical fraternity crucial.

Unfortunately, the two sectors do not interface in many of the research efforts. Funding agencies such as the Ministry of Science, Technology and Innovation (MOSTI) have in the past introduced funding guidelines that encouraged researchers and research institutions to work together. Unfortunately, these guidelines were not sustained and funds have been awarded to researchers who work in isolation or working on small projects. This weakness must be addressed to maximize the relevance of inventions and innovations for health care, and minimize wastage of resources.

Collaboration between universities, research institutions and private companies is also very limited, unlike the situation in Sweden. An example of strong collaboration between academic and private entities is in the biotechnology area where more than 90 percent of Swedish biotechnology firms collaborate with academic research groups in R&D activities. In addition, as many as 64 percent of biotechnology companies collaborate with foreign academic groups.

Lack of research infrastructure and facilities for animal studies. There is a gap in translating research findings to test its application via animal studies. In Malaysia, there are no high quality facilities for animal research with proper accreditations in spite of its necessity. While many institutions try to build their own animal house, resources get spread thinly and these facilities do not meet the required quality assurance standards and neither do they have adequate capacity to meet current and future demands in research. So while discoveries are being made in areas such as biomarkers and identification of active compound, the potential for further development is very limited. This is made even more difficult when the research institutions hesitate to share their facilities.

Insufficient number of researchers. Under the 9th Malaysian Plan, the government aimed to have 50 researchers for every 10,000 labour force. And by 2020, the Malaysian Higher Education Strategic Plan is aiming for 100 research scientists and engineers (RSE) per 10,000 labour force; the average for EU in 2003. Data shows that Malaysia has a long way to meeting the target. In 2006, there were 17.9 researchers for every 10,000 members of the workforce, which puts Malaysia alongside countries such as South Africa (20.7) and Chile (19.3) (MASTIC 2008). The figure is way behind Sweden's 126 researchers per 10,000 total employment. Moreover, comparison of the research density of full-time equivalent (FTE) researchers in Malaysia against some of the leading developed or developing nations shows a significant discrepancy in terms of skilled and employed R&D workforce, with merely 9.1 FTE researchers out of every 10,000 total workforce in the country in the same year (see Figure 2.3). The number of researchers in the health sector is even lower at 0.7 per 10,000 workforce. These ratios are considerably low for a nation which has plans to boost its science and technology industry. Malaysia can learn from the example of South Korea where the Korean Advanced Institute for Science and Technology was formed in the early 1970s with the aim of developing human resources for R&D.

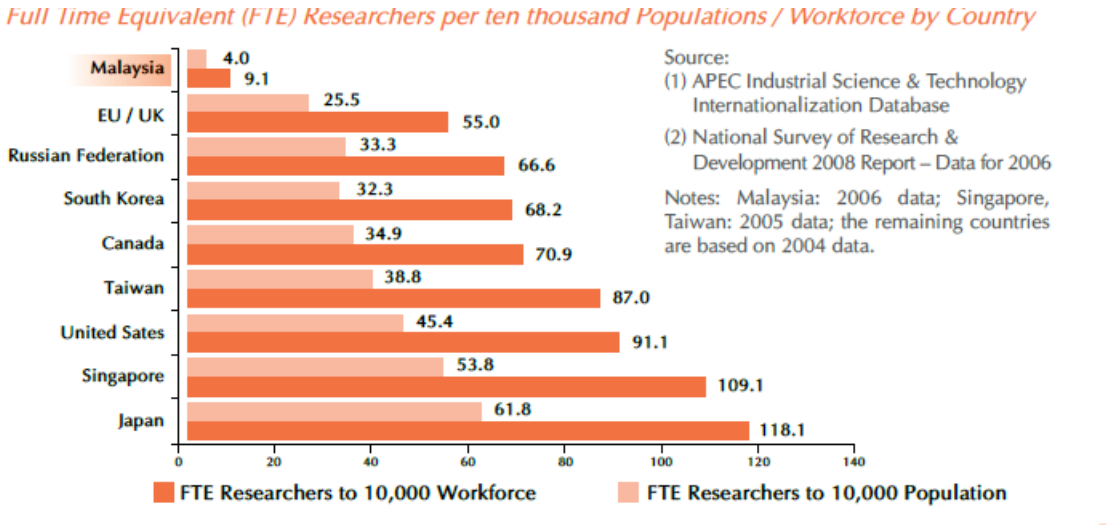


Figure 2.3: Full time equivalent researchers per 10,000 population/workforce by country

In some areas, there is insufficient in-country expertise and experience with regard to conducting fundamental research and translating fundamental research into preclinical and clinical studies. For example, in some areas such as stem cells research, most researchers had not been adequately trained. Few have had little exposure and some had taken their own initiatives to attend short courses.

The proportion of FTE researchers to the total headcount in a country illustrates the level of employability for science and technology related employment. In Singapore and Korea for example, the FTE researchers to the total researcher headcount ratio was 85 percent and 74 percent respectively in 2005, illustrating the high level of full time employment of qualified R&D professionals in their industries (Frost & Sullivan 2009). Malaysia, in comparison, is estimated to achieve a ratio of 51 percent, signalling the need for more job creation in the industry (Frost & Sullivan 2009).

Another key observation is the allocation of FTE R&D workers by sector for Malaysia is predominantly concentrated in the higher education sector. This is unlike the practices in Sweden and South Korea, in which majority of the workforce is in the private industry sector (Frost & Sullivan 2009). This again signals the lack of working opportunities for researchers in the private sector, thus resulting in a larger research workforce population in the government and higher education sectors.

Box 2.4: Human Resources in Sweden

Amidst the high level of R&D investment, Sweden has 12.6 researchers per 1000 total employment and as high as 68 percent of them work in the business sector. It has one of the highest graduation rates in advanced research programmes (PhD or equivalent) among OECD countries, and the country produces high quality research publications. The Table below shows the value of production per employee as well as the R&D as percent of value added in the pharmaceutical and medical industries, and in all industry combined.

Sector	Value of production per employee	Change 1997-2002	R&D as % of value added
Pharmaceutical industry	3.33 million SEK	35%	32%
Medical technology	1.76 million SEK	50%	
All industry	1.57 million SEK	16%	10%

Source: Medicine för Sweden 2009

Lack of a commercialization system

1. Issues related to researchers

Many academic researchers in government linked research institutions and universities are not commercially driven. It is not uncommon to see that research proposals seeking funding lack "an outcome (product) in mind" whereby the research implications are (commonly) stated as "publications and presentations of findings..." without much thought given to the potential commercialisation of the research product. For research to be driven by a commercial value, it is pertinent that this is specified at the conceptual and design phase. In addition, researchers in healthcare who view that commercialising health-related research output as inappropriate further hinder exploitation and subsequently commercialisation of research findings into useful products.

There is also a lack of understanding among researchers about the types of health products that would address health-related issues and those that are marketable. This may be a result of poor information exchange linkages between fundamental researchers in health science, technology experts, and people with business acumen, thus each is not aware of what others can contribute to addressing health issues. Such cross border linkages is still new to many researchers and the platform has neither been formalized nor well coordinated.

A conflict exists whether a research should be driven by market demands or the health needs in the population. For example, the need for a device to confirm diagnosis of typhoid is relatively low in this country but has greater market demand overseas. Hence, such products may have more economic benefits than health benefits to our population. Since the public health sector has a responsibility to ensure the health of the population, it is a dilemma whether the limited resources available should be used for research that has commercial values or attending to the need of the Malaysian population.

2. Lack of commercialisation system

A major concern voiced by both prominent researchers and private companies dealing with health products is the lack of a system for commercialising products derived from research findings. Turning a finding into a product requires a huge investment. R&D funds in Malaysia are mostly spent on fundamental research, which leaves little support for taking findings of fundamental research to the next level of pre-clinical and clinical trials. As very few investors are willing to take risks in big budget R&D, there is a void towards developing, testing and finalizing products that are ready for use, and to be commercialised. This situation de-motivates researchers and discourages further discovery work. Related, researchers have neither been trained nor have the necessary skills to convince investors about the potential economic benefits of their findings.

Other issues related to commercialisation includes (1) lack of stringency and selectiveness in the vetting of proposals and granting of funds resulted in resources being spent on projects with poor utility and commercialisation value. Allocation of funding per project is reduced in order to fund higher quantity of projects at the expense of quality, (2) poor appreciation of Malaysian made products, (3) lack of protection from foreign products in term of securing the local market (for example through government contracts), and (4) high investment costs to acquire the technology for development and innovation work. The case study of OSA Technology Sdn Bhd is a typical example (see case study below).

Case study 3: OSA Technology Sdn Bhd

OSA Technology Sdn Bhd

OSA Technology Sdn Bhd (OSA) is a wholly owned Malaysian company; the first to manufacture and market orthopaedic trauma implants. The company received a grant from the Malaysian Technology Development Corporation (MTDC) with partial support from the Perbadanan Usahawan Nasional Berhad (PUNB). The total production capacity is at RM 27 million per year, and it has achieved ISO 9000 and ISO 13845 (medical device) certification. OSA's competitors are trading companies that import products from USA, Europe and India, who control 90 percent of the local market.

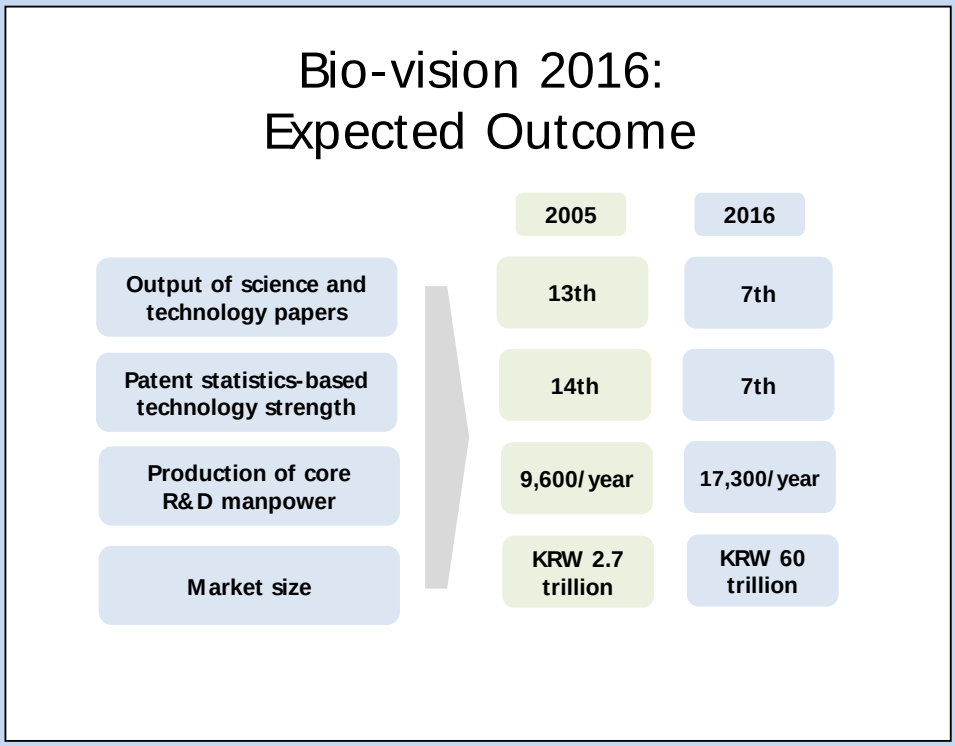
OSA encountered a number of obstacles in establishing and growing the business. Firstly, as the nature of business is the first of its kind in Malaysia, it is perceived to be of high risk by financial institutions. Related, OSA faced difficulty securing a loan from a commercial bank. Efforts to secure funds from venture capital agencies, which are limited in Malaysia, were in vain. Secondly, even though OSA products are 30 to 50 percent cheaper compared to that of its foreign competitors, it was challenging for OSA to penetrate the local markets. Despite the existence of a circular urging the public sector to "buy Malaysian," in practice this policy is seldom adhered to. OSA claims that there has been cases where the purchasing procedure was not transparent, product specification advertised favoured certain brands of products, and tenders were awarded for cheaper but substandard products from less developed countries. Thirdly, OSA's attempts to penetrate the foreign markets proved even more difficult. Thus far, the company has only made way into the Indonesian and Cambodian markets. OSA participated in a few overseas trade missions, and felt that, in general, Malaysian embassies abroad could be more responsive to its request for assistance.

'Brain drain'. There are many qualified and skilled professionals from Malaysia who have taken employment and residence in other countries. They are very productive in their new country of residence and some have made significant discoveries in various STI areas. The government is concern about this reality and has launched a number of programmes to encourage them to return to the country.

Lack of focus. Malaysia tends to join the bandwagon in exploring new areas. As such, it is involved in many a diverse initiatives and become 'a Jack of all trade but master of few'. To be a leader in any area would require focused attention and resources. For example, the lesson from South Korea in their quest to be a leader in biotechnology highlights the importance of being focused and staying the course (see Box 2.5 below). From the Korean experience, Malaysia needs to identify a few areas of focus and subsequently stay the course.

Box 2.5: Biotechnology in South Korea

Recognizing the huge global market for biotechnology goods, the country has been and continues to invest heavily in R&D in this area. Between 1994 and 2006, its R&D investment has evolved at an annual growth of 23 percent to a total of US$3.6 billion; evidence of the government's determination to operationalise its vision to become a global leader in biotechnology as envisioned in its Bio-Vision 2016. This vision is a continuation of a long-term plan which started in 1994. Biotech 2000 spanned a 12 year period (1994 to 2006), where a core function was the establishment of R&D infrastructure and system. The successes and lessons learned from Biotech 2000 laid the foundation for Bio-Vision 2016. The latter focuses on five key areas, one of which is medicine and healthcare. And it has four strategies: (1) creation of the national biotechnology promotion system, (2) expansion of infrastructure to advance R&D, (3) accelerate growth and globalization of bio-industry, and (4) establishment of regulatory and institutional reform and enhancement of public acceptance. The expected outcomes for Bio-Vision 2016 are summarized in the following graphic.



Summary

The analysis clearly shows that Malaysia has a favourable health system, economic status and STI enablers for achieving greater health and economic outcomes. While the country needs to build upon these elements in its attempt to become one of the leaders in health-related STI, it also must address the main barriers or risk missing the opportunity to excel in this sector.

CHAPTER 3
WHERE DO WE WANT TO BE?

Health

The Government is determined to improve its health services as a means to achieve greater health and economic outcomes. The journey towards this end is guided by two visions that emphasize "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (WHO Constitution 1946).

Healthy Malaysia in 2050

Malaysia is a country with a healthy population that is productive, creative and competitive; where the health expenditure is efficient and manageable; while the health service and industrial sector is a major contributor to the national economy, and Malaysia is known as a regional tropical health service and product centre.

Healthy Malaysians in 2050

Every Malaysian resident has basic education, is free from poverty and insecurity, enjoys a healthy and safe home, workplace and environment, practices a healthy lifestyle, free from physical and mental illnesses and disability, with an autonomy for self care and have ready and affordable access to essential and emergency health care.

As the country strives to achieve the two visions over the coming forty years, it must continue to honour that health is, and must remain a public good and a basic right of all Malaysians. Thus, the right to equitable and accessible healthcare of Malaysians must be protected by all means.

The two visions are contextualized within a scenario in 2050[12] where:

- Health is a right of every Malaysian, thus equity in coverage and accessibility to quality health services and health information exist regardless of race, religion, geographic location, social status, or capacity to pay.

- Health system embraces innovative public health approaches and empowerment of individuals to be responsible, and to manage their health.

- Health care lies in preventive and personalized medicine.

[12] The scenario was identified with inputs from participants in a Focus Group Discussion, participants at the Consultation Workshop, and team members of the Study.

- Advanced and cost effective medical technologies are utilized for early detection, effective treatment and/or rehabilitation of health problems.

- Vaccines and genetic engineering are widely used to eliminate acquired and inherited diseases.

- Analysis of one's genetic material for disease diagnosis and identification of tendency to acquire disease and abnormal behaviour is routine.

- Stem cells technologies are accessible and used in the treatment of numerous diseases including leukaemia, cancer, Parkinson's disease, spinal cord injuries, multiple sclerosis, and muscle damage.

- Tele-health and tele-medicine are widely available and easily accessible.

- Malaysia is a high income country, and cost of living and health care commensurate the high income.

Desired Health Outcomes

In order to achieve the above two visions, the desired health outcomes in 2050 must expand beyond the traditional health indicators such as life expectancy, infant and maternal mortality, and disease-specific mortality rates to cover the domains of wellness, well being, accessibility to affordable, quality continuum of care, and patient focus. In this connection, the Study proposes a set of holistic indicators and the anticipated achievements in 2050. While the former benefits from consultation with a panel of local experts (see Annex 1), the latter is based on global standards and rooted in achievements and best practices from Sweden, Korea, Singapore, Japan and Switzerland (World Health Statistics 2010). Where data is not available from global figures, revalidation through mathematical calculations using Microsoft Excel, and from established secondary data were imputed. The following table summarizes the proposed indicators.

Table 3.1: Health indicators: Current and expected future health outcomes

Demographic indicators

Malaysia's total population are expected to increase by 2050, although the rate of annual population growth rates will decrease to a comparable rate in high income countries. The fertility rate, given the trend of late marriage and childbearing among women, will decrease to replacement level.

Indicators	**Current Malaysia**	**Anticipated in 2050**
General Country Statistics[1]		
Total population[1](2008)	27 million	40 million
Total fertility rate (per woman) (2008)[1]	2.6	2.1
Annual population growth rates (%) (1998 – 2008)[1]	2.0	1.8

Indicators measuring the health of the population[1] (Mortality[1])

As a general rule, life expectancy rises with increasing per capita total health expenditure. The life expectancy at birth of Malaysians in 2050 will be consistent with its status of a developed country. This longevity is the result of early detection and screening of diseases and better health care thus reducing morbidity and extending healthy life years. Healthy life expectancy is expected to rise in accordance with better health technologies, quality of care and overall socio economic indicators. The projected infant mortality rate (IMR) will also be reduced by more than half as there will be improved antenatal and post natal care.

Indicators	**Current Malaysia**	**Anticipated in 2050**
Life expectancy at birth (years) (2008)[1]	73	83 (Japan)
Healthy Life expectancy (years) (2007)[1]	64	76 (Japan)
Infant mortality rate /IMR (per 1,000 live birth) (2008)[1]	6	2 (Sweden)

Cause- specific mortality and morbidity[1] (Maternal mortality ratio/MMR)

The MMR will be reduced from nearly 30 to only 2 per100,000 live births per year by 2050. Increased universal access to health propagates early care, reduction of post partum haemorrhage and better quality of care. The MMR will be limited to deaths in cases of multiple complications or iatrogenic deaths.

Indicators	Current Malaysia	Anticipated in 2050
Maternal mortality ratio/MMR (per 100,000 live births) (2000 – 2009)[1]	28	2 (Sweden)

Age-standardized mortality rates by cause (per 100,000 population)- Communicable Diseases

The incidence and prevalence of communicable diseases will be reduced to a manageable level as an outcome of (1) more effective surveillance and monitoring system through the implementations of HMIS and IT which allows for earlier notification and management of incidence, and halting transmission; (2) greater number of centres for disease management; (3) improved implementation of health and immigration laws (e.g. International Health Laws and Regulation and detection of communicable diseases of immigrants/visitors before they land in Malaysia).

HIV prevalence will decrease with greater screening and detection, prevention of transmission among groups with high risk behaviours and from mother to child. HIV retroviral drugs (most probably generic from either local or ASEAN countries) will be more accessible and affordable to the general public through better purchasing power and higher subsidization from the government and NGOs.

Treatment of TB will be more holistic and universally accessible. The upgrading of health clinics and hospitals with better facility, adequate number of physicians trained in infectious diseases in 2050 sets the stage for better responsiveness and management of TB which in turn will reduce mortality rate.

Malaria is expected to be eradicated with strongly enforced vector control, and free screening and detection for all, including among immigrants from malaria endemic countries.

Population growth will be accompanied by rapid urbanization. These two factors are associated with increase in dengue cases. Nevertheless, good public health interventions such as effective vector control, dengue virus strain surveillance and enhancement of community participation that have been incorporated in the Malaysia National Strategic Plan for Dengue Control are expected to reduce the number of dengue cases. Therefore, projection of dengue is targeted at an annual reduction of 10 percent.

Indicators	Current Malaysia	Anticipated in 2050
Communicable diseases[1]	161	19 (Switzerland)

Morbidity and mortality of communicable diseases[1]		
HIV/AIDS		
Prevalence of HIV among adults aged 15-49 (%) (2007)[1]	0.5	0.1 (Sweden)
Mortality rate (per 100,000 population (2007)[1]	15	4 (HIC)
Tuberculosis (TB)		
Prevalence of tuberculosis (per 100,000 population) (2008)[1]	120	1. (Sweden)
Mortality rate of TB (2008)[1]	15	0.4 (Sweden)
Malaria		
Mortality rate (per 100,000 population) (2006)[1]	0.1	0 (Korea)
Dengue		
Dengue/ Dengue haemorrhagic fever	49,433 cases/year	558/ year (based on MOH target of 10% reduction annually)
Non-communicable diseases[1] (NCD) (per 100,000 population) If no serious interventions are put in place, the prevalence of NCDs such as heart diseases, diabetes, cancers and disabilities will be at high levels by 2050 as seen with the trend for high income countries. The expected improvement in the country's overall health care system, and specifically early screening and referrals and timely care to manage diseases will avoid the upward trend. This will also be in tandem with a more knowledgeable population who is able to take preventive measures including healthy lifestyles (exercise, good eating habits, avoidance of smoking) and better stress management. These factors points to future prediction of an overall reduction of NCDs.		
Indicators	**Current Malaysia**	**Anticipated in 2050**
Non-communicable diseases[1] (NCD) (per 100,000 population)	623	345 (HIC)
Morbidity and mortality of non-communicable diseases		
Cardiovascular mortality rate (per 100,000 population)[2]	275	164 (Singapore)
Cancer mortality rate (per 100,000 population) (2004)[2]	137	113 (Singapore)
Diabetes mellitus mortality rate (per 100,000 population) (2004)[3]	19.6	10.9 (Singapore)

Mental health disorders

Mental health problems and disorders will be common by 2050. However, it will be at a manageable level provided that the health care system offers widely accessible and acceptable comprehensive services that include early detection and treatment. At the same time, the numbers of multi-disciplinary professionals (e.g. psychiatrist, family medicine specialist, counsellors) who are well trained in mental health problems must increase.

Indicators	**Current Malaysia**	**Anticipated in 2050**
Unipolar Depressive Disorders	5.3%	1.8 – 2.6%
Schizophrenia	0.8%	0.28 – 0.50%
Bipolar Affective Disorder	1.2%	0.37 – 0.51%

Risk factors[1]

Clean water and improved sanitation will be universal. The GINI coefficients among ethnic groups will be lower than <0.30 and reflects greater equalities among Malaysians. It is projected that pro-poor programmes will be implemented by the MOH, private entities, and NGOs. These will lead to greater universal access to health care among the population, and will have major impact on overall population's health and accomplishing health needs.

Indicators	**Current Malaysia**	**Anticipated in 2050**
Population using improved drinking-water resources (%) (2008)[1]	100	100 (HIC)
Population using improved sanitation (%) (2008)[1]	96	100 (Korea)
Alcohol consumption among adults aged ≥ 15 years (litres per person per year) (2005)[1]	12.5	2.1 (Singapore)
Obesity among adults aged ≥ 15 years (%) (2000 – 2009)[1]		
Male[1]	13.9	2.8 (Korea)
Female[1]	18.8	3.5 (Korea)
Prevalence of smoking any tobacco product among male adults aged ≥ 15 years (%) (2006)[1]	52.6	17.3 (Sweden)

Injuries[1]

Injuries statistics comprise of occupational injuries and motor vehicle accidents (MVA). In 2050, it is projected that Malaysians will have better occupational and road safety laws and regulations, and that they are consistently enforced. This will contribute to a reduction in the rate of injuries.

Indicators	Current Malaysia	Anticipated in 2050
Injuries[1]	53	27 (Singapore)

Demographic and socioeconomic status[1]

Malaysia's export diversity and trade will remain a significant driver of the economy. This, as well as an annual GDP growth that is likely to remain stable at 10.10 percent, puts the country on the upward path of income per capita; rising to US$ 47, 940 in 2050.

All Malaysians will be literate by 2050 as the education system covering primary, secondary and tertiary levels will be further improved and made universal, including Sabah and Sarawak and inner areas of West Malaysia.

The overall composite of Human Development Index will nearly reach the value of 1.0.

As life expectancy increases, so will the proportion of elderly population which is reflected by a high dependency ratio on the young and middle age population. The projected scenario in 2050 depicts (1) an elderly-friendly environment and facilities, (2) regulations and laws to protect them, (3) quality and widely available geriatric services with a ratio of 1 specialist per 4,000 population, and (4) a national gerontology centre that specializes in geriatric research and welfare.

Indicators	Current Malaysia	Anticipated in 2050
Demographic and socioeconomic status[1]		
Gross national income per capita (PPP int.$) (2008)[1]	13, 740	47,940 (Singapore)
Adult literacy rate (%) (2000 – 2007)[1]	92	100 (HIC)
Human Development Index (Rank/Value)	66/0.829	0.980 (Norway)
Ageing		
Age >60 years old[1] (%)	7	21 (HIC)
Dependency ratio[4]	13.1	19.7 (Western Pacific Region)

Indicators measuring coverage of health services [1]

Birth attended by skilled health personnel (%)

In 2050, all births will continue to be attended by trained, skilled health personnel. The public services will be complemented by affordable private health care facilities for birthing as social insurance schemes will cover private care.

Indicators	Current Malaysia	Anticipated in 2050
Birth attended by skilled health personnel (%) (2000 – 2008)[1]	100	100 (HIC)

Immunization coverage among 1 year olds (%) (2008)[1]

Immunization coverage for measles, DPT 3rd dose and Hepatitis B 3rd dose among 1 year olds will be nearly universal due to better coverage of and access to health care, affordable immunization pricing and services provided by the private health care sectors (e.g. general physicians, private clinics and hospitals).

Indicators	Current Malaysia	Anticipated in 2050
Immunization coverage among 1 year olds (%) (2008)[1]		
Measles[1]	95	97(Singapore)
DTP 3rd dose[1]	90	97 (Singapore)
Hepatitis B 3rd dose[1]	90	97 (Singapore)

Smear positive tuberculosis case detection rate (%)

The smear positive TB case detection rate (%) will increase to 90 percent by 2050 as a result of improved overall services, management and systems related to the detection and treatment of TB. The number of foreigners (immigrants/visa holders on working permits and visitors) and local Malaysians contributing to TB cases will still be at the current rate.

Indicators	Current Malaysia	Anticipated in 2050
Smear positive tuberculosis case detection rate (%)(2008)[1]	76	90 (Singapore)

Health workforce and infrastructure[1]

Density of health personnel (per 10,000 population)

As a result of better health resource planning and strategies, the ratio of health care workers by levels and categories will increase to reach optimum level.

Indicators	Current Malaysia	Anticipated in 2050
Health workforce and infrastructure[1]		
Density of health personnel (per 10,000 population) (2000 – 2009)[1]		
Physicians[1]	7	36 Sweden)
Nursing and midwifery personnel[1]	18	116 (Sweden)
Dentistry personnel[1]	1	14 (Korea)
Pharmaceutical personnel[1]	1	11 (Korea)

Hospital beds (per 10,000 population)

Numbers of hospital beds in both the public and private systems are expected to increase proportionately to meet the needs of the growing population. The increase in beds at private facilities is due to the demand created by social health financing schemes and health tourism. Greater number of beds will allow better distribution of resources and responsiveness of care among populations.

Indicators	Current Malaysia	Anticipated in 2050
Hospital beds (per 10,000 population) (2000 – 2009)	18	86 (Korea)

Health expenditure ratios [1]

The health care financing scenario in Malaysia in 2050 will be social-based; a combination of social health insurance and taxes. This method contributes to universal access to health care for all Malaysians. The private sectors will play a much bigger role in national health care, both through direct and indirect government contributions, corporate and ear marked-tax, and from private NGOs. They will offer greater coverage of health services as more Malaysians with disposable income are able to purchase private care.

The proportion of GDP spent on health will increase, but effective and efficient costing control mechanisms will be in place to control costs (some examples of the mechanism include purchasing and procurement of cost effective health technologies, drugs, cost savings benefits through nationwide Health Management Information System (HMIS), Diagnosis Related Groups (DRGs) in hospitals reimbursements and Ambulatory DRG in ambulatory reimbursements).

All indicators of government expenditure on health will increase. As evidenced from

many developed countries and elasticity of health demand, the expenditure will increase due to increasing use of technologies and pricing of services rather than treatment of essential diseases in the primary care settings.		
Indicators	**Current Malaysia**	**Anticipated in 2050**
Total expenditure on health as % of gross domestic product (2007)[1]	4.4	12-14 %
General government expenditure on health as % of the total expenditure on health (2007)[1]	44.4	61 (high income country/HIC) - 81 (U.K)
General government expenditure on health as % of total government expenditure (2007)[1]	6.9	15 (U.K)- 17 (high income country/HIC)
Per capita government expenditure on health (PPP int. $) (2007)[1]	268	2446 (U.K)-2492 (high income country/HIC)

[1]WHO/ World Health Statistics 2010
[2]WHO/ World Health Statistics 2009
[3] World Health Organization, Department of Measurement and Health Information, February 2009.
[4] WHO Global Burden on Disease, 2004
*Dependency Ratio

Chapter 2 of this Report highlighted five diseases with high disease burden that are already prevalent today – cancer, cardiovascular diseases, dengue, diabetes, and diseases related to ageing. Data and projection show that these diseases will continue to be prevalent in 2050. However, the prevalence may be controlled if effective preventive and treatment measures are in place. It is in this context that the Study recommends investments in STI to focus on addressing these five diseases.

Beyond Traditional Health Indicators

Current health indicators in Malaysia have long been established, and they will remain relevant in 2050 (see NIA in Annex 8). However, Malaysia needs new domains of health indicators such as the OECD and WHO indicators to measure how well its health vision for 2050 is being achieved. A sample of the new indicators is presented in table 3.2 below.

Table 3.2: Samples of proposed new health indicators

Indicators	**Measures**	**Examples**
Services and outcome indicators	Efficiency, effectiveness and safety	• Government funded health expenditure as percentage of GDP. • Government funded health expenditure as percent of THE. • Government funded health expenditure as percentage of total govt expenditure. • Annual HbA1c testing for patients with diabetics. • Patients with diabetics with poor glucose control. • Major amputations in diabetics. • Asthma mortality rate, ages 5-39. • In-hospital mortality rate within 30 days of hospital admission for acute myocardial infarction. • In-hospital mortality rate within 30 days of hospital admission for stroke. • Waiting time for surgery after hip fracture, over age 65. • Influenza vaccination, over age 65.
Social health indicators	Living conditions, satisfaction of daily living and environment	• Proportion of population below $1 (PPP) per day. • Poverty gap ratio. • Share of poorest quintile in national consumption. • Proportion of population with access to affordable essential drugs on a sustainable basis.
Behaviour and lifestyles indicators.		• Rate of psychiatric admission of patients under Community Psychiatric Service. • Diabetes, deaths per 100,000 population. • Overweight or obesity, percentage of males and females with a BMI>25 kg/m2.
Indicators for health resources in specific areas with high disease burden.	e.g. geriatric care	• Financial protection. • Ratio of per capita health service use of lowest income quintile to per capita health service use of highest income quintile. • Incidence of health related poverty measured as per cent of population falling into poverty due to ill health.

		• Age-standardized rate of death for selected causes per 100,000 populations.
Specific indicators for high risk groups	e.g. Urban poor, hard core poor, aborigines.	• Percentage of poor and vulnerable population covered by social safety nets. • Population suffering from catastrophic health expenditure as percent of total population. • Practicing physicians, density per 1,000 population. • Psychiatric care beds, density per 1000 population. • Unintentional injury deaths. Crude rate and age-standardized rate of death from unintentional injuries per 100,000 population.
Wellness indicators	Quality of life of the population	• Suicides, deaths per 100 000 population. • Potential years of life lost (PYLL) – suicide. • Potential years of life lost (PYLL), all causes, males and females in years. • Doctor consultations per capita. • Two-week disability days (Population aged 12 and over who stayed in bed or cut down on normal activities because of illness or injury, on one or more days in the past two weeks).

Socioeconomic Status

Malaysia is already embarking on efforts to become a high income country by 2020. This will pave the way towards achieving the target outcomes by 2050 as detailed below.

Table 3.3: Desired socioeconomic outcomes by 2050

	Current	**Desired by 2050**
Adult literacy rate	92 (2000-2007)	100
Human development index	0.82 (2007 value)	0.99 (higher than Sweden now)
GNP per capita (PPP int $)	13, 740	70,000 (more than Singapore now)

CHAPTER 4
HOW DO WE GET THERE?

This chapter will specifically review STI strategies that will serve as conduits towards achieving desired health and economic outcomes. As mentioned in Chapter 1 of this report, the Study recognizes the critical roles of other elements such as quality of health delivery and health financing in achieving greater health and wellness. However, as mandated by the TOR, the core discussion and recommendations are devoted to health-related STIs.

Medical Devices and Diagnostics

A medical device refers to an instrument or equipment or appliance which is used for the purposes of medical diagnosis, surgery or therapy. It covers a wide range of instruments for Cardiology, Oncology, Neurology, Orthopaedic, Aesthetic Devices and Healthcare Information Technology, and varies in complexity and application. Diagnostics in this context refers to clinical diagnostics (i.e. the way the doctors diagnose patients, using a variety of clinical testing, patient history and examination). Commonly used clinical diagnostic tools include glucometer and blood pressure monitor.

The medical device industry is diverse, technologically dynamic and highly competitive. Its global market value forecast for 2010 is nearly US$201.6 billion (see Figure 4.1). The largest markets are the United States, Europe and Japan, and there is a huge potential market in China. The industry has a promising future globally due to the increase in aging population and the demand of surgical procedures (medica.com). As for diagnostics, the world market is also dynamic. It was valued at $22.47 billion in 2000, and anticipated to reach US$60 billion by 2014 (see Figure 4.2). Molecular diagnostics is the fastest growing component of clinical diagnostics, valued at US$3.67 billion by 2010. This area is expected to grow at a rate of 18 percent, due to the growth of biomarkers for cardiovascular disease and oncology (Frost and Sullivan 2010).

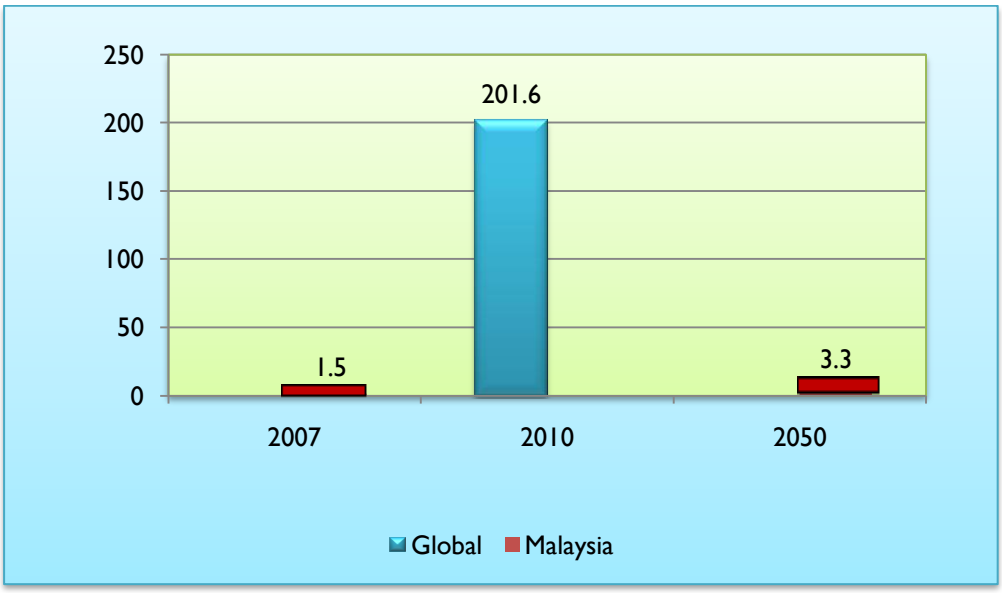


Figure 4.1: Medical devices market value (US$ billion)

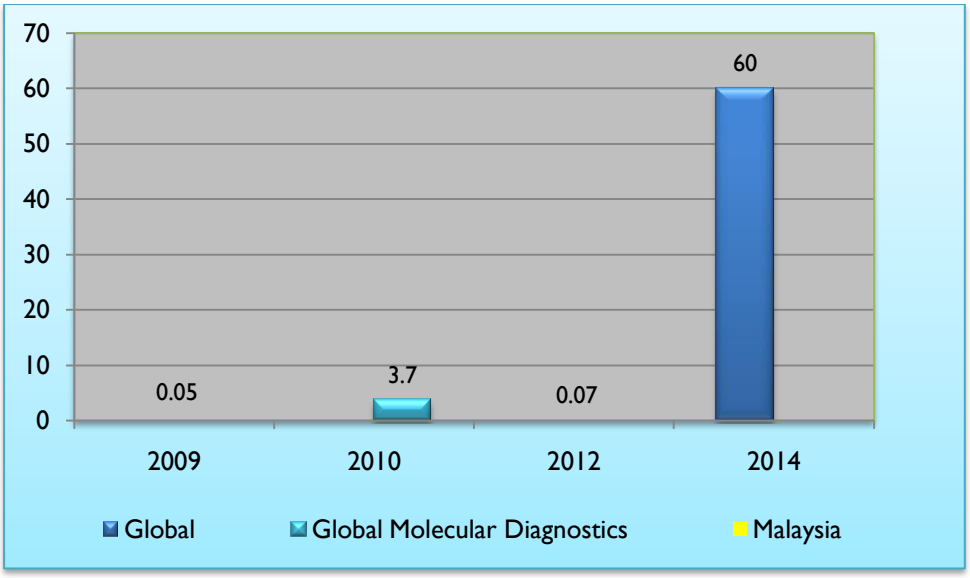


Figure 4.2: Market value for medical diagnostics (US$ billion)

Malaysian medical devices industry registered more than RM5 billion (US$1.5 billion) in revenue in year 2007, with a year-on-year growth forecast of 8 percent over several years (Association of Malaysian Medical Industries AMMI 2007). Its value is anticipated to be US$1.7 billion by 2015 (Espicom.com 2010) and US$3.3 billion by 2050 (Frost & Sullivan 2007). This, however, is a small share of the global market (see Figure 4.1). The country's revenue for clinical diagnostic registered at US$50 million in the year 2009, with an annual growth rate of 10.5 percent and anticipated to reach US$70 million by the year 2012 (Figure 4.2).

Medical devices and diagnostics are widely used in the Malaysian healthcare environment. The equipments range from high technology diagnostic equipments such as CT Scan, Magnetic Resonance Imaging (MRI) and therapeutic equipment such as laser therapy or ultrasound therapy machine, to simpler devices such as metal implants and prosthesis used in orthopaedic areas, and disposables such as surgical masks, gloves, catheters. Despite local production of some devices and diagnostics tools, the country imports more than half of its medical equipments. In recent years, domestic manufacturers are encouraged to expand production into more technologically advanced products and develop related services, and actions are put in place to enhance Malaysia's capability as a producer of medical devices and diagnostics. As of 2007, there were nearly 200 medical device companies in Malaysia (Frost & Sullivan 2007). Although rubber-based products still have the largest share, more companies are moving into manufacturing products made from plastics, silicone and metal alloys. The medical devices sector is also expanding its manufacturing value chain by moving from basic processes and conventional assembly to product and process R&D, design and prototyping, distribution and logistics. A total of RM800 million (US$234 million) was targeted as investment in medical devices for 2010 under the Third Industrial Master Plan 2006-2020 (Frost & Sullivan 2007). In March 2008, a Medical Device Bill was drafted in view to regulate medical devices. The bill is expected to be endorsed by the end of 2010.

The preparation of the relevant subsidiary legislations has also been initiated (biotechcorp.com). As for diagnostics, local manufacturers are increasing their effort in targeting opportunities in the area of molecular diagnostics. A number of rapid test kits have been developed for early detection of diseases such as dengue and typhoid. The products have penetrated market in neighbouring countries.

The growth of medical device and diagnostics industry in Malaysia is driven by several factors. The paradigm shift towards wellness and prevention contributes to an increasing demand for self health monitoring products such as glucometer and blood pressure meters. The increase in cardiovascular disease and orthopaedic injuries also place a higher demand for implants. In the area of diagnostics, growth in chronic and metabolic diseases drives increased use of molecular testing. There is also an increased demand for screening kits to detect tuberculosis and HIV and dengue, placing a demand on screening kits (Frost & Sullivan 2009). Demands for the above products create opportunities for local product development and manufacturing.

Malaysia's competitiveness lies in the quality and effectiveness of the products it has produced, steady economic growth, excellent ICT infrastructure, well-developed financial facilities, availability of a wide range of local companies as joint-venture partners, educated workforce, and readily available industrial training opportunities. These are criteria for further development of medical devices and diagnostics and attracting foreign investors in these areas.

In spite of the enablers, Malaysia's capability to advance in medical device and diagnostics is hindered by several shortcomings. Currently, there is a shortfall of trained human capital in biotechnology areas in general, and in medical devices and diagnostics industry specifically. Lack of R&D initiatives including basic research in the country limits the country's competitiveness in this industry. Translational research does not frequently result in products that may be widely commercialized. Another challenge is difficulty in securing funds from local financial institutions because this industry is considered a 'high risk business'. As a result, local companies of small capacity do not have adequate funding support to start new projects. Market penetration is also highly challenging. The MOH neither procures locally-made products nor do they demand for new and/or more effective products. Yet, there is need for local validation in order for a product to be accepted internationally. This reality de-motivates local companies to invest in this field (see case study on page 34).

At present, despite the importance for the manufacturing sector to carry out experiments and trials, there are no biohazard level three and four (BSL-3 and BSL-4) laboratories in Malaysia. The GMP and GLP certified laboratories are also limited. Thus, there is need to upgrade relevant laboratories towards WHO-certified laboratories for medical devices and diagnostics.

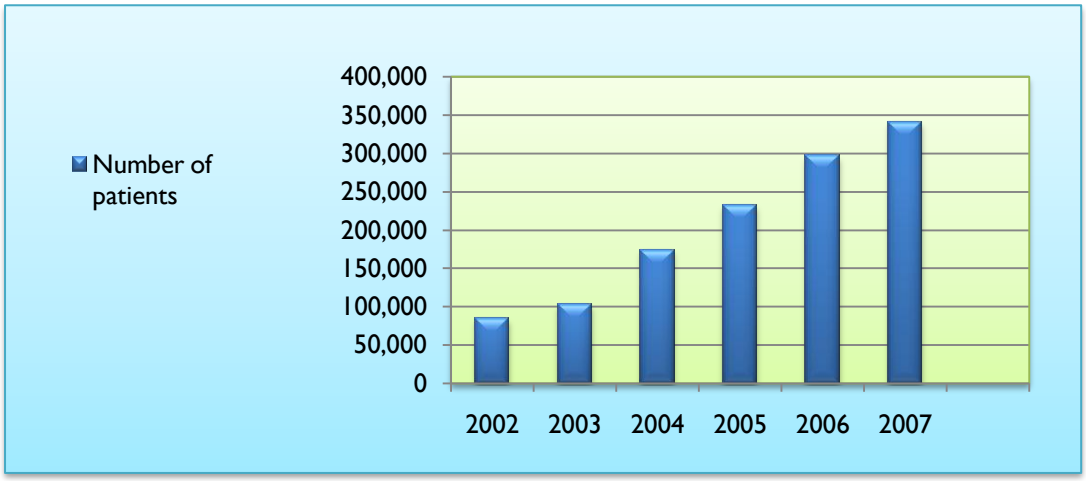
Health Tourism

Health tourism or sometimes referred to as medical tourism is broadly defined as people travelling from their place of residence for health reasons. This phenomenon is driven by a number of factors such as better specialization and quality of medical care, short waiting period, more affordable cost, and advanced technologies.

Health tourism can significantly produce economic benefits to the destination countries. This industry directly generates foreign exchange earnings (Garud 2005, Pachanee & Wibulpolprasert 2006), attract foreign investment (Wibulpolprasert et al. 2004) and create favourable balance of trade and benefits tourism services (de Arellano 2007) including hotels, airlines, and other related services (Chinai & Goswami 2007, Garud 2005). The profit generated through health tourism may serve as additional resources for investment in the health care system, thus improves the quality of the country's health care system. In developing countries, such profit may be used to upgrade health care infrastructures and technologies (Chanda 2002), which in turn helps to improve hospital reputation, create better working environment for doctors, and may potentially attract doctors who have migrated to return home (Chinai & Goswami 2007).

World Bank's estimates on health and wellness tourism worldwide is approximately US$76 billion (RM244 billion) in 2010. The growth is expected to be 30 percent per annum. In contrast, the tourism industry as a whole is only growing at a rate of 4 to 5 percent annually. Thailand is the leader in this industry in the ASEAN region, followed by India and Singapore. Health tourists to Thailand are estimated to be two million in the year 2010, generating US$2.2 billion in revenue or 3.24 percent of the global market (Frost & Sullivan 2010).

Malaysia is fast becoming an alternate destination of choice for health tourists and a strong competitor in this sector. The country's health tourism industry has experienced a consistent growth at 15 percent throughout 2008 and 2009. At this growth rate, the potential revenue generated is expected to reach RM390 million in 2010; more than doubled the revenue of RM150 million in 2005. The number of medical tourists seeking healthcare services in Malaysia has grown since 2002 to hit 341,288 in 2007 (Figure 4.3). The majority of the health tourists are from Indonesia (69 percent), Singapore (12 percent) and Japan (4 percent (Frost & Sullivan 2010). Malaysia is expected to cater for 1.3 million health tourists by 2012 (APHM 2007, Frost & Sullivan 2010).



Year	2002	2003	2004	2005	2006	2007
Number of patients	84,585	102,946	174,189	232,161	296,687	341,288
Income (RM million)	35.9	58.9	105	150.9	203.7	253.8

Figure 4.3: Number of health tourists to Malaysia and income, 2002-2007
Source: Puteri Nemie 2009

In Malaysia, health tourists seek medical treatments, cosmetic procedures, surgical procedures and medical check-ups (see Table 4.1). Data from several hospitals which offer health tourism services shows that health tourists commonly seek the following services: Cardiac Surgery, (e.g. Mitral Valve Replacement, Video Assisted Thorachoscopic Surgery, Thoracotomy, CABG, Angioplasty/Angiogram), Orthopaedic Surgery (e.g. Total Knee Replacement, Arthroscopy Total Hip Replacement, Discectomy, Decompression Carpal Tunnel Syndrome, ACL Reconstruction) and Urology Treatment (e.g. TURP and Stenting).

Table 4.1: Healthcare services sought by health tourists

Category	Case Examples	Percentage
Medical Treatment	Consultation with specialists, drug therapies	23.1
Cosmetic Procedure	Plastic surgery such as tummy tuck, face lift, nose job and liposuction	20.7
Surgical Procedure	General and specialised surgery, Cancer surgery	19.0
Medical Check Up	Full body check-ups and wellness screenings	14.9
Others	-	22.3

Source: Doshi 2008

Malaysia's competitiveness in the health tourism industry is driven by a combination of factors. Being a politically stable multi-ethnic country with multi-cultural and multi-lingual society, and as a country with a diverse landscape and rich rainforests, Malaysia is a safe and interesting place to visit. Comprehensive network of hospitals and clinics, within 5km from residential areas, highly-trained medical specialists with post-graduate qualifications from the UK, Australia and USA, and English-speaking healthcare professionals are key factors that promote the growth of this industry. The costs of medical procedures and treatment are also highly competitive and affordable when compared to developed countries and several neighbouring countries. For example the cost of cardiac bypass in 2007 was only US$12,000 compared to US$130,000 in the US and US$16,500 in Singapore. Table 4.2 shows costs for selected medical procedures in Malaysia compared to other countries. As a Muslim country, Malaysia can attract health tourists from the Middle East and other Muslim countries.

Table 4.2: Cost for selected medical procedures: Malaysia and other countries (2007)

Procedure	**Cost (US$)**						
	Malaysia	**USA**	**India**	**Thailand**	**Singapore**	**Costa Rica**	**Korea**
Heart Bypass	$12,000	$130,000	$9,300	11,000	$16,500	$24,000	$34,150
Heart Valve Replacement	$15,000	$160,000	$9,000	$10,000	$12,500	$15,000	$29,500
Angioplasty	$8,000	$57,000	$7,500	$13,000	$11,200	$9,000	$19,600
Hip Replacement	$10,000	$43,000	$7,100	$12,000	$9,200	$12,000	$11,400
Hysterectomy	$4,000	$20,000	$6,000	$4,500	$6,000	$4,000	$12,700
Knee Replacement (single)	$8,000	$40,000	$8,500	$10,000	$11,100	$11,000	$24,100

Source: Association of Private Hospitals Malaysia

The establishment of a Healthcare Travel Council in 2004 under the umbrella of the MOH, working in tandem with the Association of Private Hospitals of Malaysia, Economic Planning Unit and other government agencies demonstrates the government's commitment in developing health tourism (Malaysian Annual Report 2005). This Council functions as a coordinator in health tourism activities, and leads the promotional and marketing efforts. Soon after its establishment, the Council received an allocation of RM1.65 million to process accreditation of 35 private hospitals identified for health tourism by the Malaysian Society for Quality in Health (MSQH), and to conduct promotional activities. The government has also

offered several incentives to encourage health tourism, such as providing tax exemption for capital expenditure in the construction of new hospitals or expansion of existing hospitals registered with the MOH.

Malaysia's competitiveness in health tourism is threatened by several issues. Insufficient number of highly skilled healthcare professionals is an issue in the country's healthcare system. Although efforts were made to increase the number of training institutions and the number of skilled professionals at various healthcare levels, the 'brain drain' phenomenon, due to highly attractive incentives in other countries, continue to rise resulting in loss of experienced human capital. Another setback is the lack of coordination between the different players involved in promoting health tourism. For example, greater coordination between the immigration office and the health institutions would facilitate issuance of visas for genuine health tourists. There is also a threat from infectious diseases and re-emerging diseases such as tuberculosis and SARS resulting from an influx of immigrants seeking employment in this country. This may create negative perception among potential health tourists to this country.

In view to enhance the country's competitiveness in health tourism and to ensure success of health tourism as an income generation industry now and in the future, the government has to address the issues mentioned above. In addition, there is also a need for research to identify better marketing strategies for health tourism. The use of STI to enhance health tourism such as using electronic health records in patients' data management, more advance predictive and preventive medicine through genomics, and new therapies such as stem cells therapies should also be enhanced.

Stem Cells

Stem cells research helps us to better understand how diseases develop and spread, and serves as accurate screen for new drugs. It is also valuable in the development of cell-based therapies for diseases like diabetes, heart failure, Parkinson's disease, cancers, and Alzheimer disease. Understanding the growth and differentiation of individual cells into tissues could provide insights into the causes of birth defects, genetic abnormalities, and other disease states, and subsequently prevention or correction of some of these conditions. These could revolutionize health care and substantially improve health outcomes.

At the global level, research is currently focused on calibration of the process of cell reprogramming, ensuring the quality of induced pluripotent stem cells, and modification of the stem cells niche. Some potential stem cells therapies are already in pre-clinical tests in animals. In the skin and blood systems, stem cells research is already moving into a second phase, in which gene correction in combination with cell therapy is used to target serious inheritable diseases. In the coming 2-5 years, more stem cells based therapies are planned to enter clinical trials, notably in the areas of muscle regeneration and bone injury. Future research will

increasingly consider quality control of stem cells manufacture, delivery to the target areas, and architectural aids to ensure optimum placement and exposure of the stem cells. Another important aspect of stem cells therapeutics will be a focus on the bioengineering of materials necessary to deliver and support stem cells on their therapeutic journey.

Global stem cells market is forecasted to reach US$63.8 billion by 2015 from an estimated value of US$21.5 billion in 2010 (see Figure 4.4). Although North America will likely post highest market value by 2015, Asian economies are expected to maintain large compound annual growth rate (CAGR) of 27 percent during 2010-2015. Among the therapeutic areas, neurology is forecasted to exert the highest support to stem cells market growth with a CAGR of 24.4 percent during 2010-2015; followed by therapeutic areas for haematology and diabetes. The other major therapeutic use in stem cells market will be in oncology, cardiology, and bone and cartilage.

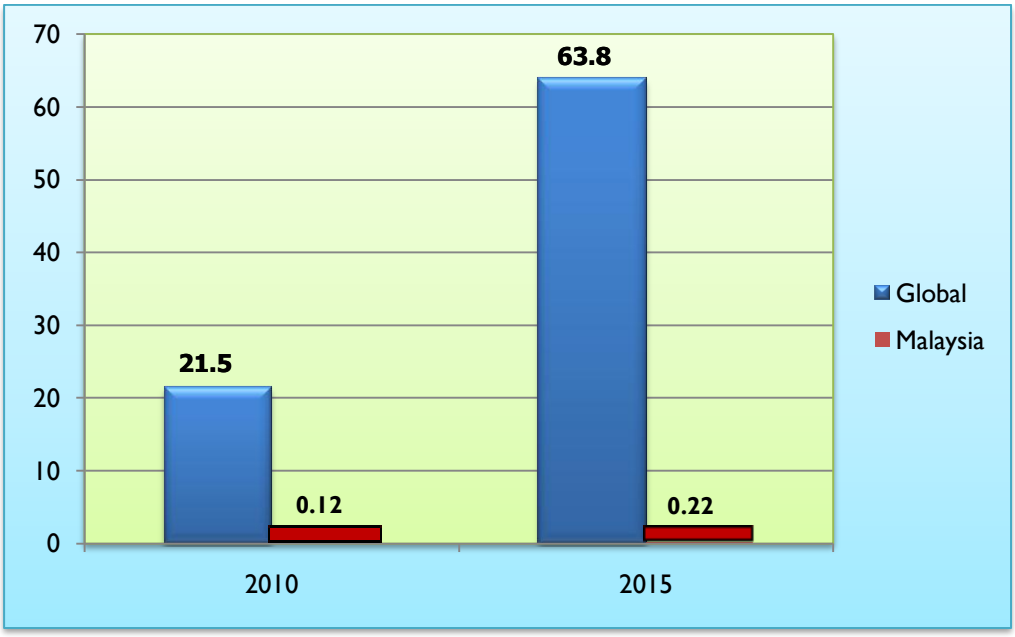


Figure 4.4: Stem cells market value (US$ billion)

Stem cells research is relatively new in Malaysia. Started around 2007, the research and therapy activities were estimated at US$157 million with year on year growth of 12 percent (Frost & Sullivan 2009). The Institute for Medical Research (IMR) had been granted with RM0.5 million to embark upon the fundamentals of embryonic stem cells research. An experimental stem cells-based therapy has been approved for clinical trial and will commence as soon as the IMR's facilities are GMP-certified. This clinical trial is a collaborative effort between IMR and ophthalmologists in Kuala Lumpur Hospital for treatment of limbal stem-cells deficiency (which may be caused by ocular burns) using limbal cells therapy.

Recently Stempeutics[13] started a clinical trial treatment of Cerebral Stroke using stem cells-based therapy[14]. In addition, there is work conducted in smaller laboratories in USM, UKM, UM and UPM, public institutes and private companies. Due to lack of coordination and database, little is known about their work.

In the private sector, the Manipal Education and Medical Group of India had recently established a stem cells research laboratory. Located at the Technology Park Malaysia, Stempeutics has begun collaborative work with leading local medical institutions to drive long-term stem cells research activities. The establishment of this facility is a significant step with multiple benefits; namely enhancing foreign direct investment of up to RM20 million in Malaysia, and building a wealth of resource in international research and expertise and expanding access and exposure for Malaysian talents in stem cells research. While the initial venture was in bone marrow derived Mesenchymal stem cells, Stempeutics is also investing heavily to develop innovative products based on adult stem cells from other sources. In addition, there will be continuous research on various diseases to improve product development for effective therapies.

Stem cells research are critical for understanding biological foundation of diseases, which in turn will support accurate identification and treatment for diseases, including diabetes, cardiovascular diseases, and Parkinson's disease (diseases that are expected to be prevalent in Malaysia in 2050). The discovery of biomarkers, stem cells therapies as well as predictive and personalized medicine will be a very important contribution towards healthcare and health outcomes, not only in Malaysia but globally. Yet, in general Malaysia faces a major gap in R&D in stem cells when compared to Singapore and other countries. The level of funding is grossly inadequate and lacks continuity to sustain the growth of stem cells research. In the future, the R&D areas in Malaysia should include: (i) Fundamental research on stem cells (ii) Quality control of stem cells manufacture, delivery to the target areas, and architectural aids to ensure optimum placement and exposure of the stem cells and (iii) Bioengineering of materials necessary to deliver and support stem cells on their therapeutic journey.

At present, all stem cells research proposals must be approved through an institutional review board (IRB) to prevent unethical research and unethical use of stem cells. However, there does not exist any legal binding for researchers to adhere to these guidelines, as long as they are able to obtain approval from any IRBs. At the moment, the existing Drug Act (FDA /PIC) does not account for stem cells products as biologics and therefore they cannot be regulated for testing (clinical trials). Without regulatory framework, laboratories cannot be monitored, and this may open doors to opportunistic companies who might offer unproven therapies. It is necessary therefore for Malaysia to develop regulations, and the

[13] Stempeutics is a first of its kind stem cell research facility in Malaysia. It was established by the Manipal Education and Medical Group of India and is located at the Technology Park.
[14] The study received approval from the Ministry of Health Research Ethic Committee (Clinical Trials Registry - Malaysia No: MoH, Malaysia Approval Ref. No. (6)dlm-KKM/NIHSEC/08/0804/P09-347).

clauses from existing Acts in countries such as Australia (Therapeutic Goods Administration) and USA (Food & Drug Administration) could be used as a guide.

Application of stem cells therapy is currently limited to hemapoitic disease such as in bone marrow transplants for leukaemia and thalassemia. Several attempts have been made in private hospitals in using stem cells therapies for diseases such as cancers and age-related diseases such as osteoarthritis. However due to lack of coordination and database, the success of such efforts could not be determined.

With an absence of a reliable database, it is very difficult to provide an accurate picture of the present number and type of human resources available. It is estimated that there are not more than 20 researchers in this field, and most did not receive extensive training. Whereas in Singapore, there are 64 scientists who specialise in the various sub-specialisations within stem cells research. It is critical to initiate collaborations with the best centres in the world and benchmark with them to achieve a critical mass of stem cells experts in Malaysia. Researchers also should pursue degrees in biomedical science, to be followed by postgraduate training and qualification in stem cells research.

Developments in this area suggest that stem cells therapy is a promising option for managing chronic and high burden diseases such as cardiovascular diseases, cancers and ageing-related conditions such as arthritis. As these diseases are expected to be prevalent in 2050, appropriate level of investments in R&D and infrastructure are needed to identify relevant stem cells therapies.

Genomics

Genomics is a term that describes the study of all of a person's genes (the genome), including interactions of those genes with each other and with the person's environment. It includes the scientific study of complex diseases such as heart disease, asthma, diabetes, and cancer; diseases that are typically caused more by a combination of genetic and environmental factors than by individual genes. Research in this area could result in major medical advances against the mentioned diseases as well as malaria, tuberculosis and AIDS (WHO 2002, Livingston and Shivdasani 2001). Pharmacogenomics is another potential development from the genomics revolution.

Many countries are investing in genomics to promote the nation's health and as a pathway to economic development. The level of investments ranges from 1 percent in Ireland to 35 percent in the United States of America as shown in Figure 4.5. Globally, there is a lag between major developments in the research laboratory and their full application in the clinic.

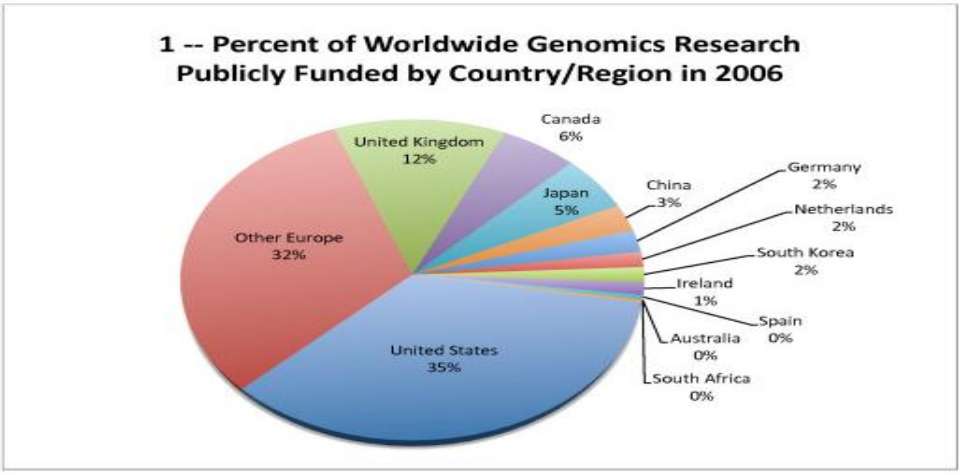


Figure 4.5: Percent of worldwide genomics research publicly funded by country/region in 2006
Source: Pohlhaus and Cook-Deegan, 2008

In Malaysia, the National Biotechnology Policy 2005 guides research in genomics and proteomics with molecular biology. The National Biotechnology and Bioinformatics network (NBBnet), launched in 1999, promotes collaboration and networking among research institutions, universities and the industry (NBBnet website) and hosts databases and information on local genetic resources and major R&D activities. The Malaysia Genome Institute (GENOMalaysia) leads genomic research, together with USM, UKM, UM and UPM as well as some smaller laboratories in other universities and private companies.

During 2001-2007, approximately RM103.7 million (US$33 million) was allocated for 47 biotechnology-related R&D projects including human genomics diversity, metagenomics, structural and functional genomics and natural products discovery (MOSTI, 2008). Specifically, between 2001 and 2005, government funds supported eight R&D projects related to genomics and proteomics at a value of RM17.9 million (US$5.7 million) (MOSTI 2008). Malaysia is part of the Asia Cohort Consortium, which is a collaboration between eight countries to harmonize and combine resources and expertise to study the interaction of genes, environment and lifestyle in causing diseases. These R&D projects have direct and indirect impacts on health.

Genomes-based research in Malaysia is still at an early stage of development. Public research institutes working on genomics research do so with inadequate infrastructure. Only three second-generation genomes sequencers are available in these institutes, which is insufficient to manage large datasets. Currently most of the sequencing work is being carried out at private laboratories at high costs. In comparison, China has two centres of excellence for genome sequencing and analysis and 200 sequencers, with funds about US$80 million per year (Pohlhaus & Cook-Deegan 2008). There is also limited number of highly qualified human resources working in this area, compared to Singapore which has approximately

250 staff members with 29 principal investigators in its Genome Institute (GIS) alone. GIS competed successfully for S$9 million of external funds in the form of research grants from the US and the European Union. This comparison shows that Malaysia is lagging behind Singapore and China in R&D investments, HR and infrastructure.

Malaysia's potential in genomes-based research lies in its rich untapped information from the multi-ethnic and multicultural population. In this connection, Malaysia should invest in R&D related to (1) laboratory analysis of mutations/polymorphisms prevalent in local population especially in the context of genotypes and phenotypes of the different ethnic groups in Malaysia; (2) molecular epidemiology of genetic variants in Malaysian populations, environmental interactions and disease outcomes, particularly for non-communicable diseases such as cardiovascular diseases, cancer (e.g. colorectal and lung cancers in men, and cervical and breast cancers in women) and diabetes. As personalised medicine will become the future trend, there should be a focus on Development of personalised, preventive medicine using information from database of personal genomes which also include cells and tissues sequenced in normal states. Products of genomics research will be in the form of personalised pharmaceuticals, vaccines, diagnostics and prognostic tools for both communicable and non-communicable diseases.

There is also great potential for improving human health through nutritional gains as a result of research into plant genomics. However, there are issues related to public safety, health of research workers, risks to the environment and the potential for social and political misuse. Without a policy which protects patients, people would not likely want to have their genomes sequenced, especially when awareness about its benefits is low. There is also a need to regulate and oversee the service providers.

Natural Products

A natural product is a chemical compound or substance derived from plant, animal or microbial sources found in nature that usually has a nutraceutical or biological activity for use in drug discovery and drug design. Drugs of natural origin have been classified as original natural products, products derived semi-synthetically from natural products, or synthetic products based on natural product models (Cragg et al. 1997). Natural products, mainly from plant origin, have been in use throughout the age of mankind as traditional remedies, health supplements, cosmetics, nutraceuticals, and pharmaceuticals. They are also used to develop medical devices (e.g. rubber gloves, catheters, urine bags etc).

Of the new chemical entities introduced worldwide as drugs during 1981-2002, 61 percent can be traced to or were inspired by natural products (Ahmed & Dar 2006). Examples of drugs of natural origin are artemisinin for malaria, lovastatin for hyperlipidemai, penicillin antibiotics, vincristine for cancer. Locally, natural products have long been used in traditional systems of medicine of different ethnic

groups. Examples include nopal (prickly pear cactus), fenugreek, and karela (bitter melon) for diabetes; Kacip Fatimah (*Labisia Pumila*) to facilitate childbirth, whereas Hempedu Bumi (*Andrographis Paniculata*) herb is used as analgesic, antimalarial, antineoplastic and antiulcerogenic in addition to other uses (IMR, 2010). Annex 9 gives a list of herbs and plants used traditionally and the ongoing research for standardization or drug development for commercialisation. Some traditional remedies such as Tongkat Ali have been extracted and standardized for safe use. Health supplements especially vitamins and functional foods have already been commercialised, and some have international recognition (e.g. palm oil vitamins; tocotrienol).

The present global market for phytomedicine[15] is US$250 billion (Samy and Gopalakrishnakone 2007). World demand for nutraceutical ingredients is expected to reach $15.5 billion in 2010; an increase from $11.7 in 2005 (Freedonia Group 2006). China is extensively utilizing its biodiversity for drug development, having more than 3000 new single chemical entities identified from traditional Chinese medicine and several drugs from herbs or mosses (Wang et al. 2007).

Domestically, the market value for vitamins and health supplement was at $375 million in 2005. The market is forecasted to reach $746.1 million in 2012 (Lam et al. 2005). In 2008, Malaysia exported $15 million worth of palm oil health supplements (Ching 2009). Figure 4.6 shows the global and local health supplements market.

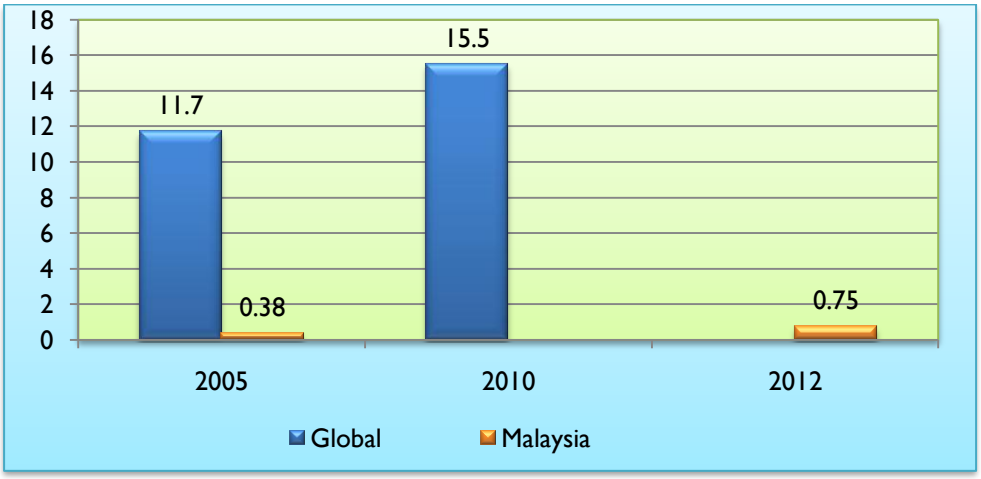


Figure 4.6: Nutraceuticals and vitamins market value ($ billions)

Natural rubber latex gloves are natural products. Malaysia is the world's leading producer and exporter of medical gloves (85 percent) and catheters (80 percent) (MIDA 2010). Figure 4.7 shows that Malaysia contributes 52 percent of global rubber gloves exports and the main competitors are Asian countries.

[15] Preparation of medicinal herb.

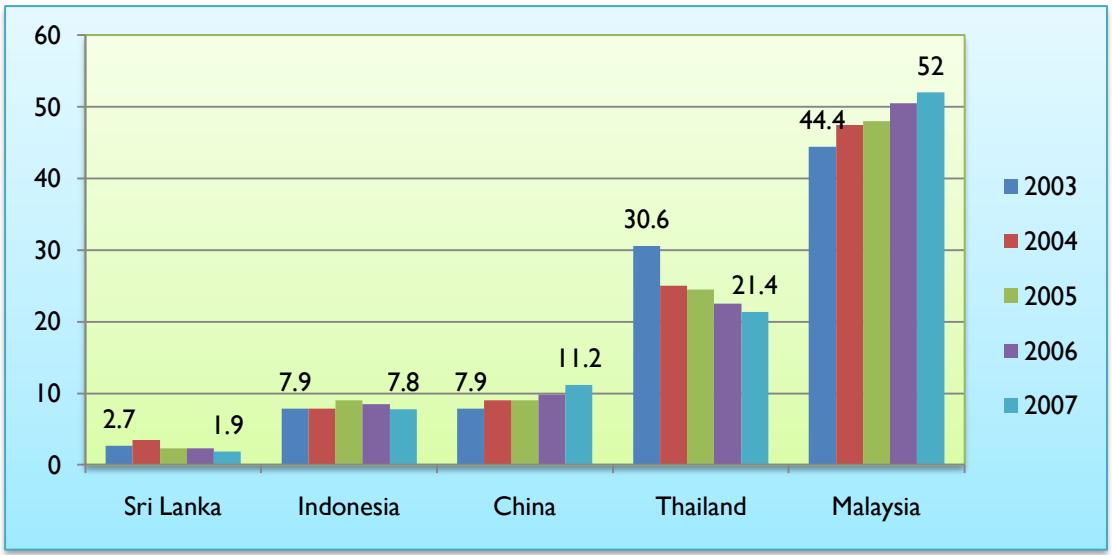


Figure 4.7: World's major exporters of rubber gloves (2003-2007, percentage share)
Source: www.latexglove.info

Malaysia's rich biodiversity of terrestrial and marine life, and the traditional use of plants and herbs as medicines by different cultures and ethnic groups, provide opportunities for identifying useful compounds and active ingredients for medicinal use. There are about 1300 medicinal plant products and herbs registered with the Ministry of Health available in the market (Hafidh et al. 2009). There is a rising demand for health supplement and functional foods locally and globally due to an increase in non-communicable diseases. However, local manufacturers of dietary supplements need to address issues of effectiveness, quality, good manufacturing practice (GMP) and undertake bioavailability[16] studies to satisfy local and global consumers and become more competitive. Policy wise, there are many policies enacted to drive R&D in biodiversity natural products, including the National Biodiversity Policy in 1998, the National Agricultural Policy (1992-2010) that specifically addresses specialty natural products for R & D and commercialisation, and Malaysia's National Biotechnology Policy (thrust two) to capitalise on the strengths of biodiversity to develop expertise in drug discovery and development based on natural resources. All of the above are drivers for growth in R&D and commercialisation of natural products.

Over the years, research institutions and research facilities related to natural products have been relatively well established. Today, several local universities and research institutions are researching local plants, herbs, and marine microorganisms to develop new drugs. The acquisition of high field Nuclear Magnetic Resonance (NMR) spectroscopy by some laboratories in the mid-nineties has had a tremendous impact on the investigation of the constituents of medicinal plants in Malaysia (Jantan 2004). There are also good relations established with

[16] Bioavailability is a term used by several branches of scientific study to describe the way chemicals are absorbed by humans and other animals.

international research institution interested in Malaysia's biodiversity and natural products research. Related, there is good research on palm oil nutraceuticals and health supplementary values, the latest is the pilot clinical trial to determine the effectiveness of tocotrienol-rich fraction combined with tamoxifen in the management of early breast cancer (NIH 2010). In the field of natural rubber, there is good R&D infrastructure. This includes the Tun Abdul Razak Research Centre (TARRC) which deals mainly in end-user research (MRB 2008). The box below gives some examples of ongoing research projects in local universities and institutions, and their international partners.

Box 4.1: Examples of R&D in natural products

- Calanolide A from Bintangor *(Calophyllum lanigerum)* for HIV and AIDS, and Silvestrol from *Aglaia stellatopilosa* for cancer are undergoing phase II and preclinical trials at the US National Cancer Institute.
- IMR-HMRC has nine research projects on plants for medicinal properties, e.g. Hempedu Bumi (*Andrographis Paniculata*) for the treatment of diabetes and Kacip Fatimah (*Labisia pumila*) for estrogenic and androgenic activities. For these projects IMR collaborates with UPM, MARDI, USM, FRIM, UMS, UKM.
- FRIM joint venture with the Massachusetts Institute Technology (MIT) to develop bio-active products from Tongkat Ali (*Eurycoma longifolia*) and Pegaga (*Centella asiatica*) Joint venture between FRIM and Nimura Genetic Solutions (NGS) of Japan to isolate useful chemical substances from soil microorganisms.

While there are numerous enablers, a few challenges as discussed in the following paragraphs, need to be addressed to stimulate growth of R&D and commercialisation in natural products. Despite policies to capitalise on the strengths of biodiversity to develop expertise in drug discovery and development based on natural resources, there is no special fund allocation for R&D in this area. The R&D funding is pooled from the overall level of R&D resources available in this country (i.e. 0.6 percent of GDP), in addition to regional and international funds. For example, the Forest Research Institute Malaysia (FRIM) secured RM5 million under the International Tropical Timber Organization (ITTO) fund in 2008 (FRIM Annual Report 2008).

There is insufficient number of researchers for natural products in general specially taxonomists to classify Malaysia's natural endowment to indicate natural relationships. There is also no proper documentation of what is already known. Most of the knowledge and work on medicinal plants have yet to be converted into commercialised products. Developing a new drug was estimated to take 12-15 years and costs between US$800 million and US$900 million (Steiner et al. 2007), but yet the current funds for R&D is far less than what is needed. In another connection, with current trend of forest destruction for the sake of development, scientists have to progress even faster in order to get at the potential natural products from the remaining forests (ARBEC 2001), in addition to the inevitable climate change which could affect yields and active components. Moreover, other countries in the region are also exploring their natural resources for potential

chances to bring new chemicals and drugs. This is a challenge for Malaysia to improve quality, safety and effectiveness of its products, as well as effectively exploit its biodiversity.

Although natural rubber latex gloves are superior to synthetic gloves in providing protection against blood pathogens and infections and many other aspects, latex allergy is a concern. This may shift the attention towards synthetic alternatives for manufacturing of gloves (e.g. vinyl, nitrile). Improved manufacturing technologies and continuous research could reduce the protein content of rubber gloves to the minimal concentration to overcome the sensitivity problem of natural rubber latex gloves.

Traditional and Complementary Medicine

Traditional medicine is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not. The terms "complementary medicine" or "alternative medicine" are used inter-changeably with traditional medicine in some countries. They refer to a broad set of health care practices that are not part of the country's own tradition and are not integrated into the dominant health care system (WHO). Traditional and complementary medicine (TCM) is used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness (WHO). Presently, in Malaysia, there are TCM centres in six public hospitals and one centre in a private hospital. These hospitals offer traditional Malay massage, acupuncture and Chinese herbal therapy as part of a comprehensive care for oncology patients in a spa-like environment. It is expected that over time additional services such as chiropractic and Ayurvedic medicine will be introduced.

Herbal treatments are the most popular form of traditional medicine, and the global market currently stands at over US$60 billion annually (WHO 2007). In China for example, the sales of herbal products totalled US$ 14 billion in 2005 alone. The World Bank projects the global market for herbal medicines to reach US$5 trillion in 2050 (Globinmed 2010). In Malaysia, the market for traditional medicine was estimated at RM2.6 billion (US$0.84 billion) in 2007, and is expected to reach US$156 billion in 2050 base on annually growth rate 10 percent (see Figure 4.8).

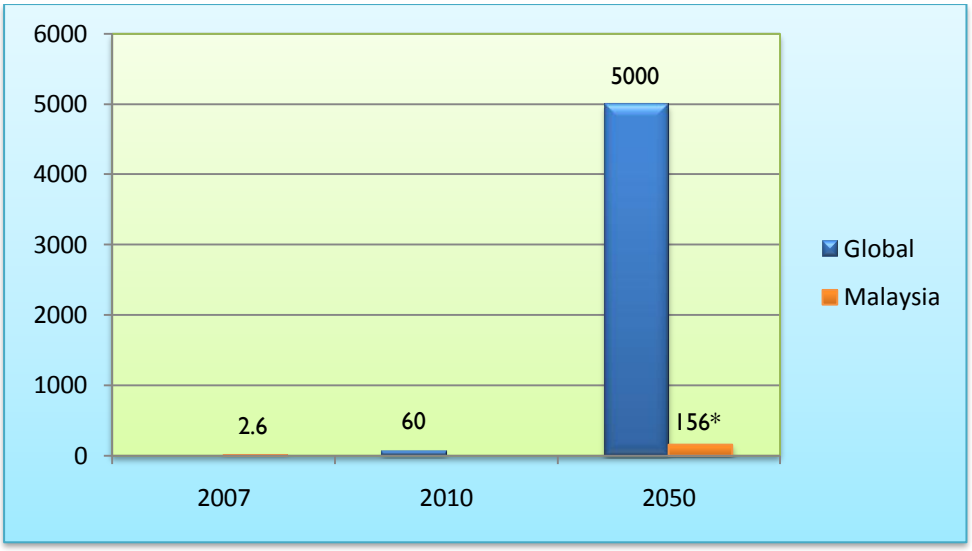


Figure 4.8: Current and project market value for TCM (US$ billion)
**based on AGR 10%*

Malaysia has a national policy on TCM which was launched in 2001, and reviewed in 2007. The policy statement features TCM as an important component of the healthcare system, co-existing with modern medicine to contribute towards enhancing the health and quality of life of all Malaysians by ensuring availability of safe and quality TCM products and practices. The strategies aim to: regulate TCM practices through statutory regulations, establish registry, approve facilities of practice, formalise training of practitioners and accreditation, promote informed decisions by the consumers, ensure sustainability and standardise raw materials, encourage industrial participation, develop and protect intellectual property, evaluate and monitor TCM products to ensure the safety, effectiveness and high quality of TCM.

The registration and licensing of TCM is legislated through the Control of Drugs and Cosmetics Regulations 1984, which also includes herbal medicines and dietary supplements. Manufacturers of traditional medicines are required to adhere to the GMP requirements for traditional products, and to adhere to product safety requirements like compliance with the limits set for heavy metals (mercury, arsenic, lead), testing for microbial and fungal contamination, other physicochemical tests and screening for adulterants. Herbal medicines are subjected to post-marketing surveillance since 1997.

The MOH established a TCM division in 2004 to promote safe and effective practice and use of TCM. This division works closely with five bodies of TCM practitioners representing different ethnic traditions and practices. There is a herbal medicine research centre under the Institute for Medical Research (IMR). In 2002 Malaysia established the Global Information Hub on Integrated Medicine (GLOBinMED), a centralised database on TCM and integrated medicine. In an attempt to enhance and promote TCM, the data is accessible to anyone for free.

Educational standards in relation to training of TCM practitioners and personnel are at present being formalised and relevant training institutions are in the process of being accredited. Importantly there is recognition that all courses should contain basic science units. Both diploma and bachelor degree programmes are being offered (see Table 4.3). The diploma courses aim to train para-professional therapists and practitioners with the knowledge and skills fundamental to the practice of TCM. The objective of the bachelor programme is to generate practitioners with higher level problem solving skills which will enable them to evaluate treatment outcomes, and to take corrective actions when required. Table 4.3 shows a list of universities and colleges that offer TCM education and training programmes.

Table 4.3: University and colleges offering TCM courses

University/College	**Programme**
Collage of Complementary Medicine, Melaka	Diploma in Natural Medicine
INTI International University College, Nilai	Bachelor of Traditional Chinese Medicine (Hons)
Cyberjaya University College of Medical Sciences (CUCMS), Cyberjaya	Bachelor of Homeopathic Medical Sciences (Hons)
Management and Science University (MSU), Shah Alam	Diploma in Traditional Chinese Medicine
Management and Science University (MSU), Shah Alam	Bachelor in Traditional Chinese Medicine (Hons)
International Medical University (IMU), Bukit Jalil	Bachelor of Science (Honours) Chiropractic

Various types of TCM are being increasingly used in both developing and developed countries. A major component of the WHO Traditional Medicine Strategy (2002-2005) was to promote the integration of TCM into national health care systems where appropriate, and to develop national policy and regulations to ensure safety, efficacy and quality. Data from a survey conducted by the Malaysian Health Ministry in 2005 revealed that 69.4 percent of respondents had used TCM during their entire life and 55.6 percent in the preceding 12 months (3rd NHMS 2007). The Drug Control Authority of the MOH reported that in December 2007, the cumulative number of registered products comprised of 18,200 traditional medicines (46.5 percent) compared to 11,805 prescription medicines (30.2 percent) and 9,098 over-the-counter medicines (23.3 percent). The above, and the global

and domestic market value point to a growing demand for TCM, and thus a good potential for achieving both the desired health and economic outcomes.

Nonetheless, there are challenges related to the promotion and practice of TCM that needs to be addressed in order to maximize both its health and economic benefits:

- Evidence for the effectiveness and safety of TCM practices and products. Apart from extensive studies on acupuncture, ayurvedic medicine, chiropractics, homeopathy and herbal remedies, the efficacy and safety of many TCM treatments remains unproven. Whilst results of studies on herbs seem convincing, researchers are unclear about most of the active components or substances of the plants being studied, nor their pharmacokinetics and pharmacodynamics.

- The practice of TCM without scientific evidence creates a conflict between the management of the patient's illness. Doctors have an obligation to direct patients' choices toward therapies that have been investigated adequately and have been shown to generate good than harm (Brevoort 1998).

- Inadequate number of highly trained TCM professionals.

- Existing legislations concerning TCM in Malaysia are limited and centred on TCM products, and do not cover TCM practices. However, a new law that will regulate the use and practice of traditional and complementary medicine is expected to be gazetted and enforced. The new law is expected to ensure safe TCM practices and to protect consumers of TCM practices.

Nanotechnology

Nanotechnology provides the ability to manipulate matter at atomic and molecular scale. It covers a wide range of interdisciplinary topics which include nano-scale cell manipulation and drug delivery, biological, metallic, polymeric, ceramic, composite, and hybrid implant materials, intelligent materials, and biomimetics. Nanomedicine is the application of nanotechnology to achieve breakthroughs in healthcare. It has the potential to enable early detection and prevention of diseases, and to improve diagnosis, treatment and follow-up. Diagnostic tests that use nanotechnology to quantify disease-related biomarkers offer an earlier and more personalised risk assessment before symptoms show up. In general, these leads to less severe and costly therapeutic demands, and an improved clinical result.

Nanotechnology is an emerging field for R&D worldwide. In 2006, the USA invested US$3.7 billion in nanotechnology, followed by the European Union at US$1.2 billion, and Japan at US$750 million (MIGHT Report 2006). Countries in Asia Pacific too have R&D initiatives but at a lower funding scale up to US$300 million (Uda 2009). Since the launch of the Nanoscience and Nanotechnology Initiative (NUSNNI) at the National University of Singapore (NUS) in 2002, Singapore has been on a rapid success path in this field. To date, this island country has

produced the world's first and only nanotechnology translucent orthodontic systems. Pasture Pharma of Singapore is one of the only two companies worldwide capable of producing FDA-approved masks (Nanotech Conference & Expo 2010). There are now more than 70 companies, research institutes, universities, and government bodies involved in various aspects of nanotechnology. It is estimated that there are nearly 1,000 researchers and engineers working both the public and private nanotechnology companies and initiatives. The NUS now offers PhD, Masters and Bachelor degree programmes in nanoscience and nanoengineering education (NUSNNI milestone 2010). Thailand established the National Nanotechnology Center (NANOTEC) in 2003. In its first 5-year plan, NANOTEC secured about US$22 million to operationalise its agenda. To develop capacity, NANOTEC developed a Masters programme in nanotechnology, which will be followed by a PhD programme. In addition, the Ministry of Science and Technology earmarked 200 scholarships for education in this field. It can be concluded that both neighbouring countries gave priority to developing human resources.

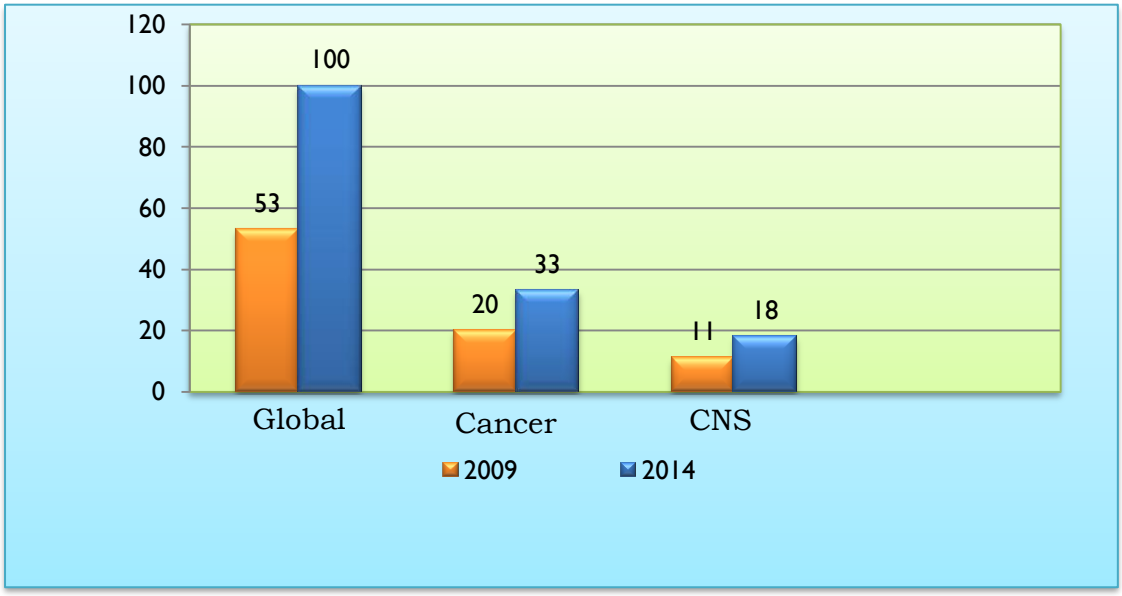


Figure 4.9: Nanomedicine market value (US$ billion)

In Malaysia, nanotechnology has been a focus since the 8th Malaysia Plan (2001-2005) as a Strategic Research programme under Intensification of Research in Priority Areas (IRPA). A total of RM2.5 billion was allocated for nanotechnology R&D under the 9th Malaysia Plan compared to RM1.2 billion in 8th Malaysia Plan (MIGHT Report, 2006). The Malaysian Nanotechnology Initiatives (MNI) emerged as a product of the Nanotechnology Taskforce at the Academy Science of Malaysia (ASM) prior to the 8th Malaysia Plan. Launched in 1997, the objectives of MNNI are to: (a) enhance nanotechnology research institutions, (b) promote strong expenditure on R&D in nanotechnology, (c) create a competitive business environment with a robust education and training system, a highly skilled, educated and diverse workforce, (d) ensure efficient infrastructure and integrated involvement in nanotechnology activities (Uda 2009). On the other hand, the strategies of MNI are

to focus on (a) improving Malaysia's economic competitiveness to compete with global challenges, (b) accelerating scientific breakthrough on selective beneficial nanotechnologies, and (c) enhancing societal and environmental contribution (Uda 2009). Today, the MNI is located within the Nanotechnology Directorate at MOSTI and its immediate task is to develop a national master plan, which will reflect strategic alliance and coordination between the scientists and researchers, policy makers, technology developers and industries, financiers and the public.

Several nanoscience/nanotechnology centres have been established such as the Ibnu Sina Institute for Fundamental Science Studies (IIS) and the National Nanotechnology Centre under MOSTI to coordinate related R&D activities. Local research include biopharmaceutical proteins for human therapeutic drugs, vaccine production, bone graft substitutes, drug synthesis, diagnostic kits, oncology – cancer treatment and antioxidants. Table 4.4 below shows examples of nanotechnology projects in medicine and health at various institutions. It can be seen that projects are aiming at addressing diagnostic, promotive, and curative health issues and drugs.

Table 4.4: Examples of nanotechnology projects in medicine and health

Application	**Areas**	**Head/ Institute**	**Funds**
Biopharmaceutical proteins for human therapeutics drugs and vaccines	Nanomedicine	UPM	MOSTI
Bone graft substitutes	Nanomaterial	MINT, SIRIM, USM, UKM, UIA	MOSTI
Diagnostic kits for infectious diseases	Nano-device Molecular Nanotechnology	USM	MOSTI
Antioxidants in preventing degenerative damage in Down Syndrome and Ageing	Nanomedicine	UKM	MOSTI
Vaccine production against infectious diseases	Nanomedicine	USM	MOSTI
Oncology: Liver Cancer	Nanomedicine	UM	MOSTI
Diagnostic kit for diabetic Vasculopathy	Nanomedicine	UM	MOSTI
Antibiotic resistance	Nanomedicine	UM, USM, VRI, MOH	MOSTI
Drug synthesis	Nanomedicine	UiTM	MOSTI

Source: Uda 2009

There are also projects related to detection of cancer bio-markers and to develop a *halal* product detection kit using silicone-based nanogap capacitors at the Universiti Putra Malaysia (UPM). Below is a brief case study on a promising research by a team at the Universiti Malaysia Perlis.

Box 4.2: Nanotechnology research for cancer screening

Early detection is very important in cancer diagnosis as it determines the treatment, prognosis, and survival of cancer patients. Therefore, a screening method to detect cancer that is relatively low cost but efficient would be very useful. Nanotechnology offers such potential as it enables detection of associated risk factors at molecular level.

At Universiti Malaysia Perlis, a team of researchers led by Professor Uda Hashim, is developing a novel technique for cancer screening using nanotechnology. They plan to produce a nanogap capacitance biosensor to detect the presence of heterocyclic aromatic amines (HAA) derivates, which are found in food and believed to be carcinogen markers in human samples. The project merges research from biological and electrical engineering sciences, and is developed in several stages. The initial stage of designing and making the photosensor masks is now completed. The study is completing fabrication of the biosensor, and characterise it to the carcinogen markers. Upon complete fabrication of the biosensor, it will undergo several tests and optimisation processes including the sensitivity and specificity test for carcinogen marker detection. Preparation of the test samples (urine, blood, saliva) and carcinogen markers for biosensor characterisation and testing has begun. The team has to develop a profile of the carcinogen concentration in the different types of samples for the finished product for reference before it can be used for screening purposes. Once completed, this innovation will benefit the health of the people and contribute to the economic growth of the country through its commercial value. The project has, thus far, progressed as a result of motivation, dedication, and collaborative work of researchers. However, it has not progressed as desired due to lack of funding, and inadequate laboratory facilities.

The lack of professionals who are well trained in this area is one of the big challenges. Current database indicates that there are about 150 local scientists directly involved in various areas of nanotechnology research, and about 300 graduate students who are actively pursuing research in nanotechnology. In addition, the current development of nanotechnology in Malaysia suffers from poor linkages between various projects, as well as a lack of (1) plan to realise and develop nanotechnology industries, (2) roadmap on nanotechnology R&D, (3) research facilities, and (4) efforts to promote awareness in nanotechnology.

Pharmaceuticals

Pharmaceuticals are all products related to pharmacy, including starting materials, active pharmaceutical ingredients and excipients[17], finished dosage forms, and

[17] An excipient is an inactive substance used as a carrier for the active ingredients of a medication. In addition excipients can be used to aid the process by which a product is manufactured. In general, the active substances (such as aspirin) may not be easily administered and absorbed by the human body; they need to be put in some appropriate form. In such cases, the active substance is dissolved

biological and other specific products (WHO 2003). WHO defines a generic drug as a pharmaceutical product, usually intended to be interchangeable with the innovator product, generally manufactured without a license from the innovator company and marketed after the expiry of the patent or other exclusivity rights relating to the innovator product.

Pharmaceuticals including biological and vaccines constitute an important components of any healthcare system; used in diagnosis treatment and prevention. About 80 percent of the drugs under the Malaysian essential drugs list are generics produced by local manufacturers (MOPI 2010). However, 70 percent of the available drugs, both branded or generics, are from multinational manufacturers (Espicom 2009). In most circumstances, the public health sector is the largest buyer of drugs, and an efficient system for drugs procurement and generic drugs prescription could lead to notable cost savings. When the Ministry of Health used a compulsory license[18] and imported generic antiretroviral (ARV) medicines from India in 2004, the cost of treatment per month per patient dropped from US$315 to US$58; equivalent to 81 percent reduction which allows more than double the number of patients who could be treated in government hospitals and clinics (Ling 2004). An example from the private health sector shows that when 157 local pharmacies were surveyed in 2007 to assess generic medicine substitution practices, the overall patients' expenditure on medicines reduced by a total of 57.4 percent through voluntary acceptance of substitution (Chong et al. 2010). An Indonesian study on antidiabetic drugs for type 2 diabetes mellitus outpatients without compelling indication, found that 96.4 percent of direct medical costs were spent on drugs (96.4 percent), and the potential saving was 6.10 percent of total drug cost if generic substitutions were prescribed (Andayani and Imaningsih 2007). Although a compulsory license to produce or export patented drugs is conditional in Trade Related Intellectual Property Rights (TRIPS) agreement, there is no doubt that generic versions of off-patent drugs are much cheaper than the original branded ones.

Frost & Sullivan estimates the global pharmaceutical market (see Figure 4.10 below) to reach US$818 billion by 2013 from around US$700 billion in 2009 (Tham and Yahya 2008). Asia-Pacific pharmaceutical industry has achieved an estimated market size of around US$187 billion in 2009. It is the fastest growing pharmaceutical market due to low costs of production, a favourable regulatory environment and developments in contract manufacturing, especially in generics and active pharmaceutical ingredients (APIs) (Pharmaceutical Drug Manufacturers 2010).

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or mixed with an excipient. Excipients are sometimes used to bulk up formulations with very potent active ingredients, to allow for convenient and accurate dosage.

[18] Government allows someone else to produce or export the patented product or process without the consent of the patent owner.

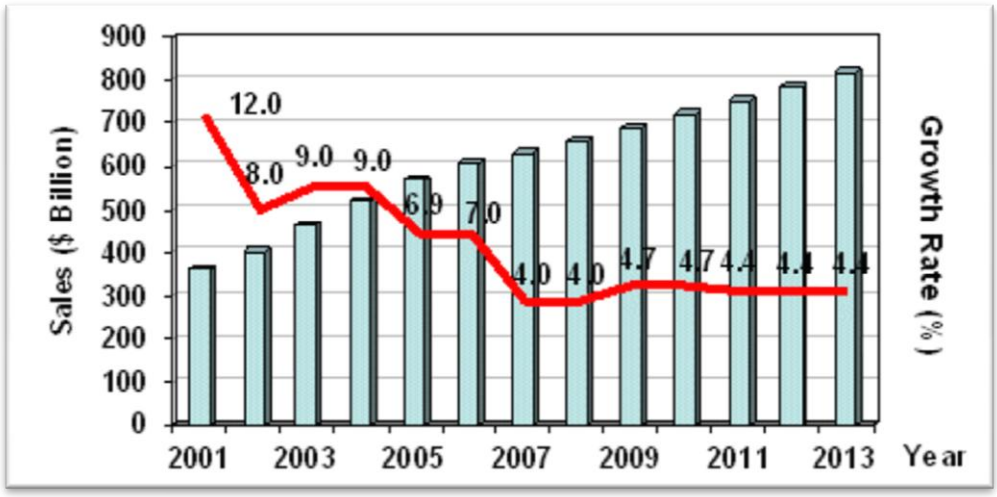

Figure 4.10: Global pharmaceutical industry annual sales (US$ billion)
Source: Frost & Sullivan 2008

The Malaysian pharmaceutical industry value was US$1.03 billion in 2007, expected to reach US$1.8 billion by 2013 (Tham and Yahya 2008). There are 87 local pharmaceutical manufacturers which almost exclusively produce generics and other off-patent medicaments (MOPI 2010). The generics market value was RM1.1 billion (US$ 316 million) in 2009 (Business Monitor International 2010). With the expected CAGR of 10.3 percent for 2009-2014 (Business Monitor International 2010), the market value will reach US$477 million (RM1.6 billion) by 2014. Figure 4.11 gives the values of current local and global generic drugs market. The total export of locally produced pharmaceuticals in 2008 amounted to RM513 million (US$142 million). This figure is very small compared, for example, to the total value of similar exports of South Korea, at US$1.11 billion in 2007 (KPMA 2010).

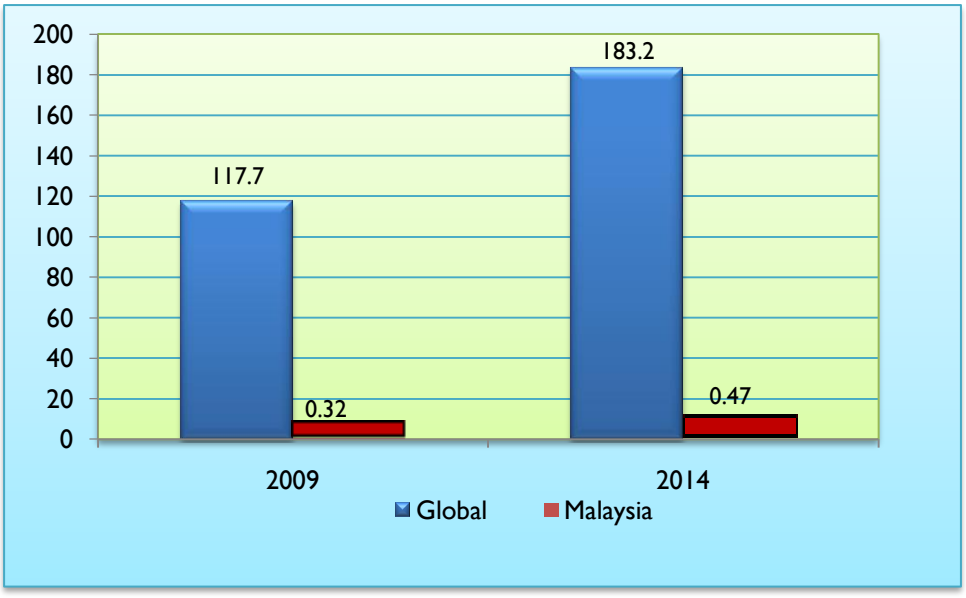

Figure 4.11: Generic drugs market value (US$ billion)

The worldwide market for pharmaceuticals based on biotechnology methods was valued by Espicom (2008) at an estimated US$80 billion in 2007, representing nearly 10 percent of the total global pharmaceutical sales. In this connection, the Malaysian Biotechnology Corporation signed a memorandum of understanding (MoU) with two Indian multinational companies in January 2010 to outsource some of their pharmaceutical biotechnology to Malaysia.

Another component of pharmaceuticals which Malaysia may consider for investment is *halal* pharmaceuticals. The current value of the global *halal* market in general is estimated at US$2.1 trillion per annum (Table 4.5) and is expected to grow with the growing Muslim population. Markets for these products include the Middle East, China and the European Union.

Table 4.5: Global *halal* market situation, 2006

US$2.1 trillion	Annual global market value for the entire *Halal* trade
US$900 million	Annual retail sales of *Halal* meat in the United Kingdom
1.6 billion	Current global Muslim population
1 billion	Muslim population in Asia
3 billion	Estimated global Muslim population in 2010

Source: Third Industrial Master Plan 2006-2020, published 2006.

The United Nations has cited Malaysia as the best country in terms of rationalisation for the labelling of *halal* food when the Codex Alimentarius Commission adopted the Codex general guidelines for the use of the term *halal* in Geneva in 1997. The establishment of the *Halal* Industry Development Corporation (HDC), *Halal* Products Research Institute (HPRI) in addition to Malaysia's *Halal* Certification and Malaysian *Halal* Standards MS1500:2004, and the development of specific strategies under the Third Industrial Master Plan (2006-2020) set the direction towards growth of this industry. The HDC is exploring the *halal* integrity of cosmetic, personal and pharmaceutical products through partnerships with several local universities. Companies such as Chemical Company of Malaysia, Halagel, and GranuLab have *halal*-certified products, and future products including health supplements, vaccines, and biosimilar products are in the pipeline. The *Halal* Pharmaceutical Standard has been drafted according to the Pharmaceutical Inspection Co-operation Scheme (PICS) and Good Manufacturing Practices (GMP) guidelines, and will be announced towards the end of 2010.

The following are drivers that will propel the growth of pharmaceuticals in Malaysia: strong industrial background; membership in Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation/Scheme (PIC/S);

government focus on technology transfer; multi-ethnicity composition for local and outsourced clinical trials; increasing demand for food supplements and generic products; patents expiration of most chronic diseases drug within the next two years. Moreover, pharmaceuticals manufacturers are enjoying tax incentives as part of the government's efforts to promote R&D and commercialisation of pharmaceuticals, particularly biotechnology-based.

An opportunity for Malaysia in the area of pharmaceuticals is more engagement in contract manufacturing to strengthen R&D capabilities, expand experience and skills in clinical trials and product commercialisation. PIC/S membership enables local pharmaceutical manufacturers to target markets in member countries including Australia, the EU, and Canada. The shifting of trend in market opportunities from Western countries to Asia in the areas of generic drugs, traditional medicine, and health supplements is another opportunity for Malaysia's pharmaceutical industry. A number of blockbuster drugs go off-patent within 2010-2012, including: Lipitor® (hyperlipidemia), Cozaar® (hypertension), Zometa® (cancer), Zyprexa® (antipsychotic), Plavix® (cardiovascular), Diovan® (hypertension), Lescol® (hyperlipidemia). Thus local manufacturers should plan to produce generic versions of these drugs. Additionally, many of our regional neighbours have limited manufacturing capacities and would require steady supply of cheap drugs.

Below are some of the challenges facing the pharmaceutical industry:

- Development of new drugs (i.e. new chemical entities) requires lengthy and costly extensive research. Production of a new drug was estimated to cost between US$800 million and US$900 million, and typically requires between 3,000 and 10,000 compounds. Yet only one out of every 250 new compounds are used in preclinical testing and 1 in 5 to 1 in 10 in subsequent human clinical trials ever receive FDA approval (Steiner et al. 2007).

- Generics production faces stiff competition from multinational generic producers and leading countries like India and China.

- Branded drugs competition (sometimes through price cutting and bonuses) with locally produced drugs in the local market makes market penetration more difficult for local manufacturers.

- Lack of infrastructure for clinical trials and GLP laboratories.

Vaccines

Vaccines stimulate the body's immune system to defend against an infection or disease. Since the eradication of smallpox through vaccination, technologies have opened the way for novel approaches in vaccination. In particular, modern vaccinology could strongly benefit from the latest developments of molecular biology and immunology. The next generation vaccines include those for

hypertension, smoking and nicotine addiction, atherosclerosis, staphylococcus infections, prostate cancer, dengue, malaria, rotavirus, and chikungunya.

Launched in 2000, the Global Alliance for Vaccines and Immunisation (GAVI) is a global health partnership representing stakeholders in immunisation from private and public sectors, nongovernmental organisations and United Nations' organisations. The alliance aims at engaging in innovative new vaccines research to prevent millions of deaths worldwide and contributes to the achievement of the Millennium Development Goals for child health.

Although Malaysia has had some achievements in developing animal vaccines, it has yet to embark on the development of human vaccines for some prevalent diseases like dengue, Japanese encephalitis (JE) and hand, foot and mouth disease. Most of the vaccines in use in humans, mainly as part of Expanded Programme on Immunization (EPI), are of the recombinant type which requires extensive research and technology. There is high vaccination coverage for children in Malaysia of up to 98 percent for DTP in 2008 (WHO 2010). Introduction of the human papillomavirus (HPV) vaccination reduced the costs related to cervical cancer treatment from US$123 million to an estimated US$48 million (Rani 2010). In a recent local study, HPV vaccination has been estimated to reduce the cost of treatment for cervical cancer from RM181 million (US$58.3 million) to RM30.8 million (US$10.9 million) per year (Sharifah Ezat 2010). This is an example how STI lead to cost-saving approaches.

The global vaccine market is expected to register revenues in excess of US$34 billion by 2012 from US$24 billion in 2005 (see Figure 4.12), and is dominated by paediatric vaccines. Projected compound annual growth rate (CAGR) for the global vaccines market is expected to be over 16 percent during 2009-2012 (RNCOS, 2008). The vaccine market in Malaysia was valued at approximately US$30 million in 2004, with an estimated annual growth of 5-6 per cent (MPS 2004).

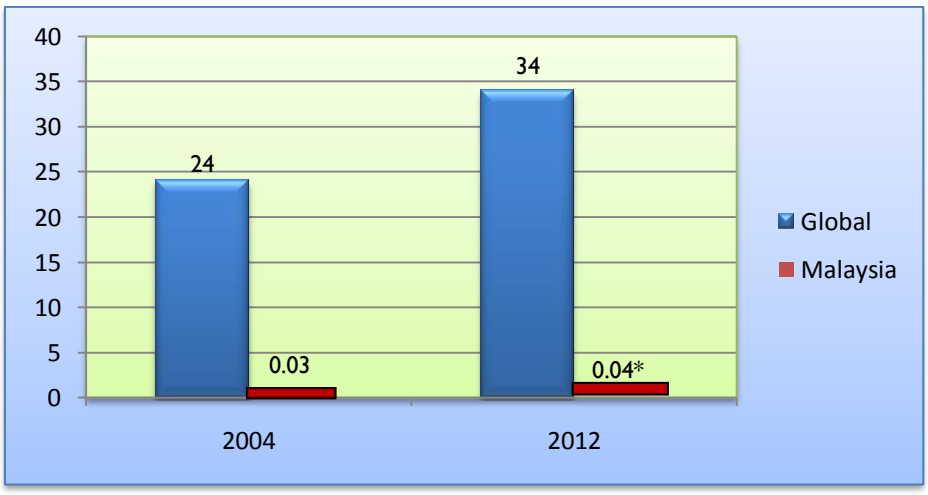

Figure 4.12: Vaccines market value (US$ billion)
** based on projected AGR 5-6%*

The USA and Europe represent the two largest vaccine markets in the world today. However, China is the largest vaccine producer worldwide, and India is expected to be a major player in vaccine research and development (see box 4.3 below).

Box 4.3: Major players in vaccine production

China

- World's largest vaccine producer.
- Vaccine market is approximately RMB8 billion (2020), and export is US$10 million (2007).
- Allowed private companies into the vaccine sector.
- Developed hepatitis A and B, measles, mumps, inactivated influenza and split-influenza vaccines.
- Vaccine industry focuses on Flu Vaccine, HBV Vaccine, Cerebrospinal Meningitis vaccine, HIV vaccine, and A/HINI vaccine.

India

- Largest producer of recombinant Hepatitis B vaccine in the world.
- Vaccine market was valued at US$ 360 million.
- 10 companies market 18 human vaccines include rabies, polio, hepatitis B and measles.
- Developed and manufactured haemophilus influenza type b (Hib) vaccine in a single-shot pentavalent combination vaccine.
- By 2012, vaccines against Japanese encephalitis, dengue, human papilloma virus (HPV), hepatitis A and rotavirus will become available.
- Tight vaccine regulatory requirements.
- Government spending in the sector would decline, leading to the emergence of a large private sector market for vaccines.

In the third Industrial Master Plan (2006–2020) the government was committed to contract research outsourcing (CRO) to make Malaysia an ideal location for international clinical trials for vaccine development and diagnostic products. Experience in veterinary vaccines research and development could provoke further research for human vaccines provided that the focus is clear (locally prevalent tropical diseases). On the other hand, vaccine development is expected to benefit from relatively untouched patient pool to undergo clinical trials. Malaysia's qualified and well trained medical professionals in modern medical facilities, strong industrial and manufacturing background are the nation's competitive strengths.

To encourage investment from private sector corporations, the government offers various tax incentives on R&D for vaccines. Current vaccine research projects are conducted by local and collaborating international companies concentrating on diseases like dengue, JE, malaria, cancer (lung, prostate and breast) and on *halal* vaccines as depicted in Table 4.6 below (not including universities and research

institutes). In addition, vaccine research centre at UPM and the National Institute of Natural Products and Vaccinology also conduct research on vaccines.

The Malaysian Biotechnology Corporation (MTDC) and the Malaysian Life Science Capital Fund (MLSCF) have respectively invested in Sentinext Therapeutics, a biotechnology company that plans to develop novel vaccines for emerging tropical infectious diseases like JE, dengue and malaria. By October 2009, MLSCF had invested RM162 million (US$47 million) in 27 companies involved in the life science sector including vaccine development (MIDA, 2009). However, this thin distribution of already scarce human and financial resources by its own is one of the challenges that face research and development activities in general. If this little amount is directed at one institution or company with clear focus on one or two vaccines, it is envisaged that a more tangible result could be expected. For example, the Bharat Biotech of India has already invested around US$30 million in vaccine development so far and is planning to spend another US$30 million on phase three clinical trials alone.

Table 4.6: Local vaccine development overview

Company	**First production**	**Investment**	**Country of origin**	**Product**	**Govt. of Malaysia**	**Future product**
Bharat Biotech International Limited (BBIL)	June 2007	MYR50m (US$13.2m)	Genome Valley, Hyderabad, India.	Chloride-free hepatitis B vaccine. DPT + hep B + Hib combination	Tax incentives and grants	Malaria and typhoid vaccine.
Sentinext Therapeutics Sdn Bhd	EV71 (2012)	MTDC + MLSCF (RM40m)	Denmark	None	MTDC company	EV71, malaria, dengue and JE
Ninebio Sdn Bhd (9Bio)	NA	NA	Malaysia	None	Owned by Ministry of Finance	Halal vaccine, Dengue, Nipah, Enteroviruses, JE. BioThrax[R] (Anthrax Vaccine Adsorbed), Hep A vaccine, (Genor BioPharma Co Ltd)
Bioven Sdn Bhd	2008	US$32m. Malaysian government: RM2 million & Cuban government: RM1.6 million (for halal vaccine)	Havana, Cuba	EGF cancer vaccine (lung)		Halal meningitis vaccine. Cancer vaccine (lung, prostate and breast). Nasal spray Hepatitis B therapeutic vaccine.
INFORMM	NA	NA	USM	None	Higher Education	Oral cholera vaccine with Cuba. Vaccines for tuberculosis and malaria.

A lot of time and investments have been spent on local vaccine research development over the years, mainly on malaria and dengue. Disappointingly, there have been no tangible results and outcomes. It is prudent to thoroughly evaluate previous vaccine R&D experiences to identify reasons that hindered the progress in vaccine research and to set directions for current work. Some difficulties facing vaccine development are (1) the national health system place little emphasis on preventive technologies such as vaccines (2) local pharmaceutical manufacturers and financial agencies may be unwilling to undertake R&D on vaccines due to complexities involved, such as cost, production and quality control issues, safety and efficacy, in addition to the uncertainties about the potential customers and commercial viability, (3) lack of specific policy or procedure to stimulate manufacturer and investor interest in this sector and (4) lack of multidisciplinary expertise required for vaccine research.

Information and Communication Technology in Health

Information and Communications Technology (ICT) is a study or business of developing and using technology to process information and aid communications. Health information technology (health IT) involves the exchange of health information in an electronic environment. Widespread use of health IT within the health care industry will improve the quality of health care, prevent medical errors, reduce health care costs, increase administrative efficiencies, decrease paperwork, and expand access to affordable health care (U.S. Department of Health & Human Services). In Malaysia, the use of IT in the health sector has changed the way data and information is collected, compiled, stored and retrieved. Implementation of IT in the MOH hospitals has thus far been an exercise of converting hospital processes into digital process (e.g. electronic health record, e–prescription and digital X-Ray), which has created 'Paperless hospitals'. Currently 12 public hospitals have installed full or partial IT systems, while four hospitals and 76 of the 808 health clinics offer teleprimary care[19] which aims to provide specialized care to rural communities.

The telehealth programme was launched in 1997 to provide the public with broad internet-based access to health information and education and to give healthcare providers an alternative means to enter, update and retrieve electronic medical records. It consists of four solutions: Lifetime Health Plan (LHP)[20], Mass Customised/Personalised Health Information and Education (MCPHIE), Continuing Medical Education (CME)[21] and Teleconsultation[22]. As of 2004, the Lifetime Health Record Application has been implemented in 4 hospitals and 42 health centres

[19] Teleprimary care is a methodology to channel the existing health services to patients and the public using information, communication and technological facilities. It also covers disease surveillance, epidemic management and technical support services such as labs, radiology and pharmacy.
[20] The Lifetime Health Plan application forms the crux of the solution which comprises the Clinical Support System and the Healthcare Information Management and Support System.
[21] Continuing Medical Education (CME) Portal provides information and education programmes for both health consumers and healthcare providers
[22] Teleconsultation serves as a channel for healthcare providers to access medical and health expertise from locations where such resources are not available.

(Mohan and Yaacob 2004). Forty teleconsultation hubs have been set up and are functional.

The introduction of the telehealth project in 1997 was very promising with the introduction of a very comprehensive blueprint, a national telehealth policy, extensive planning, and led by the private sector. A telemedicine unit was established in the Ministry of Health in 2000 to facilitate operationalisation of the project. Unfortunately, the project failed to progress due to implementation challenges. To revive the project as a tool for advancement of healthcare and generating economic growth, the Cabinet, in October 2004, approved upgrading of the telemedicine unit to a division under the Medical Services Programme. Subsequently, the project was reviewed and the scope reorganized into seven components namely Lifetime Health Record (LHR), Health On-Line, Continuous Professional Development (CPD), Teleconsultation (TC), Call Centre, Personalised Lifetime Health Plan (PLHP) and Group Data Services (GDS). Overall, despite the increase in components, the project was downscaled.

The global healthcare IT market is US$43 billion in 2010 (see Figure 4.13). It is estimated to be US$53.8 billion in 2014. The Malaysian market is US$14 million in 2010, and it is expected to reach US$6.21 billion in 2050 based on an annual growth rate 8 percent. The mobile healthcare business in Asia is currently growing at 80 percent year on year along the growth of an ageing but technology friendly population (Mobile Association Global). In 2010 the Asia Pacific mobile healthcare business is estimated to be worth just under US$1 billion with 70 percent of users in more advanced Asian economies (Solidiance 2010).

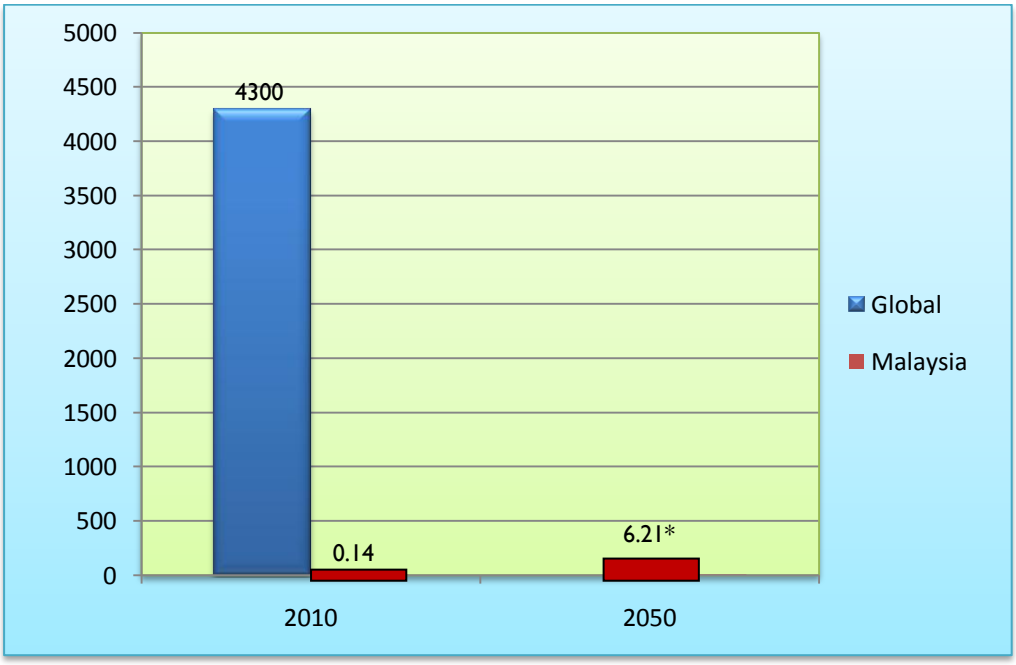

Figure 4.13: Global and Malaysian ICT Market value (US$ billion)
**based on AGR 8%*

The Telemedicine Blueprint of Malaysia "Leading Healthcare into the Information Age" is the reference document for the development of telehealth in Malaysia. It states the vision of (1) wellness of individuals and families, (2) empowerment of the individuals to enable them to play a major role in managing their health, (3) home- and community-based care, and (4) access to quality healthcare (including a shared lifetime record).

The National Telehealth Policy, as a complement to the Blueprint, aims to (1) bring awareness of the universal usage of telehealth and its integral place in the health delivery system, (2) promote safe telehealth practices, (3) ensure affordable telehealth services; (4) sustain telehealth as part of health care delivery system, (5) integrate telehealth services within and between organisations, institutions and other relevant health agencies for optimal positive health outcomes, (6) improve quality in all aspects of telehealth services and (7) improve equity and accessibility of health services at all levels.

The introduction and implementation of IT in the Malaysian healthcare environment has its challenges as reflected in the following paragraphs. Implemented in silos, there is little emphasis on creating value from the information collected through the use of IT. In order to fully utilize the potential of IT in the healthcare environment in Malaysia, it is necessary to embrace the rationale for implementing IT; that is to create value not only for the providers but at the same time creating quality care for the patients.

Telehealth applications can be implemented in healthcare facilities or a means to provide services directly to patients through the internet. In Malaysia, however, the network infrastructure may not be consistent across the country and among healthcare facilities. For example, in 2005, the average national internet penetration in Malaysia was around 14 percent (Malaysian Communications and Multimedia Commission 2005). On the other hand, the internet penetration in large cities such as Kuala Lumpur is around 50 percent. The signal can be weak and unstable, especially in rural areas. This would jeopardize the availability, accessibility and the continuous upkeep of the patient medical record.

Earlier, we have discussed the insufficient number of health care providers (see discussion in Chapter 2, page 17). Health care services and information delivered via telecommunications helps to bring health care to the population and to a certain extent address the issue of inequity. However, medical malpractice issues, liability and accompanying risk management are some of the issues in the realm of telehealth. One of the legislative initiatives by Malaysia to ensure that the law keeps pace with the development of electronic commerce is the introduction of the Telemedicine Act 1997. However, this Act does not address issues of liability for negligent by telemedicine practitioners (Puteri Nemie 2004). It is also uncertain whether the Malaysian Medical Council, which issues certificates to telemedicine practitioners, will be exposed to liability.

Operational level data is the single most important component needed to make intelligent decisions for efficiently managing the healthcare system. This can be realised by the implementation of the clinical support system (CSS) and Healthcare Information Management and Support System (HIMSS). Therefore it is important to ensure that all the necessary data elements for managing and planning purposes are included in the data repository. In this regard, the Study emphasizes the importance of Case-Mix system, which links the resources used in health care with the patient level (clinical) data. With the help of case-mix system, patients at the hospital can be easily costed against the diseases they are suffering from, thus providing the accurate resource consumption at the hospital level. Until now, this system has been the missing link in the Ministry of Health. As this system bridges the gap between the clinical side of healthcare with financial resources needed to manage patients, managers and policymakers are equipped with robust tools that can help them make the right decisions to improve efficiency of the healthcare system.

RECOMMENDATIONS

The recommendations are divided into two sections: (1) recommendations specific to the STI areas, and (2) cross cutting recommendations. These recommendations are made taking into consideration the following:

- Vision 2020, 10th Malaysia Plan, Economic Transformation Programme; regional and global changes including disease trends and burden, development, demographic, climate, etc.

- Analysis of the 11 STI areas discussed in the preceding section.

- Health sector is a contributor to economic development, thus targets for marketing of products and services must go beyond the Malaysian market.

- Focus on five diseases that carry high disease burden and tropical medicine.

Specific Recommendations

The specific recommendations are listed according to the priority which was identified through a rating done by 30 experts. The rating is based on five criteria and nine indicators: (1) Economics (market value, revenue and expected growth); (2) R&D infrastructure (current level of investment, availability of specific physical infrastructure, networking); (3) R&D Policy (supporting policy); (4) Human capital (trained/skilled researchers); and (5) R&D outputs (research publication). Economic indicators and current level of R&D investment were rated using a score of 1 (lowest score) to 3 (highest score). Scoring of 0 (lowest score) to 3 (highest score) was used to rate 'availability of specific physical R&D infrastructure, networking and indicators for human capital, R&D policy and

R&D outputs. A maximum possible score for each item is 90, and the maximum possible total score for each STI is 810. The description of scoring criteria for each item is presented in Annex 10. Table 4.7 gives a summary of the scoring analysis.

Table 4.7: Summary of scoring analysis for 11 STI areas in health

	Market value	Growth	Current Revenue	Level of R&D investment	Specific R&D facilities	Level of R&D network	Supporting policy	Human Capital	R&D Output	Total Score
Natural products	53	53	43	51	52	40	67	45	40	789
Health tourism	69	66	64	64	38	57	53	40	43	494
Pharma-ceutical	58	51	59	62	31	37	70	35	32	435
Medical devices	63	42	65	62	28	44	36	36	32	408
TCM	54	48	40	44	37	35	57	28	45	388
Medical diagnostics	44	48	34	48	24	39	44	34	45	360
Vaccine	38	45	38	50	30	53	34	29	34	351
ICT in health	45	40	41	38	28	31	53	33	36	345
Stem Cells	38	46	45	41	26	35	33	37	36	337
Genomics	42	48	41	47	25	35	27	30	37	332
Nano technology	40	36	34	46	32	41	36	24	36	325

Natural Products

The exploration of, and research into, Malaysia's rich biodiversity especially plants and herbs, have led to discoveries that benefit health. These successes, the existing infrastructure and a relatively strong capacity, put Malaysia as a competitor in this area. The recommendations are:

1. Conduct basic research to identify bioactive ingredients. Concentration should be on specific diseases including cancer, HIV, malaria and other tropical diseases.

2. Establish more cooperation with international research institutions and companies in product development and commercialisation.

3. Improve the quality of herbal products by standardizing and undertaking necessary testing for quality, safety and efficacy. Related, establish and enforce strict measures for safety, quality, and scientific evidence as prerequisites for registration of herbal products.

4. Outsource animal studies for certain tests/procedures to private entities to facilitate efficiency as speed is important especially in fundamental research. Enhance the capacity of existing researchers, biologists, chemists, physiologists and technicians involved in natural product research, and increase the number and skills of taxonomists.

Health Tourism

Health tourism is an industry that is already generating revenue for the country. The services offered within the realm of health tourism do not entail any particular STI, except for the use of existing biomedical technologies in healthcare. On the other hand, the promotion of health tourism which is primarily offered by the private hospitals has more to do with the tourism industry than the health sector. The recommendations are:

1. Assign the Ministry of Tourism, in close collaboration with the MOH and other relevant partners (private hospitals, health professional associations, Immigration authority, etc), to spearhead the health tourism industry. This ministry is suited to lead as it has been very successful in promoting Malaysia as a tourist destination, an experience that will be very useful in promoting and marketing Malaysia as a health tourism destination. As the lead agency, the Ministry of Tourism should identify strategies to (1) improve coordination among the various stakeholders, (2) enforce domestic and international accreditation for hospitals which offer health tourism services to ensure quality of services, (3) facilitate entry into the country for health tourists, and (4) promote and market health tourism.

2. Assign the Ministry of Health to take the lead in addressing and monitoring (1) ethical and safety of medical practices, (2) quality assurance, and (3) potential diversion of resources and services to cater to health tourism at the expense of quality and equitable health care for Malaysian.

3. Strengthen the capacity of human resources through advance education and training opportunities particularly in medical areas sought by health tourists, such as cardiology and orthopaedic surgery both locally and abroad. However, this is a longer-term initiative. In the meantime, increase the number of health professionals through recruitment of qualified health personnel from other countries.

4. Increase the competitiveness of participating hospitals through national accreditation such as the Malaysian Society of Quality Hospital (MSQH) and international accreditation such as the Joint Commission International (JCI).

5. Initiate R&D in marketing in view to effectively identify strategies to market the country's health tourism industry.

Pharmaceuticals

1. Support local manufacturers of generics and *halal* pharmaceutical to enhance discovery and development of drugs through a more competitive procurement process of locally produced pharmaceutical products.

2. The government should lead negotiations for generic production of expiring patent drugs to strengthen the position of local pharmaceutical companies. Plans for these negotiations should start well before the expected patent expiry date. Related, target markets in the region where there is demand for cheap generics, and countries which have minimal capacity for production (e.g. Vietnam, Africa, Middle East).

3. Establish clinical trial initiatives for discovery from fundamental research in partnership with multinational companies.

4. Enhance collaboration with multinational companies in the form of contract manufacturing organization (CMO) to build capacity and expertise especially in biopharmaceuticals production.

5. Develop the capacity of researchers to identify new chemical entities through training at the local and international levels.

Medical devices

1. Establish WHO-certified and biohazard level 3 and 4 (BSL-3 and BSL-4) laboratories.

2. Train scientists in Biomedicine and Biomedical engineering.

3. Accord high priority to locally produced devices for use in public and private hospitals. In this connection, the Medical Devices Bureau of the MOH needs to be more proactive in endorsing and promoting local products. In this connection, prepare a policy or roadmap to guide the development and commercialisation of locally produced medical devices. Participation of the relevant sectors (government and private sectors, funders) and actors (scientists, researchers, consumers, medical associations) is critical in the development of the proposed policy or roadmap.

4. Establish an electronic database and standardised web facilities for sharing data and information related to medical devices development, manufacturing and commercialisation.

Traditional and Complementary Medicine

1. Develop a research agenda that aims to generate evidence for the effectiveness, safety and quality of TCM which will be the basis for accreditation and promotion of TCM. This process must involve collaboration between the government, the private sectors, universities, TCM practitioners, TCM users, and health professionals. R&D activities should start with studies on herbal medicine which has high demand but potentially high toxicity (e.g Kacip Fatimah and Tongkat Ali), and research on current standards of TCM practices. The engagement of the private sector in R&D activities is crucial to improve commercial opportunities.

2. The TCM division of MOH needs to be more proactive in regulating and monitoring the practices of TCM to ensure safety of its users. This should involve auditing the existing TCM services, practitioners and facilities to have a better understanding of the status of TCM and its potential growth, and to address the gaps and establish priorities for action. A multi-sectoral working group could be identified to carry out this task, and to set up a database on TCM to enable wider sharing of information. To further ensure safety of TCM usage, MOH must enforce registration of all TCM practitioners.

3. Support existing institutions that offer TCM training programmes to develop skilled and professional TCM practitioners to meet the established quality standards. Ensure that the educational and training curriculum meet international standards and is standardised. Related, determine and offer an attractive package to encourage scientists, researchers and health professionals to establish career paths in TCM.

Medical Diagnostics

The recommendations for medical diagnostics are similar to that of medical device, except for the first recommendation below:

1. Develop medical diagnostic kits that address priority diseases and health problems such as cardiology, diabetes and dengue. The kits must be validated locally in collaboration with universities and research institutions. They must be cost effective to compete in the domestic and global markets.

2. Establish WHO-certified and biohazard level 3 and 4 (BSL-3 and BSL-4) laboratories.

3. Train scientists in Biomedicine and Biomedical engineering.

4. Accord high priority to locally produced devices for use in public and private hospitals. In this connection, the Medical Devices Bureau of the MOH needs to be more proactive in endorsing and promoting local products. In this

connection, prepare a policy or roadmap to guide the development and commercialisation of locally produced medical diagnostics. Participation of the relevant sectors (government and private sectors, funders) and actors (scientists, researchers, consumers, medical associations) is critical in the development of the proposed policy or roadmap.

5. Establish an electronic database and standardized web facilities for sharing data and information related to medical diagnostics development, manufacturing and commercialisation.

Vaccines

1. Conduct an evaluation of R&D and commercialisation activities in vaccines in Malaysia. The evaluation should include an investigation of the level of investment, the extent of R&D activities and outcomes, the capacity of human resources, as well as the enablers and obstacles. The findings of this evaluation will guide specific interventions to revive and stimulate the local vaccines industry.

2. Focus on developing vaccines for highest disease burden that will be most prevalent in Malaysia (e.g. cancer and diabetes), and on improving the cost-effectiveness of existing vaccines.

3. Integrate vaccine R&D and commercialisation into national STI policy and national health policy, and improve incentives to encourage private sector investment in vaccines development.

4. Enhance human resource capacity which excels in skills related to vaccine development and commercialisation.

5. Broaden community awareness, participation and ownership. The media should provide complete, accurate information about all aspects of vaccine development, production, and use in this country.

Information and Communication Technology in Health

1. Expand the use of ICT to support the healthcare system. In this scenario, ICT should be used to:

    - Input, store and share medical record data (who has a disease, type of treatment provided, and the health outcome).
    - Manage the resource utilisation data – most important data element needed to introduce efficiency in the healthcare system.
    - Improve administration and management both at the clinical as well managerial level.

- Introduce patient level costing to monitor resource utilisation.
- Generate the case-mix groups – diagnosis resource groups (DRG).
- Introduce health insurance and allow third party payment and prospective payments more efficiently.

2. Introduce the use of ICT in pharmaceutical activities. This includes implementation of e-prescription, management of drug related cost in the healthcare system which is the biggest single component in the health expenditure and implementation of pharmacy reimbursement system (i.e. separation of prescription and dispensing of drugs in the healthcare environment).

3. Use ICT to enable integration of public and private healthcare system, in view to develop a seamless healthcare system.

4. Establish nationwide network infrastructure to enable strong and stable signal coverage.

5. Offer training programme in health ICT to produce skilled professionals in this area and for existing healthcare providers to improve skills in using IT in their practice.

6. Allocate R&D fund for areas such as (1) Open Source in healthcare, (2) Development of decision support system, (3) Mobile medicine, (4) Health Information System (HIS) and (5) Disease classification system. These are important areas that will increase the efficiency of the healthcare system.

7. Introduce policy that encourages the use of locally developed ICT softwares.

Stem Cells

1. Enhance the dismally low level of investments in R&D in stem cells research (eg RM500 000 for a 2-year fundamentals of embryonic stem cells research) to a realistic level. Related, the stem cells research facility, Stempeutics[23], in close collaboration with the relevant stakeholders, could take the lead in stem cells research and development. This group should be given the necessary support to conduct successful R&D initiatives.

2. Allocate the bulk of R&D investments in: (1) fundamental research to understand how stem cells behave and differentiate, and the networks and molecules that control this differentiation; (2) short-term and long-term safety and toxicity of stem cells; and (3) clinical trials to monitor, track and prove the contribution and effectiveness of stem cells; (4) Quality control of stem cells

[23] Stempeutics is a first of its kind stem cell research facility in Malaysia. It was established by the Manipal Education and Medical Group of India and is located at the Technology Park.

manufacture, delivery to the target areas, and architectural aids to ensure optimum placement and exposure of the stem cells; and (5) Bioengineering of materials necessary to deliver and support stem cells on their therapeutic journey.

3. Develop human resources capacity, specifically experts in bioinformatics and bioethics. The roles of the primary care physician need to be redefined and their skills developed to allow them to educate patients about stem cells therapies. They also need to be trained in transplantation work when stem cells-based therapies are ready for application.

4. Prepare a regulatory framework surrounding stem cells research and therapies. While there is a National Guidelines for Stem Cells Research and Therapy, the regulatory framework needs to encompass issues of intellectual property, licensing and commercialisation. In this regard, Singapore combines voluntary and statutory regulations. Voluntary regulations, professional guidelines and quality standards, and accreditation are useful in the early stages of development of stem cells R&D. Eventually, it is essential to have concrete and effective statutory regulations at the stage of commercialisation, consumption and globalization of stem cells. In addition, the existing National Drug Act needs to be amended to allow clinical trials of stem cells therapy to be conducted within the country.

Genomics

1. Enhance the role of the Malaysia Genome Institute to undertake more research in human genomics. Currently, the Institute focuses more on genomics for plants. Related, specific infrastructure to conduct R&D in human genomics must be established.

2. Develop human resource capacity, specifically a critical mass of expertise in clinical/medical genetics and genetic counselling. The roles of the primary care physician, genetic counsellor, and medical geneticist needs to be redefined. Clinicians should be well versed in genomics so they can better inform and treat their patients.

3. Allocate R&D fund for the following areas: (1) laboratory analysis of mutations/polymorphisms prevalent in local population; especially in the context of genotypes and phenotypes of the different ethnic groups in Malaysia; (2) molecular epidemiology of genetic variants in Malaysian populations, environmental interactions and disease outcomes, particularly for non-communicable diseases such as cardiovascular diseases, cancer (examples of most common include colorectal and lung cancers in men and cervical and breast cancers in women) and diabetes; (3) clinical trials to establish efficacy of specific drug therapies as well as reduction of adverse drug reaction utilising novel pharmacogenomics approach; (4) health economic and policy analysis of

preventive genetic testing and community genetic services; and (5) development of personalised, preventive medicine using information from database of personal genomes which also include cells and tissues sequenced in normal states.

4. Prepare a National Guidelines and a regulatory framework surrounding genomics research. As recommended for stem cells, the regulatory framework needs to encompass issues of intellectual property, licensing and commercialisation.

Nanotechnology

Malaysia has already launched the Malaysian Nanotechnology Initiatives (MNI) to push the nanotechnology agenda forward. The Nanotechnology Taskforce has identified several recommendations, which the Study concurs with.

1. Form a National Nanotechnology Centre (NNC) whose key objectives are to (1) operationalise the MNI, (2) coordinate national R&D in nanotechnology, (3) strengthen existing nanotechnology research centres, equipped with state of the art research equipments and facility, to become centres of excellence for research in this area, and (4) liaise with industries to address business and economic agenda and develop international networking.

2. Establish a multi-sectoral Working Committee to coordinate activities including:

    - forming the organisational structure of NNC.
    - drafting a National Nanotechnology Policy; formulating nanotechnology Intellectual Properties and legal matters.
    - formulating the R&D agenda including resource mobilization and management, coordinating and managing R&D activities, providing, enhancing and monitoring the national nanotechnology infrastructure and research facilities.
    - identifying national nanotechnology niche areas and conduct nanotechnology foresighting exercises.
    - building the capacity of human resources through training, degree programmes, mentoring and practical attachments as well as creating and strategizing nanotechnology education programme, international collaboration and networking.
    - updating the national nanotechnology database and the national nanotechnology commercialization and investment activities; undertaking commercialization and industrial collaboration activities.
    - monitoring the potential environmental and societal impact of nanotechnology.

3. Allocate sufficient resources on the following R&D projects:

- Development of cancer biomarkers.
- Biopharmaceutical proteins for therapeutic drugs and vaccines.
- Bone graft substitutes.
- Diagnostic kits for infectious diseases.
- Diabetic vasculopathy.
- Antioxidants in preventing degenerative damage in Down's Syndrome and ageing.
- Vaccines against infectious diseases.

The recommendations above should be implemented in phases to ensure that the adoption, adaptation and innovation of technology is a gradual process and, transformation and dissemination of the technology is well infused to the Malaysian way of life (Uda 2009).

Cross-cutting Recommendations

The following recommendations are common to all the STI strategy recommendations discussed above.

Research and Development

1. Increase the level of investment from 0.6 percent to a minimum of 3 percent of the GDP

The present investment of 0.6 percent of the GDP in R&D undermines the intention for Malaysia to advance STI as drivers for better health outcomes and economic growth. Taking cue from South Korea, Sweden and Singapore, the country should attempt to allocate a minimum of 3 percent of the GDP to R&D initiatives. This will be a much needed enhancement in investment from the current RM 3.2 billion as per the 2010 GDP to RM 206.2 billion (3 percent of a predicted GDP of RM 6872.6 billion in 2050). Additionally, the allocation of funds for health R&D should be increased from a meagre 2.14 percent (RM 80 million) to 20 percent; giving a value of approximately RM 41.2 billion by 2050 (based on the predicted GDP of RM 6872.6 billion in 2050).

It is important to note that the resources for R&D will be generated from the public and private sector, as well as from foreign investments. While it is appropriate for the former to support basic research, the latter should focus on funding applied research. To attract private sector and foreign investments, the government needs to put in place attractive incentives including stronger tax incentives. External funds could be mobilized through establishing collaboration with international research institutes, international organizations such as the United Nations, as well

as international funders such as the Bill and Melinda Gates Foundation. It is important that Malaysia puts in place strategies and regulations to govern collaboration with international actors to ensure that the country will not only gain funds, but also transfer of knowledge.

On a related subject, the Study recommends the following:

- Adopt a transparent, unbiased and rigorous system for vetting research proposals which will make certain that research proposals with the most potential for significant health and economic outcomes are funded. The independent reviewers must be highly qualified and knowledgeable of the research themes being reviewed. In case local experts are not available in a particular research area, support from foreign experts should be sought. Reviewers must be recognised and rewarded for their roles and contributions.

- Establish appropriate standards and priorities for allocation of funds, and provide sufficient funds for R&D in the top five priority STI strategies as well as in basic research. Prioritisation is necessary to ensure that funding support for R&D is continued for clinical trials of products, production and commercialisation.

2. Develop a master R&D plan

   With the expected increase in R&D funding allocation, an important first step is to identify a R&D agenda to push forward basic and applied research related to the recommended STI strategies. The agenda should reflect the following:

   - Alignment of efforts towards creating solutions to the five diseases with the highest disease burden (diabetes, cancer, cardiovascular diseases, dengue and health problems related to ageing).

   - Establishment of Malaysia as a centre of excellence for health research, where the country will drive the knowledge, expertise, and management of basic and applied research to commercialisation of products and services especially in the top five priority STI areas.

     As a health research centre of excellence, Malaysia needs to enhance its clinical research and trials portfolio. Malaysia is already active in clinical trials and it will be strategic to promote Malaysia as a centre for clinical trials given its various ethnic groups, and good facilities. However, strict regulations must be in place and enforced to protect the rights and safety of those participating as research subjects.

   - Development of an epidemiological database which will facilitate the study of diseases and risk assessments. The availability of a database of this type will attract foreign investments in R&D in disease epidemiology.

- Promotion of collaborative R&D efforts between scientists, researchers, clinicians and engineers from universities, public research institutions, and industries. In this context, health and research institutes currently run by the MOH should have affiliation with universities. Such collaboration is necessary to maximise monetary and human resources, enhance research activities and promote sharing of resources and research findings. In this regard, a directive from the National Science and Research Council is necessary to promote affiliation and collaboration between these stakeholders. Furthermore, collaboration should be a criteria for vetting research proposals.

- Promotion of collaborative research with multinational science base agencies and industries. These partnerships have potential for generating resources for R&D and transfer of knowledge and expertise to local researchers and health professionals.

- Development of a database of research findings that will be easily accessible to relevant stakeholders. Related, establish a forum for interactive reviews, analysis and discussion of data and research findings.

- Implementation of a long-term plan for human resources and infrastructure, including development of centralised facilities.

In accordance with international best practice, development of the R&D agenda must be a consultative process that involves relevant stakeholders: the government, scientists, academics, private sector and industries, engineers, health professionals, and the civil society. It must also be evidence-informed.

3. Establish R&D structure and improve coordination

The Study strongly supports the formation of the National Science and Research Council (NSRC), and stresses that the Council must be strictly autonomous, and be given sufficient amount of financial support and human resources with extensive knowledge and experience in order to effectively perform its proposed roles to:

- Provide advice to the Government on S&T related matters on the formulation, formation, development of any laws, policy and strategies, including on S&T related investments.

- Propose priorities and direction on R&D taking into account the multi-disciplinary and cross cutting nature of the various Ministries involved in R&D.

- Identify and ensure initiatives are implemented effectively.

- Evaluate and monitor the performance of projects implemented under R&D grants by relevant Ministries.

- Become a one stop Centre for all aspects of R&D matters in the country.

The NSCR will have about 15 members representing government agencies, the academia, industries and a few imminent figures. The proposed structure is presented in Figure 4.14. In this Council, it is the scientists who should have the greater authority to influence decision-making based on evidence, knowledge, and merit.

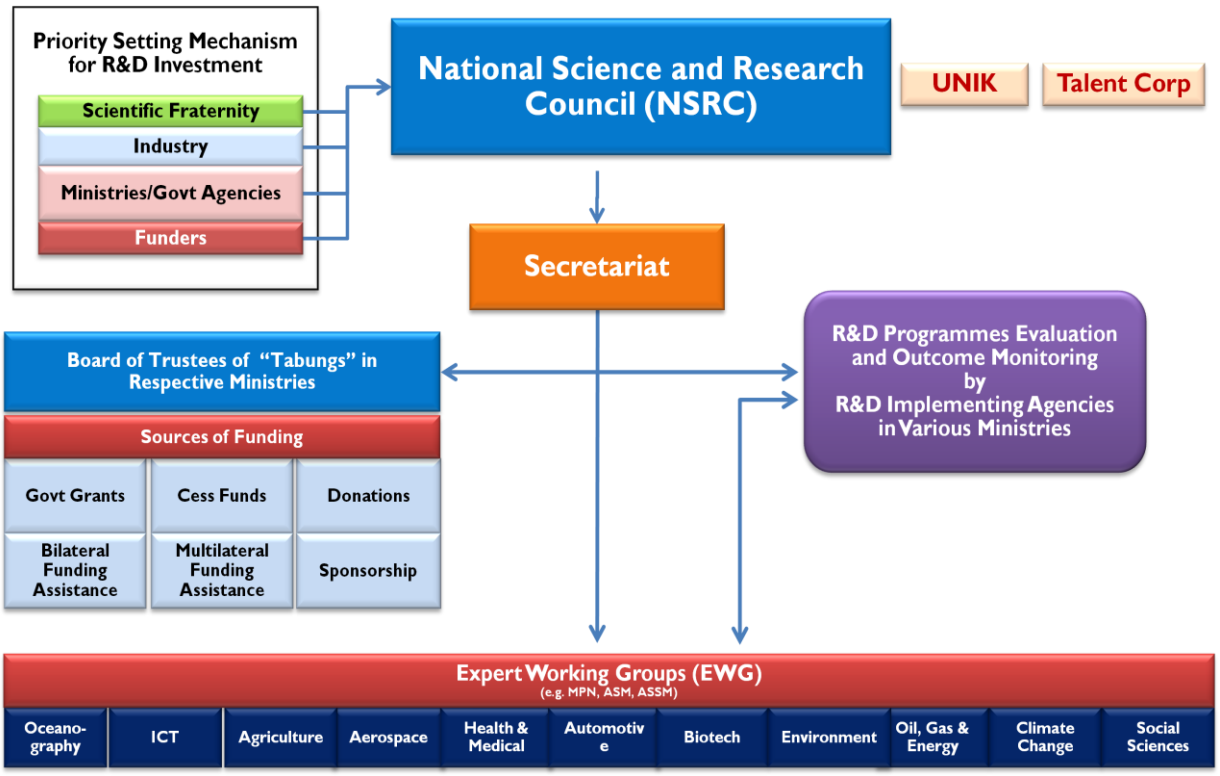

Figure 4.14: Proposed National Science and Research Council (NSRC)
Source: MOSTI presentation

4. Improve R&D infrastructure

While the R&D infrastructure is relatively well developed, their efficiency and quality could be enhanced by:

- Controlling the procurement and setting up of very expensive facilities and equipment, and strategically locating them at the most appropriate institutions. Related, encouraging collaboration and sharing of facilities and equipment amongst research institutions.

- Encouraging private sector involvement for routine experiments such as toxicity and efficacy test of a compound and characterisation of the properties of a material (e.g. material testing) as well as animal studies for certain tests and or procedures.

- Structuring and clustering research to coordinate and optimize resources.

5. Improve legal and regulatory framework

   - Establish an Act to promote R&D as a national priority. This Act should facilitate investment in R&D by both the government and the private sectors.

   - Develop new regulations (where relevant as per the recommendations in the specific STI areas) and enforce existing regulations to ensure ethical and safe R&D practices.

6. Strengthen commercialisation of research outputs

   - Offer incentives to promote partnership between researchers and investors, and between private and public sectors.

   - Offer greater monetary and recognition to researchers for their discoveries.

   - Engender awareness among researchers and companies about domestic and global markets and opportunities.

   - Support research proposals that identify commercial value of research outputs.

   - Develop marketing strategies for penetrating regional and global markets.

Human Resources

In general, Malaysia has to promptly strengthen its competency in STI. In particular, as research and development is fundamental in the development of STI, there needs to be a coordinated long-term master plan for human resources and education with the objective to produce highly skilled and innovative researchers and professionals in R&D and STI.

Within this context, the following long-term priorities must be attended to:

- Enhancement of the number of researchers from 9.1 per 10,000 total employment to 150 researchers per 10,000 total employment. Specifically, there should be 30 researchers working on health issues per 10,000 total employment.

- Promotion of creativity and innovation that is inculcated in children's basic education (as is the case in South Korea) all the way to tertiary education. This would imply a paradigm shift in children's education, and a review of the current education curricula and making the necessary changes, as well as changes in the training of teachers.

- Promotion of science and mathematics at all level of education to improve the country's competitiveness and innovativeness.

- Strong basic and tertiary programmes in STI especially for the top priority areas (natural products, health tourism, pharmaceuticals, medical device, TCM).

In the short term, the options include:

- Intensive training, both locally and abroad for qualified professionals to enhance their knowledge and skills in STI areas.

- Post-doctoral programmes that support STI especially in the top five priority STI areas.

- Development of research management skills for senior professionals involved in managing and coordinating research activities. This is crucial if Malaysia aims to become a centre of excellence for health research (see Recommendation 2 under R&D recommendations on page 92).

- Greater incentives and attractive benefits packages for national professionals who are already engaged in STI areas.

- Attractive career pathways and recognition to promote engagement in STI in health. Related, emphasis must be on placing the right talent at the right place.

- Recruitment of foreign expertise to work in Malaysia. This implies offering desirable salary and benefit packages, and easing of immigration bureaucracy and allowing foreign spouses to seek employment.

- Enhanced incentives to lure skilled Malaysians who are working abroad. This implies easing immigration bureaucracy for foreign spouses and allowing foreign spouses to seek employment.

Policy

1. Finalize the draft National Health Policy

The linkage between health and economic growth makes health a non-negotiable priority. As health is inter-related with other development sectors, the government must give a strong message to all sectors about its importance. As an immediate

step, the draft National Health Policy crafted by the Ministry of Health needs to be finalised. The policy must ensure that STI is integrated as an important element. Following best practice, the policy should only be finalised after consulting with a wide cross-section of stakeholders[24] and getting their 'buy-in'. This is important to create a sense of ownership so that the stakeholders will contribute towards implementation of the policy.

It is important to distinguish between a health policy and a healthcare policy. The latter is confined to a set of rules, regulations, and guidelines that exist to operate, finance, and shape healthcare delivery. The former encompasses a myriad of factors that affects health including education, STI, welfare, environment, etc. While the Ministry of Health is perhaps the most appropriate guardian of the healthcare policy, it is a legitimate question to ask if the same Ministry should be responsible for the national health policy. As the health vision in 2050 is overarching and goes beyond the confines of health alone, the Study recommends a review of the role of the MOH in developing and implementing the national health policy. As in the case of South Korea and Sweden, the Ministry of Health is the lead agency for setting legislation and guidelines, and is not responsible for health delivery. This review should also explore other models for healthcare delivery including public-private integration.

2. Implement existing STI policies

As highlighted in Chapter 2 (see page 26), there are numerous policies that support STI as well as STI related to health. What is most important is to implement them efficiently and effectively. Any barriers and inconsistencies of policies must be addressed to ensure smooth implementation.

3. Establish a 'Buy Malaysia' policy

A 'buy Malaysia' policy is needed to give priority to locally made products, thus increasing the local demand which will facilitate marketing same products globally. A growth in the local market will also act as incentives to local companies and manufacturers to invest in R&D and commercialisation of products. In this connection, regulatory supervision for efficacy, safety and quality of products must be put in place and enforced.

Pre-requisites

In addition to the recommendations, several non-negotiable pre-requisites must exist in order for Malaysia to achieve the desired health outcomes. These include:

- A comprehensive national health policy.

[24] Health professionals, academics, ministries, research institutes, private sector, medical association, pharmaceuticals, civil society, etc.

- A strong health financing strategy.
- Significantly improved and efficient health care delivery, including research on the health care delivery system.
- Enhanced research in the area of wellness as the vision for healthy Malaysians in 2050 embrace a comprehensive definition of health and wellbeing.

ROADMAP

The Study proposes the following roadmap which is based on the specific and general recommendations (page 98 to 113). In this Roadmap, the recommendations are presented as challenges while the recommendations are short term (five years) and long term strategies to meet the challenges.

The following table presents a roadmap for the cross-cutting recommendations in R&D, human capital development and policy.

Research and Development		
Challenges	**Action Plans**	
	Short term	**Long term**
Increase the level of investment from 0.6% to a minimum of 3% of the GDP Increase the allocation of funds for health R&D from 2.14 percent to 20 percent of total R&D by 2050.	Increase public allocation for R&D. Increase private allocation for R&D through more attractive incentives including improved tax incentives for private sector and foreign investments.	Establish collaboration with international research institutes, international organizations such as the United Nations, as well as international funders such as the Bill and Melinda Gates Foundation.
Develop a master R&D plan	Focus R&D efforts on diseases with the highest disease burden (e.g. diabetes, cancer, cardiovascular diseases, dengue and health problems related to ageing). Promote collaboration between scientists, researchers, clinicians and engineers from universities, public research institutions, and industries. Enhance clinical research and trials portfolio. Strict regulations	Promote collaborative research with multinational science base agencies and industries. Develop an epidemiological database which will facilitate the study of diseases and risk assessments. Implement a long-term plan for human resource and infrastructure

	must be in place and enforced to protect the rights and safety of those participating as research subjects.	
Establish R&D structure and improve coordination	Strengthen R&D facilities recommended for the five priority STI areas (see specific STI recommendations pages X) Control the procurement and setting up of expensive facilities and equipment, and strategically locate them at the most appropriate institutions. Related, encourage collaboration between local and foreign researchers in research that uses expensive equipments or facilities. Provide incentives to private sector to encourage their involvement in routine experiments such as toxicity and efficacy test of a compound and characterisation of the properties of a material (e.g. material testing) Outsource animal studies for certain tests/procedures to private entities. Structure and cluster research to coordinate and optimize resources.	
Improve legal and regulatory framework	Develop new, and enforce existing regulations to ensure ethical and safe R&D practices. This should be linked with the master R&D plan. Establish an Act to promote R&D as a national priority. This Act should facilitate investment in R&D by both the government and private sectors.	
Strengthen commercialization of research outputs	Enhance existing reward system: Offer incentives to promote partnerships between researchers and investors, and between private and public sectors. Offer greater monetary and recognition to researchers for their discoveries.	Develop marketing strategies for penetrating regional and global markets.

	Engender awareness among researchers and companies about domestic and global markets and opportunities. Give priority to research proposals that identify commercial value of research outputs.	

Human Capital Development		
Challenges	**Action Plans**	
	Short term →	**Long term**
Enhancement of the number of researchers from 9.1 per 10,000 total employment to 150 researchers per 10,000 total employment. Specifically, there should be 30 researchers working on health issues per 10,000 total employment.	Offer intensive training, both locally and abroad for qualified professionals to enhance their knowledge and skills in STI, especially in the five priority areas. Establish post-doctoral programmes that support STI, especially in the priority STI areas. Develop research management skills for senior professionals involved in managing and coordinating research activities. Provide greater incentives and attractive benefits packages for national professionals who are already engaged in STI areas. Enhance incentives to lure skilled Malaysians who are working abroad. Offer attractive career pathways and recognition to promote engagement in STI in health. Recruit foreign expertise to work in Malaysia in STI areas where there is a shortage of local experts.	Promote creativity and innovation in children's basic education all the way to tertiary education. Promote science and mathematics at all level of education to improve the country's competitiveness and innovativeness. Develop basic and tertiary programmes in STI, especially the priority health related STI areas in selected Universities.

Policy		
	Action Plans	
Challenges	**Short term** →	**Long term**
Strengthen leadership and coordination	Establish a decision-making and coordinating STI structure at the highest government level (i.e. *National ST Council of South Korea)*	
Ensure strong policies to support STI development	Finalize the draft Health Policy – ensure STI is integrated in the health policy and wide consultation with various stakeholders. Enforce implementation of existing STI policies and regulations. Develop policies and regulations in STI areas where there is none, including a policy for utilisation of local STI product.	Review and revise policies to reflect new developments and global changes.

The following is the roadmap the five priority STI areas (natural products, health tourism, pharmaceuticals, medical devices and TCM).

Natural products		
Challenges	**Action Plans**	
	Short term →	**Long term**
Develop capacity to explore, identify and classify natural endowment (e.g. plant species, marine biology) and determine relationships between them.	Recruit foreign taxonomist to work with local researchers to intensify effort to identify and classify plants and to conduct basic research to identify bioactive ingredients of plants with medicinal value.	Train more taxonomists locally or abroad.
Convert existing scientific knowledge of country's medicinal plants into real products that can be commercialized. Focus should be on specific diseases including cancer, HIV, malaria and other tropical diseases.	Support key research institutions such as FRIM with adequate funds, researchers and equipments for ongoing R&D activities. Develop database on scientific knowledge of medicinal plants that are already known, in view to facilitate the conversion of fundamental research into clinical trials. Focus on producing high quality herbal products through necessary testing for quality, safety, and efficacy. Outsource animal studies for certain tests/procedures to private entities to facilitate efficiency.	Pool experience researchers from various institutions to work under the National Institute of Natural Products, Vaccines and Biologicals (as the Centre of Excellence). Develop the capacity to produce drugs out of natural resources with medicinal value.

Health tourism		
Challenges	**Action Plans**	
	Short term →	**Long term**
Ensure successful promotion of Malaysian health tourism	Appoint the Ministry of Tourism to lead initiatives to develop strategic plan for promotion of health tourism, in close collaboration with the Ministry of Health and other relevant partners such as the Association of Private Hospitals and the Immigration Department. This includes research in marketing to effectively identify strategies to market the country's health tourism industry. Simplify visa issuance process to facilitate entry into the country for health tourists and their accompanying family members. Strengthen data management system such as electronic health record to facilitate information sharing and case management between Malaysia and other countries.	Continuous collaborative efforts to implement agreed upon strategies and plans. Appoint and train agencies in target countries to promote health tourism.
Enhance competitiveness of the hospitals which offer health tourism at regional and international levels.	Enhance quality of services through: • Enforcement of domestic accreditation for the participating hospitals. The MOH to take the lead in monitoring the accreditation processes. • Introduction of a system that ranks hospitals based on quality of services at domestic and regional level.	Achieve world class hospital standards and ranking through: • International accreditation of the participating hospitals. • Participating in global ranking.
	Improve capacity of human resources through recruitment of highly qualified health professionals from other countries, to serve in medical areas mostly sought by health tourists, such as cardiology and orthopaedic surgery	Offer advance training opportunities to existing health professionals both locally and abroad.
Protect the right of Malaysian to quality and equitable health care.	Limit health tourism to private hospitals only. Offer better career pathway and remuneration to highly skilled health professionals working in public hospitals to avoid brain drain into private hospitals. Close monitoring of the progress of health tourism to minimize effect on local populations and maximize profits.	Develop a clear policy on health tourism. MOH to continually improve the quality of services in public hospitals to ensure equitable health care for Malaysian.

Pharmaceuticals		
	Action Plans	
Challenges	**Short term** ⇒	**Long term**
Enhance competitiveness of local manufacturers of generics to be a leading producer at regional level.	Offer incentives (e.g. tax breaks) for manufacturer s to upgrade existing GLP laboratories and infrastructure for clinical trials. Support local manufacturers to collaborate with (1) international research centres or multinational companies to conduct clinical trials, (2) multinational companies in the form of contract manufacturing organization (CMO) to build capacity and expertise especially in biopharmaceuticals production. Identify the appropriate government agency to lead negotiations for generic production of expiring patent drugs to strengthen the position of local pharmaceutical companies. Target markets in the region where there is demand for cheap generics, but where countries have minimal capacity for production (e.g. Vietnam, Africa, Middle East)	Strengthen R&D capacity to become a regional hub/centre for production of generics.
Increase the development of *Halal* pharmaceuticals as a revenue generating industry.	Establish a research agenda for *halal* pharmaceuticals. Support SMEs that venture into *halal* pharmaceuticals with tax incentives.	Establish *halal* pharmaceuticals development as a niche area in relevant research institutes and manufacturers.

Medical Devices		
	Action Plans	
Challenges	**Short term** →	**Long term**
Develop medical devices that address high burden diseases and health problems, and have high potential for commercialization in tropical countries.	Establish R&D agenda with a focus on medical devices with high demand (e.g. devices for orthopaedic conditions). Upgrade existing laboratories to become WHO-certified and biohazard level 3 and 4 (BSL 3 and BSL-4 laboratories.	Establish a world class Centre of Excellence for medical devices.
Develop critical mass of human capital capable of innovation and invention in medical devices.	Recruit biomedical engineers from countries with more advanced medical device industries. Offer advance training in developed countries to select biomedical engineers.	Produce highly skilled local scientists in biomedical engineering through basic and postgraduate training courses. Related, establish more biomedical engineering courses in local universities.
Ensure successful commercialisation of locally produced medical devices.	Encourage local health institutions to procure and use devices produced by local manufacturers. Appoint the Medical Device Bureau of MOH to be more proactive in endorsement and promotion of local products. Prepare a policy to guide the development and commercialization of locally produced medical devices. Medical device can be specifically mentioned under the proposed 'Buy Malaysia Product Policy'.	

Traditional and Complementary Medicine		
	Action Plans	
Challenges	**Short term** →	**Long term**
Establish evidence for the effectiveness and safety of existing TCM practices and products.	Conduct research to generate evidence for the effectiveness, safety and quality of TCM products and practices. Research should start with low risk studies such as studies on herbal medicine which has high demand but potentially high toxicity. Empower relevant research institutions to conduct R&D activities in this area.	Establish a multi-sectoral working group to develop and coordinate implementation of research agenda for TCM.
Regulate and monitor TCM practices to ensure safety of consumers.	Appoint the TCM division of MOH to be more proactive in regulating and monitoring TCM practices. Upgrade existing legislations and guidelines concerning TCM to cover TCM practices (Current guidelines cover TCM products only).	Appoint the MOH to enforce registration of TCM practitioners with its TCM division.
Ensure adequate number of highly trained TCM professionals in an effort to promote TCM.	Support the existing institutions that offer TCM training to develop skilled and professional TCM practitioners to meet the established quality standards.	Determine an attractive package to encourage scientists, researchers and health professionals to establish career pathways in TCM.

The following is the roadmap for the STI areas identified as having lower priority.

Medical Diagnostics		
	Action Plans	
Challenges	**Short term** → **Long term**	
Develop medical diagnostics that address high burden diseases and health problems, and have high potential for commercialization in tropical countries.	Establish R&D agenda with a focus on medical diagnostics with high demand and have shorter production time (e.g. tools for cancer detections/genetic testing/HPV detections). Upgrade existing laboratories to become WHO-certified and biohazard level 3 and 4 (BSL 3 and BSL-4 laboratories.	Establish a world class Centre of Excellence for medical diagnostics.
Develop critical mass of human capital capable of innovation and invention in medical diagnostics.	Recruit biomedical scientists from countries with more advanced medical device industries. Offer advance training in developed countries to select biochemist and biomedical engineers.	Produce highly skilled local scientists in biomedical engineering through basic and postgraduate training courses. Related, establish more biomedical engineering courses in local universities.
Ensure successful commercialisation of locally produced diagnostic tools.	Encourage local health institutions to procure and use diagnostic tools produced by local manufacturers. Appoint the Medical Device Bureau of MOH to be more proactive in endorsement and promotion of local products. Prepare a policy to guide the development and commercialization of locally produced medical diagnostics.	

Vaccines		
	Action Plans	
Challenges	**Short term** →	**Long term**
Determine capacity in vaccine development.	Conduct an evaluation of previous and existing R&D and commercialization activities in vaccines development, including the extent of R&D outcomes, the capacity of human resources, as well as the enablers and obstacles.	
Develop vaccines for diseases with high burden (e.g. cancer and diabetes), and focus R&D efforts on improving the cost-effectiveness of existing vaccines.	Integrate vaccine R&D and commercialization into national STI policy and health policy to ensure allocation of adequate funding for vaccine R&D. Improve incentives (e.g. tax incentive) to encourage private sector investment in vaccines development. Enhance human resource capacity to strengthen competencies related to vaccine development and commercialization.	Establish a centre of excellence for vaccine research and development.

ICT in Health		
	Action Plans	
Challenges	**Short term** → **Long term**	
Expand the use of ICT to support the healthcare system.	Expand implementation of ICT for: • managing medical records and other health related data (e.g. resource utilization data, case-mix system in public hospitals) • improving administration and management at the clinical and managerial levels. • implementing pharmaceutical activities (e.g. e-prescription, pharmacy reimbursement, and management of drug related costs). • integrating public and private healthcare system.	Expand use of IT to facilitate wider and easier access to health care (e.g. e-health). Expand use of IT in all hospitals and clinics to improve sharing of information between healthcare providers.
Establish strong and stable signal coverage that reaches rural and remote areas.	Ensure nationwide network infrastructure.	Maintain quality of signal coverage.
Ensure adequate number of highly trained professionals in health ICT	Offer intensive training on IT in health to selected healthcare professionals.	Develop strong programmes in health ICT in local universities
Develop R&D in ICT which has potential for commercialization.	Allocate R&D funds for areas such as (1) Open Source in healthcare (2) Development of decision support system (3) Mobile medicine (4) Health Information System (HIS) and (5) Disease classification system; which are important areas that increases the efficiency of the healthcare system.	
Enhance policy to support local health-related ICT initiatives	Introduce policy that encourages the use of locally developed ICT softwares (e.g. case mix system).	

Stem Cells		
	Action Plans	
Challenges	**Short term** → **Long term**	
Stimulate competitiveness in stem cells R&D	Enhance the current low level of investments in R&D in stem cells. and investing: (1) fundamental research to understand how stem cells behave and differentiate, and the networks and molecules that control this differentiation; (2) short-term and long-term safety and toxicity of stem cells; and (3) clinical trials to monitor, track and prove the contribution and effectiveness of stem cells**;** (4) Quality control of stem cells manufacture, delivery to the target areas, and architectural aids to ensure optimum placement and exposure of the stem cells; and (5) Bioengineering of materials necessary to deliver and support stem cells on their therapeutic journey.	Evaluate competitiveness in stem cells R&D and define its future agenda.
Develop human resource capacity in stem cell research and therapies	Train experts in bioinformatics and bioethics. Redefine the roles of the primary care physician to allow them to educate patients about stem cells therapies, and train them in transplantation work when stem cell-based therapies are ready for application.	
Ensure availability of strong supporting policies.	Prepare a regulatory framework surrounding stem cell research and therapies, which address issues of intellectual property, licensing and commercialisation. Amend the existing National Drug Act to allow clinical trials of stem cells therapy to be conducted within the country.	

Genomics		
	Action Plans	
Challenges	**Short term** →	**Long term**
Develop capacity in Genomic R&D	Enhance the role of the Malaysia Genome Institute to undertake more research in human genomics. Establish specific infrastructure to conduct R&D in human genomics must be established. Develop human resource capacity, specifically a critical mass of expertise in clinical/medical genetics and genetic counselling. Redefine the role of primary care physician, genetic counsellor, and medical geneticist engage in genomics-related activities.	
Ensure competitiveness and uniqueness in Genomics R&D	Allocate R&D fund (1) laboratory analysis of mutations/polymorphisms prevalent in local population; in the context of genotypes and phenotypes of the different ethnic groups in Malaysia; (2) molecular epidemiology of genetic variants in Malaysian populations, environmental interactions and disease outcomes, particularly for non-communicable diseases such as cardiovascular diseases, cancer and diabetes; (3) Clinical trials to establish efficacy of specific drug therapies as well as reduction of adverse drug reaction utilising novel pharmacogenomics approach; (4) Health economic and policy analysis of preventive genetic testing and community genetic services; and (5) Development of personalised, preventive medicine using information from database of personal genomes.	Evaluate competitiveness in genomics R&D and define its future agenda.
Ensure availability of strong supporting policies.	Prepare a National Guidelines and a regulatory framework surrounding genomics research, encompassing issues of intellectual property, licensing and commercialisation.	

Nanotechnology		
	Action Plans	
Challenges	**Short term** → **Long term**	
Develop R&D capacity in Nanotechnology.	Form a National Nanotechnology Centre (NNC) with well-defined roles. Establish a multi-sectoral Working Committee to coordinate R&D and commercialisation activities. The committee should look into pre-requisites such as National Nanotechnology Policy; nanotechnology Intellectual Properties and legal matters; R&D agenda including identifying national nanotechnology niche areas, and resource mobilization and management; monitoring the potential environmental and societal impact of nanotechnology.	
Establish competitive edge in nanotechnology R&D	Update the national nanotechnology database and the national nanotechnology commercialization and investment activities. Allocate sufficient resources for 1)Development of cancer biomarkers, 2)Bio-pharmaceutical proteins for therapeutic drugs and vaccines, 3)Bone graft substitutes, 4) Diagnostic kits for infectious diseases, 5) Diabetic vasculopathy, 6)Antioxidants in preventing degenerative damage in Down's Syndrome and Ageing, and 6)Vaccines against infectious diseases	
Develop the capacity of human resources	Offer advance training to existing researchers to develop their knowledge and skills in nanotechnology research.	Create and strategize nanotechnology education programme, with emphasis on nanomedicine, in local universities.

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ANNEXES

ANNEX 1

List of Experts

Experts For Health Sector And Health Outcomes

Dr Molly Cheah President Primary Care Doctors' Organization of Malaysia.	Dr Zainal Ariffin Timbalan Pengarah Bahagian Kawalan Penyakit Cawangan Penyakit Tidak Berjangkit Kementerian Kesihatan Malaysia
Dr Zainuddin Wahab Timbalan Pengarah (Kesihatan Awam) Jabatan Kesihatan Negeri Selangor	Prof Dr Abu Bakar Abdul Majid Persatuan Perubatan Islam Malaysia CyberJaya University College of Medicine Science
Assoc Prof Dr Mohamed Rusli Head of Department of Community Medicine School of Medical Sciences Health Campus University of Science Malaysia	Dr. Othman Warijo Vice President of Persatuan Pakar Perubatan Kesihatan Awam Malaysia (PPPKAM) Pegawai Kesihatan Putrajaya Pejabat Kesihatan Putrajaya
Assoc Prof Dr Mohd Yusoff Adon Head of Department of Community Health Faculty of Medicine and Health Sciences Universiti Putra Malaysia	Assoc Prof Dr Retneswari Masilamari Head of Department of Social and Preventive Medicine Faculty of Medicine University of Malaya
List Of Expertise Who Were Invited But Unable To Participate	
Dr Safurah Jaafar Bahagian Pembangunan Kesihatan Keluarga Kementerian Kesihatan Malaysia	Dr Rohaizat Yon Timbalan Pengarah Bahagian Perkembangan Perubatan Kementerian Kesihatan Malaysia
Dr Hj. Abdul Rahim B Hj Mohamad Pengarah Bahagian Perancang & Pembangunan Kementerian Kesihatan Malaysia	Dato' Dr NKS Tharmaseelan Malaysian Medical Association
Dato Dr Jacob Thomas President of Association of Private Hospital Malaysia	Dr Azman Abu Bakar Pengarah Institute for Health System Research
Dr. Inderjit Singh Ludher President of Academy Of Family Physicians Of Malaysia	

Experts For STI Strategies and Research, Development and Commercialization

Dr David Perera Deputy Director of Institute of Health and Community Medicine Universiti Malaysia Sarawak (Representative for Prof Dr Mary Jane Cardosa)	Prof Dr A Rahman A Jamal Director UKM Medical Molecular Biology Institute (UMBI)
Assoc Prof Habibah A Wahab Director of Hits-to-Lead Division Malaysian Institute of Pharmaceuticals and Nutraceuticals (IPHARM) Ministry of Science, Technology & Innovation	Prof Dr Ibrahim Jantan Dean of Faculty of Pharmacy Universiti Kebangsaan Malaysia
Associate Professor Dr Amin Ismail Head of Laboratory of Analysis and Authentication Halal Products Research Institute Universiti Putra Malaysia (Representative for Prof. Yaakob Che Man)	Tan Sri Dato' Dr Salleh Mohamed Yasin Director of UNU-IIGH UNU - International Institute for Global Health
Datin Paduka Siti Sa'diah Sheikh Bakir Managing Director KPJ Healthcare Bhd	Encik Jaafar Lassa Director of Traditional and Complementary Medicine Division, Ministry of Health Malaysia
Dr Mohd Hishamuddin Harun (TeleHealth) AIH GROUP (Malaysia) Sdn Bhd Kuala Lumpur	Prof Dr Uda Hashim Director of Institute of Nano Electronic Engineering (INEE) Universiti Malaysia Perlis (UniMAP),
Assoc. Prof. Dr. Ahmad Fuad Shamsuddin Faculty of Pharmacy Universiti Kebangsaan Malaysia	Prof Dr Mary Jane Cardosa Director of Institute of Health and Community Medicine, Universiti Malaysia Sarawak
Prof Dr Asma Ismail Deputy Vice Chancellor (Research and Innovation) Division of Research & Innovation Universiti Sains Malaysia	Dato' Iskandar Mizan Healthcare Industry Development Division Malaysian Biotechnology Corporation Sdn Bhd
Mrs Maryam Abdul Latif Halal Industry Development Corporation (HIDC)	Mr Leonard Ariff Abd Shattar Manager (HalalPharmaceuticals) Chemical Company Malaysia Berhad
Dr Zubaidah Zakaria Head of Hematology Unit Institute of Medical Research	Dr. Zamri Ishak Deputy Director Biotechnology Research Centre, MARDI
Dato' Dr Gan Ee Kiang (Commercialisation) Group Managing Director USAINS Group of Companies Universiti Sains Malaysia	Mrs Sudha Sivadas Assistant Director General (Representative: Dato' Noriyah Ahmad, Director General)

Datin Paduka Prof Dr Khatijah Mohd Yusoff Deputy Secretary General (Science Service) Ministry of Science, Technology & Innovation	Mrs Eziatul Nurin Ahmad Sapawi Assistant Secretary General Service Sector, Development Division, Malaysia International Trade & Industry (Representative: Dato' Kamarudin Ismail, Deputy Secretary General)
Dr Hyzan Mohd Yusof Chief Executive Officer OSA Technology Sdn Bhd Smart Technology Centre, UKM	Assoc. Prof. Dr. Zarida Hambali Assistant Secretary General (Representative: Dato' Dr. Ramli bin Hasan, Deputy Secretary General)
Tan Sri Dato' Azman bin Hj Mokhtar Managing Director Khazanah Nasional Berhad	Ms Doreen Leong Mun Yan Corporate Communication Manager Top Glove Corporation Berhad
Professor Dr Rusli Ismail Director Institute for Research in Molecular Medicine, Universiti Sains Malaysia	Encik Norhalim Yunus Chief Executive Officer Malaysian Technology Development Corporation Sdn Bhd (MTDC)
Dr. Prashanth Bagali, PhD (Genetics) Chief Operating Officer / Senior Vice President Science & Technology Geneflux Biosciences Sdn. Bhd	
List Of Expertise Who Were Invited But Unable To Participate	
Prof Dr Nor Muhammad Mahadi Director General Malaysia Genome Institute Ministry of Science, Technology & Innovation Heliks Emas Block UKM-MTDC Technology Centre	Dr Norwati Muhammad Director Forest Biotechnology Division Forest Research Institute Malaysia (FRIM)
Dato' Dr Jacob Thomas President of APHM (Association of Private Hospital of Malaysia)	Dato' Ooi Say Chuan Chief Executive Officer Malaysia Healthcare Travel Council Ministry of Health.
Dr Ramli Abd Ghani Director of Traditional and Complementary Medicine Division, Ministry of Health Malaysia	Dr Shahnaz Murad Director of Institute of Medical Research MOH
Dato' Dr Mohd Hashim Tajudin Managing Director of Chemical Company Malaysia Berhad (CCM)	Mr Selvaraja S. Seerangam National Pharmaceutical Control Bureau (NPCB)

ANNEX 2

STI and Health in South Korea

Background

The Republic of South Korea has achieved remarkable economic growth over the last four decades, which transformed the nation from one of the poorest agriculture based societies into a strong and competitive knowledge-based economy. It has an annual population growth rate of 0.33 percent (WHO, 2009). Life expectancy at birth for adults is 79.2 in 2007, and is ranked 26th in the Human Development Index out of 182 countries, with a value of 0.937 (UNDP, 2009).

South Korea joined the Organization for Economic Cooperation and Development (OECD) in 1996. Its GDP in 2009 was US$ 1 201.7 billion, with GDP per capita of US$ 24,801 (OECD, 2009). It is ranked fifth in Science and Technology Achievement Index (TAI) among 72 countries with the TAI value of 0.666, after Finland, the US, Sweden and Japan (Desai et al. 2002). It is ranked first in Technology Achievement Index-09[25] (TAI-9) among 91 countries with the TAI value of 0.765 (Nasir et al. 2010).

The proportion of high and medium high technology products among South Korea's exports increased from 46.2 percent in 1992 to 74.4 percent in 2004. This shows that the Korean industry has become more knowledge-intensive and shifted to high technology sectors, while economic activities such as agriculture, forestry and fishing, mining and construction have declined in importance (OECD, 2009).

In 2007, the total health spending accounted for 6.8 percent of the GDP and the total expenditure of health per capita was US$1688 (OECD, 2009). The per capita government expenditure on health (PPP int, $) was $817 in 2007 (WHO, 2009). South Korea has universal government-mandated national health insurance (NHI) coverage since 1989 (Lee, 2003). During the period 1976 to 1989, the country experienced the most rapid growth in per capita income of any country in the world, growing from US$87 in 1962 to US$4,830 in 1989 (Savada and Shaw, 1990). Twin factors of universal health coverage and economic growth contributed to significant improvements in the health status of the population as measured by life expectancy at birth—80 years (World Health Statistic, 2010).

The National Innovation System (NIS) plays an important role in the development and growth of South Korea's national economy. The theory of an innovation system which focuses on the relationships and processes between various innovation actors was an attraction to policy makers since the 1990s; a time when globalization of science and technology emerged as a big agenda in the science and technology policies (Yim, 2006). The NIS is based on the concept that progress in innovation and technology is determined by a complex set of relationships among

[25] composite index which aggregates national technological capabilities and performance in terms creation/diffusion and development of human skills

actors producing, distributing and applying various kinds of knowledge. These actors are primarily private enterprises, universities, public research institutes, government and the people within them. The linkages among them take the form of various kinds of collaboration, joint research, personnel exchange, cross patenting and a variety of other channels (Suh, 2000).

Science, technology and innovation play a very significant role in the health care system and health care delivery and efficiency. Innovative medical interventions and products including pharmaceuticals, drug delivery, gene therapy, and medical technology, implants, imaging, use of ICT and new diagnostic equipment have contributed significantly to addressing health problems, and promoting wellbeing. The following sub-sections describe the status of STI in health in Korea.

STI areas

Biotechnology

South Korea is a strong competitor in the global biotechnology industry. It produces numerous biotechnology products such as vaccines for Hepatitis B, typhoid and bacterial meningitis, therapeutics for diabetes, various cancers and damaged cartilage, diagnostics for Hepatitis C, osteoporosis, as well as in DNA microarrays and sequencing and genomics. Table 1 shows some examples of biotechnology products in health sector. The country is also active in the pharmaceutical industry and has developed and market drugs for diabetes, arthritis, gastritis, and hepatitis among others. Winning the bid in 2000 to host the International Vaccine Institute[26] confirmed the country's solid global reputation in the biotechnology field.

Table 1: Examples of South Korean health biotechnology products

Sector	**Type**	**Product**	**Application**	**Producer**
Vaccines	Recombinant hepatitis B surface antigen	Euvax-B	Hepatitis B	LG Life Sciences
	Purified capsular polysaccharide Vi of Salmonella typhi	Typhoid-Kovax	Typhoid	Korean Vaccine (Seoul)
	Haemophilus influenzae type B small polysaccharide	Hib TITER	Bacterial meningitis	Dong Shin Pharmaceutical
	conjugated to CRM197 mutant Corynebacterium diptheriae			(Seoul)

[26] The International Vaccine Institute develops vaccines for diseases including influenza, pneumonia, meningitis, cholera and dengue fever.

	toxin protein			
Therapeutics	Recombinant human interferon α-2b	Alphaferon	Various cancers (e.g., renal cell carcinoma)	Cheil Jedang (Seoul)
	Recombinant human epidermal growth factor	Easyef	Antiulcerant for diabetics	Daewoong Pharmaceutical
	Autologous chondrocyte transplantation	Chondron	Cartilage damage	Cellontech (Seoul)
	Plant cell culture–derived paclitaxel	Genexol	Cancer	Samyang Genex (Seoul)
Diagnostics	Enzyme-linked immunosorbent assay for hepatitis C , core/NS3 FP, E1/E2/NS4 FP NS4 antigens	LG HCD 3.0	Hepatitis C	LG Life Sciences
	Enzyme-linked immunosorbent assay for cross-linked N-telopeptides of bone type I collagen	OSTEOMARK NTx	Osteoporosis	Dong Shin Pharmaceutical
Other	DNA synthesis	N/A	Biomedical research	Bioneer
	384 human cDNAs from a Korean individual on a microarray	MAC Karyo 4000	Genotyping	Macrogen
	Cryopreservation of cord blood stem cells	N/A	Potential for developing cell therapies	Lifecord (Seoul)

Recognizing the huge global market for biotechnology goods, the country has been and continues to invest heavily in R&D in this area. Between 1994 and 2006, its R&D investment has evolved at an annual growth of 23 percent to a total of US$3.6 billion; evidence of the government's determination to operationalise its vision to become a global leader in biotechnology as envision in its Bio-Vision 2016 (Figure 1). This vision is a continuation of a long-term plan which started in 1994. Biotech 2000 spanned a 12 year period (1994 to 2006), where a core function was the establishment of R&D infrastructure and system. The successes and lessons learned from Biotech 2000 laid the foundation for Bio-Vision 2016. The latter focuses on five key areas, one of which is medicine and healthcare. And it has four strategies: (1) creation of the national biotechnology promotion system, (2) expansion of infrastructure to advance R&D(3) accelerate growth and globalization of bio-industry, and (4) establishing regulatory and institutional reform and

enhancement of public acceptance. The expected outcomes for Bio-Vision 2016 are summarized in the following graphic.

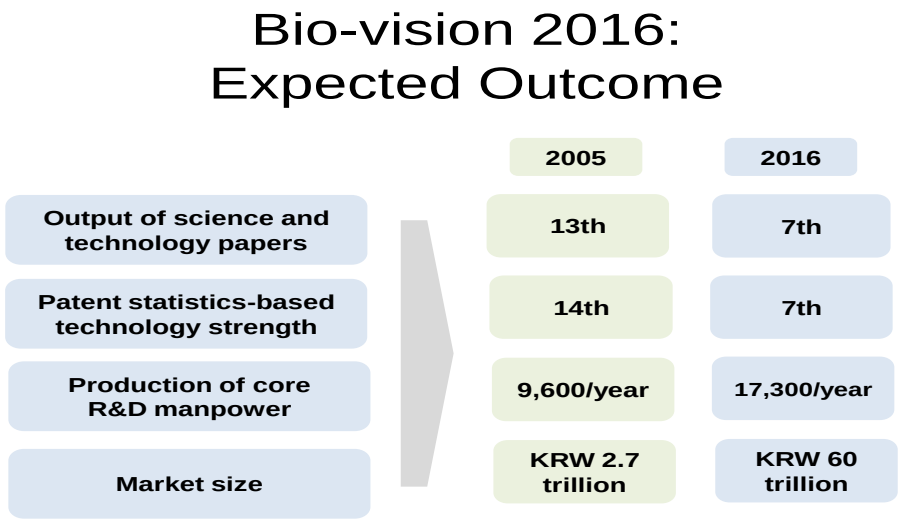

Figure 1: Bio-Vision 2016
Source: Yang 2010

In this connection, the implications for the health sector are:

- Support R&D on high national priority biotech areas, including platform technologies, creative technologies, and future-promising technologies.
- Commercialization of biotech through the linkage between biotech and industrialization technology.
- Develop manpower in basic medical science, pharmaceutical science, and new convergence technologies.
- Train human resources in response to actual needs of industrial and government research community.
- Develop cutting-edge medical research cluster.

Related, the government and Korean companies jointly launched a 10-year 'Bio-Star' project in 2005 to assist local biotechnology companies and research institutes with research and development (R&D) activities and clinical tests. The focus was on commercialization of biotechnologies. The budget for this project was a further US$253 million (investkorea.org 2005).

As a result of the above, numerous companies are focusing their efforts primarily on the development of new drugs, medical devices, bioinformatics and functional genomics research. According to government figures, over one third of biotechnology products developed are in the biomedical field and the product pipeline is growing. Over 40 South Korean pharmaceutical firms have 130 new drugs in either phase 1 or 2 clinical trials. At the same time, the number of health biotechnology–related publications by South Korean researchers increased tenfold

from 1992 to 2002 (Thorsteinsdóttir 2005). The Korean Intellectual Property Office (KIPO) granted over 800 genetics and biotechnology patents to domestic inventors in 2002 alone.Between 2002~2007, 377 Korean biotechnology patents registered, including 170 registered in the in 2006-2007 USA (www.mest.go.kr 2009, investkoreasmes.com 2009).

Information and communication technology (ICT) in health

The health sector has capitalized the widely accessible information and communication technology is South Korea to support and deliver healthcare. Since 2004, the government has been promoting a national e-health project which includes electronic health record (EHR), telemedicine, technology standardization and technology interoperability. E-health allows wide sharing of medical information and technology among hospitals. Through such innovative efforts, it is expected that a total reform of the existing health and medical system will be accomplished. A critical factor for the introduction of e-health in Korea is the support from various stakeholders such as the Korean Medical Association and citizen's groups, as well as complementary R&D budget.

The health services in South Korea is characterized by a large number of private hospitals and medical centres; each with its own database of patients' medical records. Thus, the use of ICT increases efficiency of sharing medical records to improve accessibility and quality of health services.

This paragraph provides some examples of e-health initiatives in Korea. The Seoul National University Hospital Telecare Centre demonstrated the model of a video-conferencing link with patients located at a company about 100 miles away. The system integrates video images with medical records of the patient, allowing the doctor to type entries, order investigations and prescribe drugs as he speaks to the patient. In addition, the use of a remote oral examination and stethoscope was demonstrated. At present, the number of patients using the system is very limited. On the other hand, U-Health is a network of portable diagnostic sensors and real-time monitoring of patient health information to support efficient health care provision in remote areas. This innovation facilitates access to early diagnosis and prevention of diseases among the elderly and population in remote areas, while at the same time reduces costs of medical care. The use of U-health is expected to reduce US$2.9 billion in health expenditure by 2014 (Ministry of Knowledge Economy, 2010). Some applications of U-health are in Table 2.

Table 2: U-health policy

	Target	Objective	Present services, Pilot projects
U-Medical	The chronically ill	Cure/prevention	Telemedicine, Tele-consultations
U-Silver	The Elderly (≥65) Who live alone	Recuperation	Safety management
U-Wellness	The general public	Healthcare	None(seeking relevant model)

Source: Ministry of Knowledge Economy (2010)

Medical Tourism

According to the Ministry of Health and Welfare, in 2009 a total of 60,201 foreign patients sought health treatment in South Korea. In the same year, the profits from medical tourists totalled US $50 million. People from the United States (32.6 percent) and Japan (30.3 percent) constituted more than half of the foreign patients, followed by Chinese (11 percent), Russians (4.1percent), Canadians (2.3 percent), Mongolians (2 percent) and patients from the Middle East (1.4 percent).

A market research survey showed that foreign patients who visited South Korea in 2009 sought health examinations, aesthetic treatment such as skincare and plastic surgery, oriental medicine, as well as spine, heart, and prostate treatments and surgery. The study also revealed that 50 percent of respondents cited 'the quality of medical service and technology' as the reason for choosing Korea. Quality of cancer, infertility and dental treatments, and plastic surgery services are considered to be equivalent to that in the United States of America.

Gangnam-gu Medical Tour Business:
A health tourism model

Standing in the spot light, Gangnam-gu is home to 70 percent of plastic surgery and dermatology clinics in Seoul. Here, clients may choose treatment of diseases to skin cosmetics from more than 2000 hospitals that are equipped with the advance technology and skills. Gangnam-gu is famous for its plastic surgery and dermatology clinics in Korea. The comprehensive premium service package provides various services from the time tourists arrive until their departure. Gangnam-gu's medical tourism coordinators and interpreters help facilitate communication between the clients and South Korean physicians. It's beautiful nature and easy accessibility, makes Gangnam-gu an attractive health tourism destination.

The first step towards developing Seoul's medical tourism took place in 2007 with the signing of a Memorandum of Understanding (MOU) between the Seoul Business Agency (SBA) and the Seoul National University Hospital Healthcare System (SNUHHS) Gangnam Center. Subsequently, SBA set up a Seoul Tourism Marketing Division (SMTD) to promote medical tourism by linking up with major medical institutions in Seoul. At the same time, professional coordinators were trained to promote health tourism. In recent years, the national and regional governments

actively promoted a plan that links medical industry with tourism, including a bill that permits direct marketing of medical services to foreign patients. The South Korean immigration issues visas to foreign patients and accompanying family members to facilitate access to medical treatments.

STI enablers

Research and development

Research and development (R&D) is a key element in South Korea's success. Recognizing its critical importance, the government enacted the Research and Development Promotion Act and introduced R&D tax credits as early as in 1970s. This Act prompted an increase in R&D funding from just 0.31 percent of GDP in early 1970s to 3.32 percent (equivalent to US$312,9 million) in R&D initiatives in 2007; the 5th country globally with the highest R&D investments (OECD, 2009). In general, more than 75 percent of R&D investments are derived from private and foreign sector contributions, with the remaining 25 percent from the government and the public sector (Yim, 2006). Nearly 6 percent of the total R&D funds were allocated for the health industry in 2007 (Table 3), of which about 43 percent was allocated for to the development of drugs, biologics, and medical devices and diagnostics (Yang 2010). A substantial amount of public R&D funds support basic science research projects. On the other hand, an important source of productive growth for South Korea manufacturers are related to the ability of companies to acquire new technology from abroad and to adapt it to the domestic context.

Table 3: Health R&D investment (100M KRW)

	2003	2004	2005	2006	2007
Total R&D	65 ,154	70,827	77,996	89,096	97,629
Health Industry R&D	3,131	3,633	4,189	5,324	5,774
Percentage (%)	4.8	5.1	5.4	6.0	5.9

Source: 2008 Health Industry Annual, KHIDI

Human resources

Korea's well-educated professionals are the country's major asset in driving the country's success. Throughout the 1970s and 1980s, the government sponsored many graduate students to study science and technology at prestigious institutions such as Harvard University and the Massachusetts Institute of Technology. As an example, the Pohang Institute of Science and Technology and the Research Institute of Industrial Science and Technology offered lucrative contracts to lure back more than 100 top South Korean scientists and researchers who had

emigrated abroad, and to educate future scientists. The Bio-Vision 2016 also invests in building capacities of researchers in medical science, pharmaceutical science, and new convergence technologies.

Table 4 shows that in 2007, there are 8.7 researchers per thousand employment; nearly double the rate in 1998. More than 60 percent of the researches are employed in companies, while 30 percent work at the universities and 10 percent are engaged in public research institutes, R&D expenditure per researcher is US$ 171,900 dollars (Yim, 2006). The table also shows a big jump in the number patents between 1998 and 2007, upstaging United States, Japan and Sweden.

Table 4: Number of researchers (FTE) per thousand employment and number of patents (1998-2007)

	Korea		**U.S.A.**		**Japan**		**Sweden**	
	1998	2007	1998	2007	1998	2007	1998	2007
Researchers (per thousand employment, full-time equivalent on R&D)	4.7	8.7	9.3	9.6	9.8	11.1	9.5	9.8
Patents**	462	2785*	14402	1594*	11336	1418*	849	847*

**latest Data available for 2006; ** Indicates the number of Triadic patent families*
Source: OECD Factbook 2009: Economic, Environmental and Social Statistics

Policy

The South Korean government clearly recognizes the importance of science and technology to transform the country into an advanced nation and shape its laws, policies and programmes accordingly. The Ministry of Science and Technology (MOST) was established in 1967 to direct the STI policy and programmatic framework and coordination; a role it continues to play until today. Subsequently, the government introduced the Science and Technology Act following which several government research institutes (GRIs) in the areas of machinery, shipbuilding, chemicals, marine science and electronics came into existence. The Research and Development Act enacted in 1972, enabled contractors including GRIs, universities, and private firms to hold title to inventions. The 70s was an era of imitation, with South Korea putting in place a science and technology system that would allow it to absorb and adapt foreign technologies in support of its burgeoning industrialization process (OECD, 2009).

The launch of the National R&D programme in 1982 prompted various ministries to engage in countless research activities in the areas of information and communications, environment, construction and transport, agriculture, and health (OECD, 2009). The tax credits for R&D investments (introduced in 1974) as well as

financial incentives encouraged participation of, and investments from, the private sector. This strategy resulted in a significant increase in R&D investments and the growth of industries. Thus, the 80s is known as an era of transformation, with the government aggressively targeting core technologies that would drive the country's economic growth (OECD, 2009). In 1990s and onwards, the government promoted university-based Science Research Centres and injected more resources into fundamental research so that South Korea could expand its knowledge frontiers. It adopted an innovation policy framework that emphasized a diffusion-oriented approach to programming.

A key driver for the STI was the formation of the National Science and Technology Council in 1999 under the Special Law for Scientific and Technological Innovation (See Figure 2). The goal is to ensure coordination at the highest level. The Council is chaired by the President of South Korea and co-chaired by the Minister of Education, Science and Technology. The members consist of 13 multidisciplinary science experts from the public and private sectors, as well as 10 ministers. The council gives academicians and researchers a leading role in setting R&D policy directions and priorities, R&D allocation and evaluation of national R&D programmes. The bureaucrats in most cases play supporting roles during deliberations by the Council.

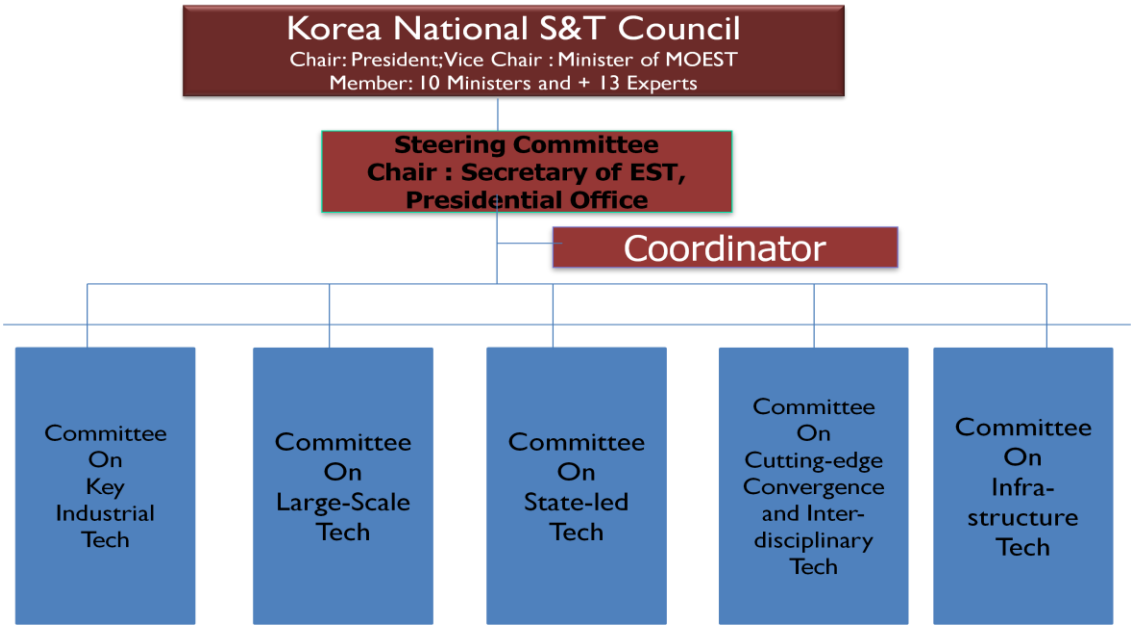

Figure 2: National Science and Technology Council

The government, in 1999, launched a long-term Vision for Science and Technology Development toward 2025 or Vision 2025 (see box). This Vision envisages an advanced and prosperous economy through the development of science and technology by (1) creating, utilizing, and disseminating knowledge, (2) heightening

scientific literacy, and (3) establishing a national management system through the advancement of science and technology.

Within a year of launching Vision 2025, the National Technology Roadmap (NTR) was developed to align the national R&D programmes more closely with market demands. The main objectives of the NTR are to (1) identify promising products and core technologies that are essential to secure global competitiveness in the succeeding 10 years henceforward, (2) draw up a technology roadmap at national level for promoting strategic research and development projects, (3) provide guidelines for sharing strategies related to key technologies among the government and private sectors, and (4) conducting research and development activities through identifying key technologies at national level.

Efforts to promote technology transfer from the public to private sector began in the 1970s. Since then a number of laws were enacted to promote and regulate commercialization of technology including the Technology Transfer Promotion Act. The Act stipulates that all public research institutes (PRIs) should have a technology licensing office (TLO) with at least one dedicated professional staff member who is responsible for technology transfer. Following enactment of the Act, the Korea Technology Transfer Centre (KTTC) was established in 2000 to act as a technical and coordinating hub for nation-wide technology transfer, and to work closely with the PRIs in forming and managing national and regional networks for technology transfer. Lessons from implementation of the Act show that (1) the government's commitment to technology transfer with sufficient financial support is much needed, (2) the government should empower PRIs to negotiate licenses free of restrictions on technology payment, (3) measures of technology transfer effectiveness should be established, and (4) TLO consortia should be enlarged by including more universities and non-commercial civilian research institutes as well as GRIs to make a nationwide network based on regional networks.

The government revised the Patent Law in 2001, bringing South Korea's patent regime in line with international standards and strengthened both enforcement and noncompliance measures. In 1998, the government reorganized the South Korean Food and Drug Administration (KFDA) to become a centralized administrative agency legally overseen by the government, although in practice it functions as an autonomous regulatory institution.

Infrastructure

An early initiative in science and technology was the foundation of the Korean Institute for Science and Technology (KIST) in 1966. A year later, the Ministry of Science and Technology (MOST) was established to direct the STI policy and programmatic framework and coordination; a role it continues to play until today. In the same year, the government introduced the Science and Technology Act. The 1990s onward has been described as a period of innovation and has been marked by substantial increases in R&D spending by both the public and private sectors and by attempts to improve knowledge flows and technology transfer across the

system. Korean Advanced Institute for Science and Technology (KAIST) was formed in 1972 with the aim of developing human resources for R&D.

In the 1970s, in order to better coordinate research and development, two scientific communities were established--one in Seoul, the other near Taejon. The Seoul complex included the Korea Institute of Science and Technology, the Korea Development Institute (affiliated with the Economic Planning Board), the Korea Advanced Institute of Science, and the Korea Atomic Energy Research Institute. Plans for the Daeduk Science Town near Taejon were far more ambitious. Modelled after the Tsukuba Science City in Japan, by the late 1980s the Daeduk Science Town accommodated laboratories specializing in shipbuilding, nuclear fuel processing, metrology, chemistry, and energy research. The government founded the Korea Advanced Institute of Science to develop and offer graduate science programmes, and it also encouraged universities to develop their own undergraduate programmes in science.

Conclusion

In 1987 the Korea Development Institute issued a report “KOREA YEAR 2000” that profiled South Korean economic development in 2000. The report noted that the industrial structure would be highly developed and would resemble that of advanced countries in as much as high value-added industries, high-technology industries, and soft industries grew relatively rapidly. Today, the country has successfully achieved its vision of being a developed and highly industrialized nation.

ANNEX 3

STI and Health in Sweden

Background

Sweden is a rich, high income country. It created its wealth through innovation and export. The country's Gross Domestic Product (GDP) per capita is US$ 43,654 (World Bank, 2009); amidst the quest for development of industries with high productivity to maintain its economy and high income status.

Sweden enjoys a high ranking for best healthcare systems (The Local, 2007). Report of Euro Consumer Index (2009) ranked Sweden at 9th place. However, the country has a comprehensive health agenda that provides universal and equitable quality health care to its citizens. Highly decentralized, the system is mostly managed at county council level, while the role of the central government is to make available overall framework and guidelines. Sweden invests nine percent of its GDP in healthcare; primarily from taxes at the county and municipal level. Health insurance is universal and compulsory, with only three percent of the population is covered by private insurance schemes. As healthcare is almost free in Sweden, the out-of-pocket fees are kept at a low three percent of the national health expenditure. The Swedish Council on Technology Assessment in Health Care (SBU) promotes efficient utilisation of resources through assessing new and established technologies.

Historically, Sweden has exploited science to discover technology and innovations to advance its health sector. For many years Sweden has been a leading country of innovative medical technology solutions. The Swedish inventions of pacemaker, stereotactic radio surgery, the ultrasound, the incubator, the haemodialysis and many other innovations have increased the prospect for healthcare to save, prolong and improve the quality of life for Swedish population and millions others worldwide. These successes are the foundation for the Swedish government and companies to advance the development of new innovations and improvement of existing products and services.

STI areas

Biotechnology

The Swedish biotechnology industry is highly focused on healthcare (SwedenBio 2003). The health care system is the main user of products from the biomedical industry. Presently, Sweden ranks in the top five in this industry in Europe. It is well known for its pharmaceuticals and medical technologies because of outstanding research institutions such as Karolinska Institute, universities such as Lund and Uppsala, companies such as Pharmacia and AstraZeneca and its position as a host country for many clinical trials. The pharmaceutical sector was the first to start commercial activities in the biotechnology field (Swedish Institute

2007), dominating the biotechnology-related industry in Sweden in terms of revenues and number of employees, while drug discovery and development is the dominant sub-sector (ISA 2007). Thus, pharmaceuticals are one of the country's main exports, including some of the world's best sellers; the asthma medicines Bricanyl® and Pulmicort®, the growth hormone Genotropin®, and the gastric ulcer drug Losec®. The example of AstraZeneca gives an idea on how successful the pharmaceutical industry is; in 2007, the company's profit of US$30 billion was equivalent to 9 percent of the country's GDP (US$340 billion). Table 1 depicts the major biotechnological and biomedical industries in Sweden.

Table 1: Biomedical industry in Sweden

Sector	**Number of firms**	**Employees**
Pharmaceutical development	165	19600
Total biotechnology	216	22400
Medical technology	360	10700
Biotechnological tools	100	3500

Source: VINNOVA 2003, 2004

The Swedish Biotechnology Industry Organization (SwedenBIO), in 2003, identified the National Biotech Agenda for Growth to boost growth of research and development in biotechnology industry. Elements of the Agenda are as in Box 1.

Box 1: SwedenBIO National Biotech Agenda for Growth

SwedenBIO National Biotech Agenda for Growth

Strengthen the science and knowledge base:

1. Increase R&D funding
2. Stimulate investments through tax incentives
3. Work permits for foreign scientists
4. Extend tax break for foreign specialists
5. Re-focus university education by funding more post-docs
6. Co-fund a two year Post-Doc Program for the life science industry
7. Stimulate interest for biotech at elementary schools
8. Focus R&D funding to 3-4 geographic centres-of-excellences
9. Focus R&D funding to key scientific areas

Strengthen the capital supply:

10. Create a pre-seed fund for innovators
11. Business Angels to invest in early-stage, biotechnology ventures
12. Seed and bridge fund to co-invest with private investors
13. Outsourcing fund for companies to collaborate with universities
14. Encourage Pension Funds to invest in Biotechnology

Strengthen the governmental leadership:

15. Establish a National Biotechnology Committee at the Department of Industry Employment and Communications
16. Establish centre of excellence network Program
17. Secure the leading position in clinical trials
18. Educate the public in the benefits of Biotechnology.

Source: SwedenBIO

Sweden has good infrastructure for basic research, and places great emphasis on basic research for knowledge generation and application of the findings up the stage of commercializing the products. The Figure below summarizes the short term focus of the National Biotech Agenda for Growth (read Figure 1 by referring to Box 1 above):

1. Increase R&D funding
2. Stimulate investments through tax incentives
4. Extend tax break for foreign specialists
10. Create a pre-seed fund for innovators
12. Seed and bridge fund to co-invest with private investors
15. Establish a National Biotechnology Committee at the Department of Industry Employment and Communications

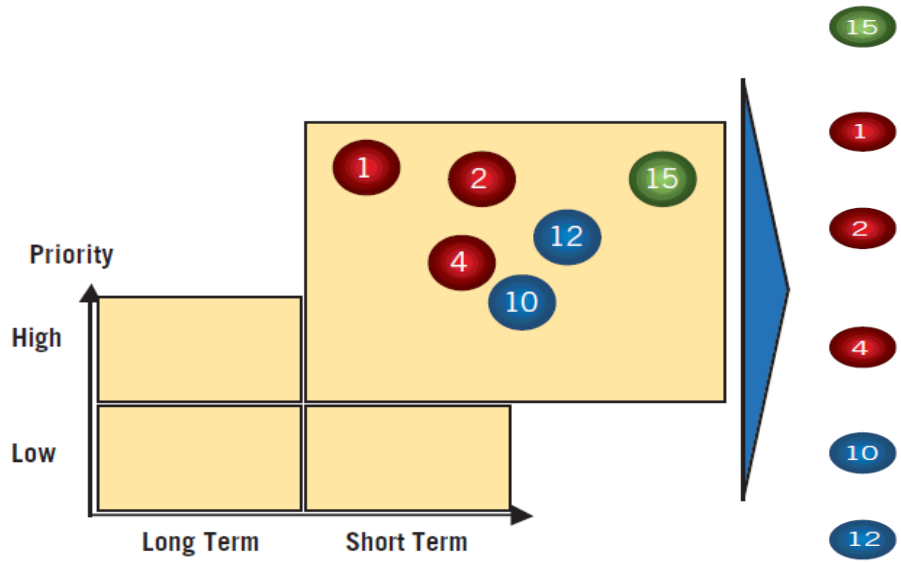

Figure 1: Summary of the short term, high priority actions
Source: SwedenBIO (2003)

Medical devices

Development and commercialization of medical devices in many disease areas are another niche area for Sweden. The success of Swedish medical device industry has been enabled by two primary factors: (1) high quality evidence-based healthcare and healthcare system, as many companies wish to leverage "approved in Sweden, used by Swedes" brand. The brand also represents a well-educated, socio-economically stable population, with high trust in their healthcare system, and a greater willingness to participate in clinical trials than in many other countries; and (2) a network of large, internationally unique, coordinated disease databases that capture input from extensive "patient registers" for measuring outcomes of devices being tested and further required developments (CTMH 2007).

Other factors that benefited the medical device industry are: government initiated institutions focus on early stage commercialization and funding, competent and efficient regulatory authorities, and teacher's exception[27] (lärarundantaget) that gives researchers and scientists personal incentive to commercialize findings. Some of the devices include imaging equipment, orthopaedic implants, dialysis equipment, heart-lung machines and ECG equipment, and devices for monitoring cardiovascular function and microcirculation. The estimated market for medical device in 2020 is US$2.6 billion. This amount is equivalent to 5.3 percent of the total health expenditure, 0.8 percent of the world market and 0.6 percent of Sweden's GDP.

Finally, the Swedish biomedical industry driving forces for growth are seen in the global context of increasing number of elderly persons and as a consequence increasing chronic illness, increasing health care expenditures both in developed and developing countries, and globalisation of health care markets with opportunities for increasing exports, or increasing costs for importing these products from other countries.

ICT and E-health

Information and communication technologies (ICT) are widely used in the health sector in Sweden. The existing ICT systems allow for the following:

- Relational databases that facilitate the retrieval of data for multiple purposes without re-keying
- Manipulation of data to create information and knowledge
- Point-of-care devices, computerized patient records and/or electronic health records
- Clinical repositories as a strategic resource for quality and practice
- Electronic interfacing systems to facilitate the sharing of data. The storage of electronic patient data or health records is nearly universal (96 percent) in hospitals and primary care
- Management and administrative purposes (payroll, personnel management, accounts payable, billing functions, general ledger, financial reporting)
- E-prescription. Nearly 80 percent of all prescriptions in Sweden are conducted through electronic prescription. This system handles on average 2.5 to 3 million e-prescriptions a month.

Nonetheless, wireless internet and mobile phones for information related to health prevention and management of chronic illness is underexploited. Despite its huge potentials, this idea and technology is ahead of the will to put it into practice.

The use of ICT improves productivity and efficiency of health care system, which in turn offer opportunities to save costs and improve quality. On the other hand, ICT

[27] Teachers, researchers and PhDs are the owners of the patents even if they are developed at their workplace at a university (Centre of Excellence for Science and Innovation Studies, CESIS 2007)

also save travel costs and time of the individuals as they can access health information from just about anywhere at any time. While the benefits are significant, the full potential of ICT is yet to be fully exploited. The technology has yet to be applied to help develop activities optimally, or to tailor health and social care to individuals and their needs.

At the heart of the eHealth strategy, launched in 2006, is the determination to ensure safe, accessible health and social care that is of high quality and is based on public need. Figure 2 summarizes the eHealth strategy.

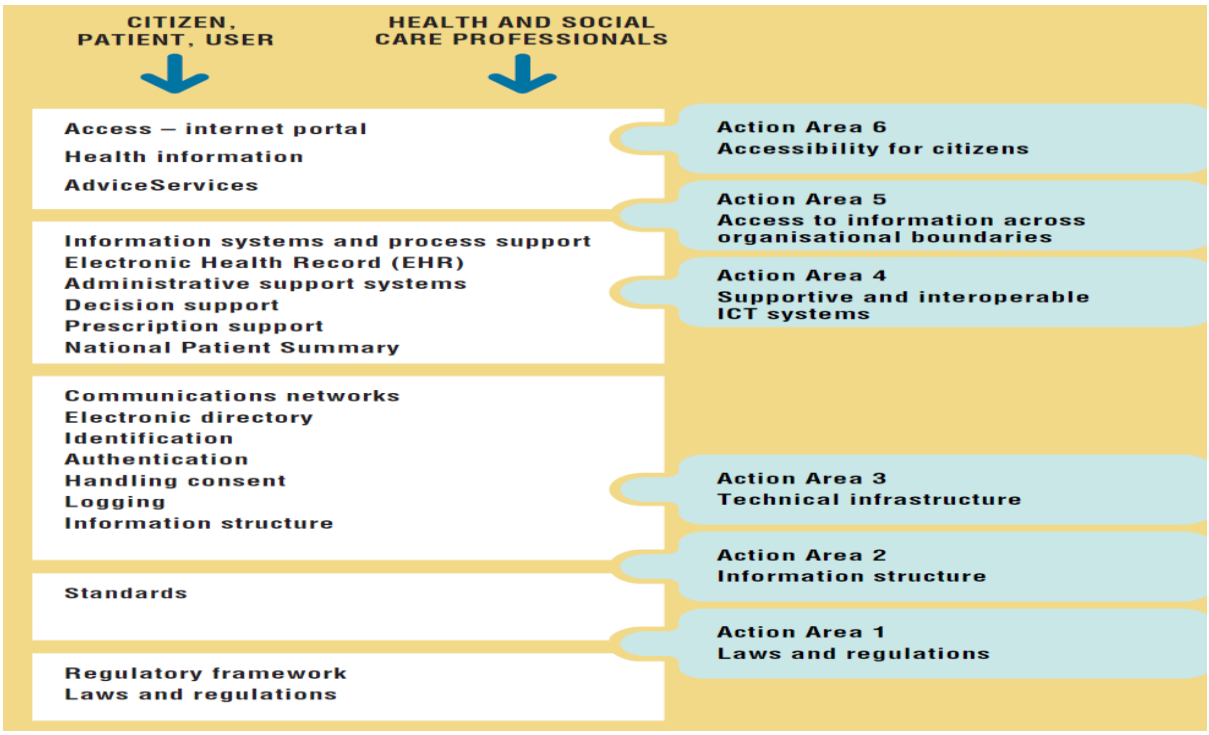

Figure 2: Sweden's National Strategy for E-Health
Source: Ministry of Health and Social Affairs, Sweden

STI Enablers

Research and development

There is strong support for R&D as a means to stimulate innovation and economic growth. Sweden boasts one of the highest R&D spending in the world at the rate of 3.7 percent of its GDP. The percentage equals to approximately 100 billion SEK where the share from the private sector is 70 percent.

R&D and commercialization of innovations is dominated by big multinational companies. They drive the research agenda which is closely linked to priorities that will generate revenues. The Universities and research institutes are key players in public supported R&D, and the focus is on basic research. Efforts to promote innovation in the universities include allowing universities to have holding

companies and own research findings, as well as appointing the science and engineering faculties to formulate commercialisation strategies.

The two divides come together in collaborative research projects. The strong public-private collaboration, and the legal and policy framework that supports researchers and universities to have economic gains from their research work, have significantly enhanced commercialization of research findings. Furthermore, an initiative called the Technology Bridge Foundation, involves seven regional independent foundations to promote university-based innovations.

VINNOVA is the lead agency for innovation under the Ministry of Industry, Employment and Communication, with a budget of 150 million Euros in 2006 and a staff of 176; 49 of whom have PhDs. Its mission is to promote sustainable economic growth by financing need-driven R&D and strengthening innovation systems.

Established in 2001 within the Ministry of Education and Research, the Swedish Research Council (replaced five previous research councils including arts, medicine, natural sciences) is a government agency that provides funding for basic research of the highest scientific quality in all disciplinary domains. It has a Scientific Council for Medicine and Health that supports research within the entire area of medical science (i.e. medicine, dentistry, pharmacy and health care sciences) according to national priorities (vr.se, 2010). The scientific council has eleven members, of which nine are active researchers with great academic competence and are chosen by the research community. The other two members also have connection to the medical research area, and are appointed by the government.

Collaboration, exchange of knowledge and expertise, and interaction between all players (researchers, business, universities, SMEs etc) involved, both at local and international levels is one of the driving forces for Swedish R&D. A survey by VINNOVA showed that about 93 percent of Swedish biotechnology firms were involved in R&D collaboration with academic research groups (Asian Biotechnology and Development Review 2003). Another survey highlights that as many as 64 percent of Swedish biotechnology companies have collaborated with foreign academic groups in their research and development activities, and 49 percent of the companies collaborated with and/or outsourced work to companies abroad (Swedish Institute 2007). This gives an idea on the importance of institutional links in research and development. The output is measured by co-publication, co-patenting or co-inventing and joint R&D projects.

Both public and private research funding institutions allocate resources based on the scientific merits of applications through a competitive and rigorous peer review process. This ensures that funds are efficiently used for strategic purposes. Furthermore, Centres of Excellence have been established as instruments to promote excellence in R&D.

Human resources

Amidst the high level of R&D investment, Sweden has 12.6 researchers per 1000 total employment; second only to Finland. More than 60 percent of them work in the business sector. Sweden also has one of the highest graduation rates in advanced research programmes (PhD or equivalent) among OECD countries. Scientific publications increased since the 1990s to reach 1109 articles per million population in 2005, placing the country second only to Switzerland. The output is also of high quality, whereby in 2003 Sweden ranked fourth worldwide in terms of citations of literature. Table 2 shows the value of production per employee as well as the R&D as percent of value added in the pharmaceutical and medical industries, and in all industry combined.

Table 2: Value of production per employee and R&D

Sector	**Value of production per employee**	**Change 1997-2002**	**R&D as % of value added**
Pharmaceutical industry	3.33 million SEK	35%	32%
Medical technology	1.76 million SEK	50%	
All industry	1.57 million SEK	16%	10%

Source: Medicine for Sweden, 2009

Policy

Overall, the health policy for the health sector has three main objectives:

1. Improved efficiency in the national economy. The aim is to achieve high growth rates that are generated by a successful expert oriented life sciences industry which is supported by sufficient resources for R&D from the private and public sectors.

2. Improved efficiency in the health care sector. A key task for an efficient health care sector is to further improve the management and organization of the system through the use of information technology. The other task is recruitment and training of health care providers as they are at the forefront in the delivery of quality services and safe practices in a timely and efficient manner. In-spite of the universal coverage for healthcare, there are efforts to reduce regional differences in order to ensure equity needs to be improved.

3. Improved efficiency in the production of health. The objectives are three-fold: (i) to promote prevention, health education and primary care services, (ii) to reduce inequalities in income and education, and (iii) to enforce Health

Technology Assessment[28] to comprehensively and critically assess methods used to prevent, diagnose, and treat health problems from medical, economic, ethical, and social perspectives.

The core thrusts of the STI policy are: (1) investments in R&D and higher education, (2) creation of a demand for innovations through procurement, quality criteria, and tax incentives, (3) an organisational development where the principle theme is the collaboration and networking between government machinery, universities and industries, and (4) supporting activities for innovating companies.

The research policy issues are treated as components of the relevant sectors although the Ministry of Education and Science coordinates research policy activities through the Swedish Research Council. A major thrust of the policy is to guarantee excellence in research by supporting researcher-initiated basic research and promoting diversity in research funding through sectoral research agencies. The main strategies of the Scientific Council for Medicine and Health under the Swedish Research Council are:

- increased state funding for Swedish medical research
- increased support for research which maintains the highest quality
- the recruitment of new researchers and talent
- collaboration and co-ordination of resources
- equality of opportunity within medical research
- strengthening public knowledge about medical research and its results

Infrastructure and financing

Research infrastructure encompasses facilities and other resources that are available for research purposes and can be used by several research groups. Examples of this are expensive equipment, certain organisations or extensive computer networks that are used nationally or internationally. The structure of housing various partners in a common location promotes partnership. A good example is the Medical Valley Region which accommodates 11 university hospitals, 130 medical technology companies, 70 pharmaceutical companies, and 15 clinical research organizations. In addition, Sweden also has more than 30 science and technology parks.

Venture capital is a major source of financing for companies in search of technological innovations in Sweden. There are approximately 200 venture capital investment companies in Sweden, of which 30 of them have special interests in biotechnology industry. Recognizing the need for government-supplied capital resources for start-up companies, the Swedish National Board for Industrial and

[28] The Swedish Council on Health Technology Assessment is an independent assessment that focuses on three questions: (1) Which treatment options are most effective? (2) How can problems be diagnosed most accurately? (3) How best to use healthcare resources to achieve optimum benefits?

Technical Development (NUTEK), ALMI and Teknikbrostiftelsen operate as adjuncts to a venture investor, supplying approximately 30 – 50 percent of the total initial investment to SMEs. The capital is supplied as a loan to the entrepreneur at a favourable rate. The loan can be deferred if the project does not meet its goals. Another source of capital is a network of business bodies that bring knowledge or intellectual capital.

The public sector allocates 22 billion SEK to universities. The Swedish Research Council is the largest state funding agency for basic research at Swedish universities, colleges and institutions, allocating around four billion annually for research in five discipline areas including health and medicine (www.vr.se). VINNOVA is responsible for managing and channelling public funds for R&D and demonstration activities for both private and public sectors. Medicine and bioscience is one of the three priorities for the public research budget[29], receiving about 25 percent of all investments in public R&D in Sweden

Conclusion

Sweden has laid strong foundation to drive the country towards successful STI growth, including in the health sector. The main enablers for this success include well-defined policies, high quality human resources and excellent R&D infrastructures.

[29] The three priorities are medicine and bioscience, technology and sustainable development.

ANNEX 4

Expert Advisory Group

Confirmed	
1. Professor Dr Mak Joon Wah Division of Pathology School of Medial Sciences International Medical University	2. Prof. Looi Lai Meng Department of Pathology, Faculty of Medicine, University of Malaya
3. Prof. Dato' Lokman Saim Dean Faculty of Medicine Universiti Kebangsaan Malaysia	4. Tan Sri Dato' Dr Abu Bakar Suleiman President International Medical University
5. Prof. Dr Victor Lim Executive Dean Faculty of Medicine and Health International Medical University	6. Dr David Quek Kwang Leng President Malaysian Medical Association.
7. Dr Othman Warijo Vice President Public Health Specialist Association of Malaysia	8. Dr Molly Cheah President Primary Care Doctors' Organisation Malaysia
9. Dato' Dr M. Jegathesan Fellow of Academy of Science, Malaysia	
Awaiting confirmation	
1. Tan Sri Datuk Seri Dr. Hj. Mohd Ismail Merican Director General of Health Ministry of Health	2. Dato' Dr Noor Hisham bin Abdullah Deputy Director General of Health Ministry of Health

ANNEX 5

List of participants at the Consultation Workshop, October 26-27, 2010

Prof Dr Rofina Yasmin Dato Othman Ministry of Science, Technology and Innovation. (MOSTI)	Prof Dr A Rahman A Jamal Director UKM Medical Molecular Biology Institute (UMBI)
Assoc Prof Habibah A Wahab Director of Hits-to-Lead Division Malaysian Institute of Pharmaceuticals and Nutraceuticals (IPHARM) Ministry of Science, Technology & Innovation	Assoc. Prof. Dr. Ahmad Fuad Shamsuddin Faculty of Pharmacy Universiti Kebangsaan Malaysia
Dr Othman Warijo Vice President Public Health Specialist Association of Malaysia	Dr Molly Cheah President Primary Care Doctors' Organisation Malaysia
Dr Er Ah Choy Universiti Kebangsaan Malaysia	Encik Jaafar Lassa Director of Traditional and Complementary Medicine Division, Ministry of Health Malaysia
Tan Sri Dato' Dr Abu Bakar Suleiman President International Medical University	Datin Hatijah Yusof Malaysian Nurses Association (MNA)
Dr Sirajuddin Hashim Division of Communicable Diseases Ministry of Health	Ms Harsuzilawati Muhammed Universiti Kebangsaan Malaysia
Dr Hajjah Rasidah Mohamed KPJ International College of Nursing and Health Sciences	Dr Nik Musaadah Mustapha Forestry Research Institute of Malaysia (FRIM)
Hajjah Azizah Pondar KPJ International College of Nursing and Health Sciences	Dr KV Anita KPJ Healthcare Sdn Bhd
Prof Dato Dr Mohamed Isa Abd Majid Malaysian Institute of Pharmaceuticals and Nutraceuticals (IPHARM) Ministry of Science, Technology & Innovation	Mr Nik Md Salihin Ministry of International Trade & Industry (MITI)
Dr Ahmad Zorin Sahalan Department of Biomedical Science Faculty of Allied Health Sciences, UKM.	Dr Hing Hiang Lian Malaysia Qualification Accreditation (MQA)
Dr Puteri Noor Institute for Medical Research (IMR)	Ms Mardiana Mohd Yusof Ministry of International Trade & Industry
Tan Sri Dato Dr M. Jegathesan Academy of Sciences Malaysia	Prof Dr Mohd Ismail Noor Academy of Sciences Malaysia

Prof Emeritus Dato Dr CP Ramachandran Academy of Sciences Malaysia	Prof Dr Victor Lim Kok Eow Academy of Sciences Malaysia
Tan Sri Dato' Dr Salleh Mohamed Yasin Director of UNU-IIGH UNU - International Institute for Global Health	Ms Asmahani Atan Universiti Kebangsaan Malaysia
List Of Experts Who Were Invited But Unable To Participate	
Prof Dr Nor Muhammad Mahadi Director General Malaysia Genome Institute Ministry of Science, Technology & Innovation Heliks Emas Block UKM-MTDC Technology Centre	Dr Norwati Muhammad Director Forest Biotechnology Division Forest Research Institute Malaysia (FRIM)
Dato' Dr Jacob Thomas President of APHM (Association of Private Hospital of Malaysia)	Dr Zainal Ariffin Timbalan Pengarah Bahagian Kawalan Penyakit Cawangan Penyakit Tidak Berjangkit Kementerian Kesihatan Malaysia
Dr Ramli Abd Ghani Director of Traditional and Complementary Medicine Division, Ministry of Health Malaysia	Dr Shahnaz Murad Director of Institute of Medical Research MOH
Dato' Dr Mohd Hashim Tajudin Managing Director of Chemical Company Malaysia Berhad (CCM)	Mr Selvaraja S. Seerangam National Pharmaceutical Control Bureau (NPCB)
Assoc Prof Dr Retneswari Masilamari Head of Department of Social and Preventive Medicine Faculty of Medicine University of Malaya	Assoc Prof Dr Mohamed Rusli Head of Department of Community Medicine School of Medical Sciences Health Campus University of Science Malaysia
Dr Hj. Abdul Rahim B Hj Mohamad Pengarah Bahagian Perancang & Pembangunan Kementerian Kesihatan Malaysia	Dr Azman Abu Bakar Pengarah Institute for Health System Research
Prof Dr Uda Hashim Director of Institute of Nano Electronic Engineering (INEE) Universiti Malaysia Perlis (UniMAP),	Prof Dr Mary Jane Cardosa Director of Institute of Health and Community Medicine, Universiti Malaysia Sarawak

Dato' Iskandar Mizan Healthcare Industry Development Division Malaysian Biotechnology Corporation Sdn Bhd	Mr Leonard Ariff Abd Shattar Manager (HalalPharmaceuticals) Chemical Company Malaysia Berhad
Dr Hyzan Mohd Yusof Chief Executive Officer OSA Technology Sdn Bhd Smart Technology Centre, UKM Professor Dr Mak Joon Wah Division of Pathology School of Medial Sciences International Medical University	Dr. Prashanth Bagali Chief Operating Officer / Senior Vice President Science & Technology Geneflux Biosciences Sdn. Bhd Dato' Dr NKS Tharmaseelan Malaysian Medical Association (MMA)
Prof. Dato' Lokman Saim Dean Faculty of Medicine Universiti Kebangsaan Malaysia	Prof Dr Noor Hassim Ismail Head of Department of Community Health Universiti Kebangsaan Malaysia
Prof. Looi Lai Meng Department of Pathology, Faculty of Medicine, University of Malaya	Tan Sri Dato' Seri Dr. Hj. Mohd Ismail bin Merican Director General of Health Ministry of Health
Mr.Zainal Mohd Noor Abidin Chief Executive officer Malaysia National Insurance Bhd	S.M.Mohamed Idris President Consumer Association of Penang (CAP)
Prof Dr Asma Ismail Deputy Vice Chancellor (Research and Innovation) Division of Research & Innovation Universiti Sains Malaysia	Datin Paduka Prof Dr Khatijah Mohd Yusoff Deputy Secretary General (Science Service) Ministry of Science, Technology & Innovation

ANNEX 6

List of public and private medical schools

Key Medical Schools

Faculty of Medicine, University of Malaya	The oldest university in Malaysia. Located in Kuala Lumpur.
Faculty of Medicine, Universiti Kebangsaan Malaysia	Also known as National University of Malaysia.
Universiti Sains Malaysia	Main entrance to Malaysia's third medical school in Kubang Kerian, Kelantan

Other Universities with Medical Schools

Universiti Malaysia Sarawak	Located in East Malaysia
Universiti Putra Malaysia	Formerly Serdang College, now a Medical Faculty
International Medical University	First private medical school in Malaysia
UniKL RCMP	Universiti Kuala Lumpur Royal College of Medicine Perak
Penang Medical College	Private medical school in the Pearl of the Orient
Melaka-Manipal Medical College	Offers a Medical (MBBS) Twinning Programme with Manipal Medical School
International Islamic University of Malaysia	Islamic Medical School in Pahang
Universiti Malaysia Sabah	New School of Medical Sciences in East Malaysia. First intake was in June 2003
Universiti Teknologi Mara Medical School	The first intake of medical students was in June 2003
UCSI School of Medicine	Attached to the University College Sedaya International
Monash University Malaysia	Attached to Monash University in Melbourne. First intake was in 2005
AIMST	AIMST University School of Medicine. Located in Kedah
ACMS	Allianze College of Medical Sciences. Based in Penang
CUCMS	Cyberjaya University College of Medical Sciences
USIM	Universiti Sains Islam Malaysia Medical Faculty
NU Medicine Malaysia	Newcastle University of Medicine Malaysia. First intake in 2009
MAHSA	MAHSA University College. First intake in 2009
IMS-MSU	International Medical School, Management & Science University. Campus located in Bangalore, India
UniSZA	University Sultan Zainal Abidin in Trengganu. First intake in 2009
Taylor's University School of Medicine	Medical Degree Transfer Program. First intake in 2010
UTAR	University Tunku Abdul Rahman. First intake in 2010
SEGi UC	SEGi University College. First intake in 2010
Masterskill	Masterskill University College of Health Sciences. First intake in 2010

ANNEX 7

Health indicators: Malaysia, South Korea, Sweden and select Asian countries

Indicators	Malaysia	South Korea	Sweden	Global	Singapore	Indonesia	Vietnam	Phillipines	Brunei
General Country Statistics									
Total population[1]x 1000 (2008)	27,014	48,152	9,205	6,737,480	4,615	227,345	87,096	90,348	392
Annual population growth rates (%) (1998-2008)[1]	2.0	0.5	0.4	1.3	1.9	1.3	1.3	1.9	2.1
Indicators Measuring The Health Of Population									
Life expectancy at birth (years)[1]	73	80	81	68	81	67	73	70	76
Healthy Life expectancy HALE (years) at birth [1]	64	71	74	59	73	60	64	62	66
Infant mortality rate (per 1,000 live birth) [1]	6	5	2	45	2	31	12	26	5
Cause- specific mortality and morbidity (2008)									
Maternal mortality ratio (per 100,000 live births) [1]	28	15	2	NA	14	420	150	230	13
Age-standardized mortality rates by cause (per 100,000 population) (2004*)[1]									
- Communicable	161	32	22	275	79	272	170	285	37
- Non-communicable	623	470	372	612	345	690	611	620	473
- Injuries	53	67	32	93	27	233	64	59	29
Morbidity and mortality of communicable diseases									
HIV/AIDS									
Prevalence of HIV among adults aged 15-49 (%) (2007)[1]	0.5	<0.1	0.1	0.8	0.2	0.2	0.5	-	-
Mortality rate (per 100,000 population (2007) [1]	15	<10	<10	30	<10	4	27	<10	-
Tuberculosis									
Prevalence of tuberculosis (per 100,000 population) [1] (2008)	120	50	3	170	27	210	280	550	43
TB Mortality rate among HIV-negative people[1] (per 100,000 population) (2008)	15	5.5	0.4	21	2.5	27	34	52	4.2
Malaria									
Mortality rate (per 100,000 population) (2006) [1]	0.1	0.0	NA	17	-	1.5	0.2	0.3	-

Indicators	Malaysia	South Korea	Sweden	Global	Singapore	Indonesia	Vietnam	Phillipines	Brunei
Morbidity and mortality of non-communicable diseases									
Cardiovascular mortality rate (per 100,000 population)[2] (2004)	275	168	171	301	164	344	295	320	193
Cancer mortality rate (per 100,000 population) [2] (2004)	137	161	115	130	113	127	115	95	106
Diabetes mellitus mortality rate (per 100,000 population) (2004)[3]	19.6	32.5	20.3	-	10.9	22.0	15.7	15.3	22.7
Septicaemia (%) MOH Health Facts 2008	13.18%	-	-	-					
Risk factors									
Population using improved drinking-water resources (%)[1] (2008)	100	98	100	87	100	80	94	91	-
Population using improved sanitation (%)[1] (2008)	96	100	100	60	100	52	75	76	-
Alcohol consumption among adults aged ≥ 15 years (litres per person per year) (2005) [1]	0.5	11	6.6	4.4	2.1	<0.1	6.9	4.2	1.7
Obesity among adults aged ≥ 15 years (%)[1] (2008)									
• Male	13.9	2.8	13.0	NA	6.7	1.1	-	3.0	-
• Female	18.8	3.5	12.0	NA	4.7	3.6	-	5.7	-
Prevalence of smoking any tobacco product among male adults aged ≥ 15 years (%) (2006) [1]	52.6	53.3	17.3	41.1	36.3	61.7	31.6	53.2	-
Demographic and socioeconomic status									
Gross national income per capita (PPP int.$) [1](2008)	13, 740	28, 120	38,180	10, 290	47,940	3,830	2,700	3,900	11,950
Adult literacy rate (%)[1] (2000-2007)	92	NA	NA	81	94	92	-	93	95
Total fertility rate (per woman) [1](2008)	2.6	1.2	1.9	2.5	1.3	2.2	2.1	3.1	2.1
Human Development Index (Rank/Value) (2007) [4]	66/0.829	26/0.937	7/0.963	0.753	23/0.944	111/0.734	116/0.72	105/0.751	30/0.9
Indicators Measuring The Health Services And Expenditure									
Health service coverage									
Birth attended by skilled health personnel (%)[1]2000-2008	100	100	NA	66	100	73	88	62	100

Indicators	Malaysia	South Korea	Sweden	Global	Singapore	Indonesia	Vietnam	Phillipines	Brunei
Immunization coverage among 1 year olds(%)[1] (2008)									
• Measles	95	92	96	83	95	83	92	92	97
• DTP3	90	94	98	82	97	77	93	91	99
• HepB3	90	94	NA	69	96	78	87	88	99
Smear positive tuberculosis case detection rate (%)[1] (2008)	76	87	87	62	87	80	62	67	87
Indicators	**Malaysia**	**South Korea**	**Sweden**	**Global**	**Singapore**	**Indonesia**	**Vietnam**	**Phillipines**	**Brunei**
Health workforce and infrastructure									
Density of health personnel (per 10,000 population) [1] (2000-2009)									
Physicians	7	17	36	14	15	1	6	12	11
Nursing and midwifery personnel	18	44	116	28	44	8	8	61	61
Dentistry personnel	1	14	8	3	3	<0.5	-	6	2
Pharmaceutical personnel	1	11	7	4	3	<0.5	3	6	1
Hospital beds (per 10,000 population) [1]	18	86	NA	27	32	6	28	5	26
Health expenditure Ratios (2007)									
Total expenditure on health as % of gross domestic product[1]	4.4	6.3	9.1	9.7	3.1	2.2	7.1	3.9	2.4
General government expenditure on health as % of the total expenditure on health[1]	44.4	54.9	81.7	59.6	32.6	54.5	39.3	34.7	81.5
General government expenditure on health as % of total government expenditure[1]	6.9	12.1	14.1	15.4	7.2	6.2	8.7	6.7	6.7
Out-of pocket expenditure as % of private expenditure on health[1]	73.2	79.2	87	43.9	93.9	66.2	90.2	83.7	98.9
Per capita government expenditure on health (PPP int. $)[1]	268	927	2716	493	536	81	72	45	958

ANNEX 8

NIA Indicators

1. PATIENT CARE

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
	GENERAL SURGERY		
1.	Mild Head Injury Case Fatality Rate	≤ 5 %	No. of deaths due to mild head injury x 100% No. of admissions with a diagnosis of mild head injury
2.	Rate of White Appendix	≤ 20 %	No. of white appendix x 100% All appendicectomy specimens removed for acute appendicitis
3.	Elective Operations Cancellation Rate	≤ 15 %	No. of cases cancelled x 100% No. of cases listed on the elective list
4.	Percentage of patients whose waiting time for elective surgery (thyroidectomy OR Cholecystectomy) is less than 3 months	>90 %	
	ORTHOPAEDIC SURGERY		
5.	Incidence of Wound Infection in Clean Elective Orthopaedic Surgery	Less than 3 %	No of clean elective orthopaedic wound infection x 100 % Total no. of clean elective orthopaedic surgery
6.	Incidence of Unacceptable Fracture Fixation Requiring Revision	Less than 3 %	Rate-based Outcome indicator x 100 % Total no. of unsatisfactory fracture internal fixation required revision
7.	Unplanned Return to the Operating Room / Theatre within 24 hours of Surgery	< 1 %	Total no. of post-op complications that require immediate operative intervention to reduce mortality and morbidity x 100 % Total no. of orthopedic surgeries performed
8.	Waiting Time of less than 3 Days for Fixation of Long Bone Closed Fracture	100 %	No. of patients whose waiting time for fixation of long bone closed fracture is 3 days or less x 100 % Total no. of elective long bone closed fracture fixation
	UROLOGY		
9.	Rate of Safe Performance of Percutaneous Nephrolithotripsy (PCNL)	≥ 85 %	No. of PCNL cases performed safely x 100 % Total no. of PCNL performed
10.	Rate of Safe Performance of Transurethral Resection of the Prostate (TURP)	≥ 90 %	No. of TURP cases performed safely x 100 % Total no. of TURP performed
11.	Rate of Safe Performance of Ureterorenoscopy (URS) with Lithotripsy	≥95 %	No. of Ureterenoscopy (URS) with Lithotripsy cases performed safely x100% Total no. of Ureterorenoscopy (URS) and Lithotripsy performed

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
	OTORHINOLARYINGOLOGY (ENT)		
12.	Occurrence of Post-Tonsillectomy Haemorrhage	< 5 %	No. of post tonsillectomy haemorrhages occurring in the month x 100 % Total no. of tonsillectomies conducted in the month
13.	Elective Operations Cancellation Rate	≤ 15 %	Total no. of cases listed in the final OT list, cancelled x 100 % Total no. of cases listed in the final OT list
	NEURO SURGERY		
14.	Wound Infection Following Elective Craniotomy for Brain Cancer	Less than 8 %	Total no. of patients diagnosed with infected craniotomy wound within hospitalization x 100 % No. of elective craniotomy for brain cancer
	OPHTHALMOLOGICAL SURGERY		
15.	Rate of Infectious Endophthalmitis following Intraocular Surgery	< 0.2 % (2 cases per 1000 operations)	Total no. of patients developing post-operative endophthalmitis following intraocular surgery performed in a specified month x 100 % Total no. of intraocular surgeries performed in the corresponding month
16.	Rate of Posterior Capsular Rupture during Cataract Surgery	> 5 % (50 cases per 1000 operations)	Total no. of cases of posterior capsular rupture during cataract surgery performed in a specified month x 100 % Total no. of cataract surgeries performed in the corresponding month
17.	Best Corrected Visual Acuity of 6/12 or better within 3 Months following Cataract Surgery in Patients without Ocular Co-Morbidity	> 85 % (850 cases per 1000 operations)	Total no. of patients *without ocular co-morbidity*, who underwent cataract surgery in a specified month and attained visual acuity of 6/12 or better within 3 months following surgery x 100 % Total no. of patients *without ocular co-morbidity*, who underwent cataract surgery in the corresponding month
	ANAESTHESIA		
18.	Incidence of Intubation in the Recovery Room	≤ 0.3 %	Total no. of patients requiring intubation in the Recovery Room x 100% Total no. of anaesthetics administered
19.	Percentage of Postoperative Patients Leaving the Recovery Room with Pain score of ≥ 4	<10 %	Total no. of patients leaving the recovery room (RR) with pain scores ≥ 4 x 100 % Total no. of anaesthetics

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
			administered
20.	Percentage of Patients Awaiting Emergency Surgery for more than 24 hours	≤ 1 %	Total no. of patients who waited more than 24 hours for emergency operation under anaesthesia x 100 % Total no. of emergency anaesthetics
	OBSTETRICS & GYNAECOLOGY		
21.	Incidence of Massive Primary Post-partum Haemorrhage (PPH)	Not > 0.5 % of total no. of deliveries	No. of cases of Primary PPH with blood loss > 1.5 liters x 100 % Total no. of deliveries
22.	Incidence of Recurrent Eclamptic Fits Occurring after Hospital Admission	Sentinel Event (No cases)	No. of eclampsia patients experiencing more than one fit in hospital
23.	Occurrence of Urinary Tract Injury Following Hysterectomy	Not more than 1 %	No. of deaths due to Heart Disease in Pregnancy
24.	Deaths Due To Heart Disease in Pregnancy	Sentinel Event (No cases)	No. of patients with urinary tract injuries following hysterectomy x 100% Total no. of obstetrical and gynaecological hysterectomies performed
	GENERAL MEDICINE		
25.	Acute Coronary Syndrome (ACS) Case Fatality Rate	≤ 20 %	No. of DEATHS from Acute Coronary Syndrome x 100 % Total no. of CASES of Acute Coronary Syndrome
26.	Percentage of Acute ST Elevation Myocardial Infarction (STEMI) Patients Receiving Thrombolytic Therapy within 30 Minutes of Presentation at the Emergency Department	≥ 70 %	Patients admitted with STEMI who received thrombolytic therapy within 30 minutes of presentation in the Emergency Department x 100% Patients admitted with STEMI who received thrombolytic therapy in the Emergency Department
27.	Percentage of Asthma Patients Discharged with Asthma Discharge Plan Document	Not < 75 %	No. of asthmatic patients discharged with Asthma Discharge Plan x 100 % Total no. of asthmatic patients discharged
28.	Percentage of Patients with Ischaemic Stroke treated with Anti-platelet Therapy within 48 hours	≥ 80 %	Total no. of patients with Ischemic stroke treated with Anti-platelet therapy within 48 hours of clinical diagnosis x 100 % Total no. of patients with Ischemic stroke
29.	Dengue Case Fatality Rate	<0.2%	
30.	Dengue Hemorrhagic Fever Fatality Rate	<1%	
	PEDIATRIC MEDICAL		
31.	Community-acquired Pneumonia Death Rate in previously healthy	≤ 2.5 %	No. of deaths due to Community-Acquired pneumonia for age > 1

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
	children aged from ≥ 1 month to ≤ 5 years		month to < 5 years x 100% No. of cases admitted for Community-Acquired pneumonia for age ≥ 1 month to < 5 years
32.	Survival of Very Low Birth Weight (VLBW) infants 1000 grams to 1499 grams in hospitals WITH neonatologist (s)	At least 85 %	No. of VLBWs 1000g to 1499 g who are discharged alive x 100 % No. of VLBWs 1000g to 1499 g admitted to NICU
33.	Survival of Very Low Birth Weight (VLBW) infants 1000 grams to 1499 grams in hospitals WITH paediatrician but WITHOUT Neonatologist (s)	At least 80 %	No. of VLBWs 1000g to 1499 g who are discharged alive x 100 % No. of VLBWs 1000g to 1499 g admitted to NICU
34.	Dengue Hemorrhagic Fever Deaths in Pediatric cases	Sentinel event (No deaths)	No. of dengue Hemorrhagic fever deaths (Any death due to DHF to be investigated)
35.	Death due to Acute Gastroenteritis in Paediatric patients	Sentinel event (No deaths)	No. of acute gastroenteritis deaths (Any death due to acute gastroenteritis to be investigated)
36.	Number of Paediatric Patients Who are Readmitted to Hospital for Acute Exacerbation of Asthma Within 28 Days of Discharge	Sentinel event (No cases)	No. of paediatric patients who are readmitted to hospital acute exacerbation of bronchial asthma within 28 days of discharge (Any readmission due acute exacerbation of bronchial asthma has to be investigated to determine root causes)
	DIAGNOSTIC IMAGING		
37.	Proportions Radiographs Rejected	< 5 %	Total no. x-ray films rejected x 100% Total no. of x-ray films used
38.	Turnaround Time for Reports of Special Radiological Examinations for Inpatients	97 % of reports should be available within 2 working days	No. of in-patient special examinations reported within 2 working days x 100% Total no. of in-patient special examinations performed
39.	Morbidity Associated with Percutaneous Needle Aspiration Cytology / Biopsy Of Chest - Significant Pneumothorax	Not more than 10%	Total no. of patients undergoing percutaneous biopsy of the CHEST for which there is documented evidence of significant PNEUMOTHORAX following the procedure x 100% Total no. of patients undergoing percutaneous biopsy of the chest
40.	Morbidity associated with Percutaneous Needle Aspiration Cytology / Biopsy Of Abdomen - Haemorrhage	Not more than 10 %	Total no. of patients undergoing percutaneous biopsy of the ABDOMEN, for which there is documented evidence of significant HAEMORRHAGE following the procedure x 100% Total no. of patients undergoing percutaneous biopsy of the ABDOMEN

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
	DERMATOLOGY		
41.	Infection Rate of Skin Biopsy Wounds	< 2 %	Total no. of infected skin biopsy wounds in a 6 month period (Jan-June or July – December) x 100% Total no. of skin biopsies performed in that 6 month period(Jan-June or July – December)
42.	Defaulter Rate Among Leprosy Patients	< 10 %	Total no. of defaulters (who were on treatment with MDT) in a 6 month period (Jan-June or July – December) x 100% Total no. of Leprosy patients treated with MDT in that 6 month period (Jan-June or July – December)
	NEPHROLOGY		
43.	Delivered KT/V in Patients on Centre haemodialysis	At least 80 % of patients should have average delivered KT/V ≥ 1.2 yearly	Patients on haemodialysis in the centre with average delivered KT/V ≥ 1.2 in the calendar year x 100 % Total no. of patients on chronic haemodialysis in the centre in the calendar year
44.	Peritonitis rate in Adult Patients on Continuous Ambulatory Peritoneal Dialysis	< 1 episode per 24 patient months in adult patients in the CAPD unit	No. of peritonitis episodes in patients on CAPD in the calendar year in the CAPD unit Total no. of patient days, months and years of treatment on CAPD for the calendar year.
45.	% of Patients with Diabetic Nephropathy in the Nephrology Clinic who have acceptable Blood Pressure Control	Blood pressure ≤ 130/80 mmHg in ≥ 25 % of patients with diabetic nephropathy in Nephrology Clinic	No. of patients with diabetes mellitus from the random sample who have BP < 130/80 mmHg x 100 % 100 active clinic records of patients with diabetes selected randomly from Nephrology clinic
	PSYCHIATRY		
46.	Unnatural Death	No Death	No. of deaths x 100 % Not relevant
47.	Rate of Re Admission within 6 Months of Last Discharge	Less than 25 %	No. of patients readmitted within 6 months of last discharge x 100 % Total no. of patients admitted in the same month
48.	Defaulter Rate of Psychiatric Patients Attending Outpatients Clinic	Less than 15 %	No. of psychiatric patients who failed to attend outpatient clinic within one month of the appointment date x 100 % Total no. psychiatric patients given appointment over the same period of time. This does not include those who come without appointment. Denominator: excluded

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
			appointment to counselors, new cases and those who comes without appointment dates
49.	Rate of Psychiatric Admission of Patients Under Community Psychiatric Service	Less than 10 %	No. of patients who have been under the care of community psychiatric admitted to the psychiatric unit for the current month x 100 % Total no. of patients at the end of the current month who have been under the care of community psychiatric services for at least 3 months Denominator: excluded appointment to counselors, new cases and those who comes without appointment dates
	EMERGENCY MEDICAL & TRAUMA SERVICES		
50.	Dispatch and Ambulance Preparedness for Primary Response	> 90 % with dispatch time of 5 minutes or less	No. of Dispatches with dispatch Time of less than 5 minutes x 100 % Total No. of Ambulance calls
51.	Inappropriate Triaging (Under-triaging) : Percentage of Category Green Patients Who Should Have Been Triaged as Category Red	Not > 0.5 %	No. of "under-triaged" patients ("Green" Patients who should have been "Red") x 100 % Total no. of MTC GREEN patients
52.	Inappropriate Triaging (OVER-TRIAGING) : Percentage of Cat. Red Patients Who Should Have Been Triaged As Cat. Green	Not > 0.5 %	No. of "Over-triaged" patients ("Red" patients who should have been "Green") x 100 % Total no. of MTC RED patients
	PHYSIOTHERAPY		
53.	Burns Sustained During Delivery of Electro-Therapeutic Modalities and Thermal Agents	No cases of burns (Sentinel events)	No. of Cases
54.	Patients with Backache Achieving Highest Level of Function Within 24 visits (or 6 month period) in a Single Continuous Episode of Care	Not less than 80 %	No. of Backache patients achieving highest level of Function within 24 visits or 6 months period during a single episode of care in physiotherapy outpatient department x100% Total no. of Backache patients managed in Physiotherapy out-patient department (as stated in inclusion criteria)
	OCCUPATIONAL THERAPY		
55.	Measurement of Improvement of ADL (Activities of Daily Living) Independence for Stroke Patients after ADL Intervention	75 % of target group should obtain a score of 70 % MBI after a minimum of 8 treatment sessions in 12 weeks	The total no. of STROKE patients who attain a score of 70% and above MBI after minimum of 8 treatment sessions X100% The total no. of STROKE patients who attain a score of 70% and

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
			above MBI after minimum of 8 treatment sessions
	DIETETICS & FOOD SERVICES		
56.	Delay in Response to In-patient Referral by Dietitian	Critical Case ≤ 5 **%** Non-critical case ≤ 10 %	Total no. of Delay in response by dietitian within a stipulated time period x 100% Total no. of patients referred to the dietitian during the same time period
57.	Incidence of Physical Food Contamination of Food Served to Patients	0 % (Sentinel event) No physical contamination of food	No. of Cases
	NURSING		
58.	Incidence of Thrombophlebitis Among ADULTS In-patients Receiving Intravenous Therapy	<9 cases per 1000 lines set (<0.9%) based on national averages	No. of cases of Thrombophlebitis x 1000 x 100 % Total no. of intravenous lines set up
	MEDICAL RECORDS		
59.	Timeliness in the Preparation of Medical Reports	Not less than 95 % of completed medical reports General hospitals < 8 weeks District hospital with specialist <4 weeks District hospital without specialist < 2 weeks	Total no. of Medical Reports completed on time x 100 % Total no. of complete requests for medical reports
60.	Timeliness in Dispatching Medical Records of Discharged Patients to the Medical Records Department	Not less than 95 % of medical records dispatched within 72 hours of discharge	No of medical records dispatched within 72 hrs of discharge x 100% Total no. of patients discharged

2. PUBLIC HEALTH

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
	DISEASE CONTROL		
A	**COMMUNICABLE DISEASE**		
1.	Sputum conversion rate (SCR) for Tuberculosis	85 %	No. of smear positive cases converted to negative after 2 months of treatment x 100% No. of smear positive cases at beginning of treatment

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
B	**VECTOR CONTROL**		
2.	Dengue outbreak control index (DOCI)	100% of outbreaks must be controlled within 14 days after reporting of the 2nd case	No. of dengue outbreaks controlled in a period x 100% Total no. of outbreaks in a period
3.	Malarial deaths (ZERO)	Actual number of deaths in a year due to malaria	Actual number of deaths in a year due to malaria
4.	Dengue notification time index (DNTI)	80 % of cases must be reported within 24 hours	No. of cases notified within 24 hrs x 100% Total no. of cases notified in a month
C	**OCCUPATIONAL HEALTH**		
5.	Incidence rate of needle stick injuries amongst health care workers within the Ministry of Health	Zero case per 1000 HCW	No. of new cases of NSI for a particular year x 100% Total No. of HCW handling/exposed to needles and syringes of that particular year
	FAMILY HEALTH DEVELOPMENT PROGRAMME		
A	**FAMILY HEALTH PROGRAMS**		
6.	Incidence rate of severe neonatal jaundice (NNJ)	Less than 100 cases per 10,000 live births	No. of severe neonatal jaundice (NNJ) x 10,000 live births Total no. of live births
7.	Visual defect detection rate among standard one school children	5%	No. of visual defect cases detected x 100% Total no. of standard one school children
B	**PRIMARY CARE**		
B1	**DIRECT PATIENT CARE**		
8.	% of asthmatic patients that received appropriate Management of Asthma at the health clinics	Beating own standards annually	Collective marks attained through a set of questionnaire Maximum marks allocated for the set of questionnaire
9.	Glycaemic Control:% of diabetes patients with HbA1c < 7%	≥30%	Number of diabetes patients with Hb1Ac, 7.0% x 100% Total Number of cases sampled
10.	% of clients perceived the service provided as client friendly	Beating own standards annually	Collective marks attained through a set of questionnaire Maximum marks allocated for the set of questionnaire
B2	**SUPPORT SERVICES**		
11.	% of radiograph accepted	>95%	No. of radiographs acceptable to diagnostic criteria x 100% Total no. of films used for diagnostic purpose
12.	Total turn-around-time (TTAT) for Full Blood Count (automation	>90%	No. of cases done within specified time frame x 100%

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
	and manual)		Total no. of cases within the specified period
13.	Total turn-around-time (T-TAT) for Urine FEME	>90%	No. of cases done within specified time frame x 100% Total no. of cases within specified period
14.	Proportion of wrongly filled prescription detected before dispensing	ZERO	No. of wrongly filled prescriptions x 100% Total no. of prescriptions filled
15.	Proportion of prescription intervened by the pharmacist	<2.5%	No. of prescriptions intervened x 100% Total no. of prescriptions received
	FOOD SAFETY		
	OPERATIONAL SERVICES		
16.	Rate of Closure of Unsanitary Premises	>80%	Total No. of Closure of Premises scored below 50% x 100% Total No. of Premises scored below 50%

3. DENTAL HEALTH SERVICES

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
1.	Percentage of repeat amalgam fillings done on posterior permanent teeth	1%	Total repeat amalgam fillings done on post. teeth x 100 Total post. amalgam fillings done during the current year
2.	Percentage of schoolchildren maintaining orally fit status Primary schoolchildren Secondary schoolchildren	Primary 55%	Total no. of NTR primary schoolchildren X 100 Total no. of new attendances of pri. sch. children
		Secondary 70%	Total no. of NTR secondary schoolchildren X 100 Total no. of new attendances of sec. sch. children
3.	Percentage of 16 year-olds children free from gingivitis. (85%)	85 %	No. of 16 year-olds children free from gingivitis x 100 Total no. of new attendance of 16 year-olds children
4.	Percentage of non-conformance of optimal fluoride level at reticulation points. Levels<0.4ppm 25% Levels >0.6ppm 7 %	<0.4ppm 25%	No. of non-conformance(<0.4ppm) x 100 Total no. of readings at all reticulation points.
		>0.6ppm 7%	No. of non-conformance(>0.6ppm) x 100 Total no. of readings at all reticulation points.

4. LABORATORY SERVICES

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
	1. ACCURACY OF LABORATORY REPORTS		
	1.1 CHEMICAL PATHOLOGY		
1.	Performance in chemical pathology (measuring the analytical performance of maximum 28 analytes based on accuracy score. Accuracy score is a measure of how close the laboratory participants result to the "mean of comparator" of each analyte	Scale of "accuracy score" of 0 to 10 (0 means ideal score; 10 means poor score) 0 to 3 (< 3) indicates good analytical performance; 4 to 5 (<5) indicates satisfactory analytical performance; 6 to 8 (>6) indicates unsatisfactory analytical performance; 9 to 10 (>9) indicates poor analytical performance. 0 is the best analytical performance; while 10 is the very poor analytical performance	1. The assayed control materials are distributed by the biochemistry unit, imr. (organizing unit) 2. The sample of the control material is assayed by the participating laboratory. 3. The results of the assayed analytes are sent back to the biochemistry unit, imr. (organizing unit) 4. The data is processed. The sd, cv and the sdi for each analyte are computed. 5. The results are issued to the participating laboratory. 6. For each analyte which score more than + 2 sdi, the possible causes of poor performance have to be identified and remedial actions taken. 7. The remedial actions taken are entered in form b and returned to the organizing unit.
	1.2 MEDICAL MICROBIOLOGY INDICATORS		
2.	Performance in medical bacteriology	Overall scores: 80% accuracy failure to attain an 80% overall performance for two surveys of the year is considered unsuccessful performance	One batch of bacterial pathogens are sent to the participating laboratories for bacterial identification (species level) and antibiotic sensitivity testing
3.	Performance of hiv antibody testing	Correctly identify positive and negative samples	Samples are sent to anti-HIV screening laboratories for EIA and PA testing .The results are analysed for: 1)Response 2) Turnaround time 3) Accuracy of testing (Sensitivity & Specificity)
4.	Performance in antinuclear antibody testing (ana) using eia/if	At least 80% correct	batch of sera is sent to all the participating laboratory for antinuclear antibody testing (ana) using eia/if. The results are analyzed. And feedback is

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
			given to the participating laboratory.
5.	Performance in laboratory diagnosis tuberculosis – microscopy	Correctly identify all positive and all negative slides for TB bacilli on microscopy	The Public Health Laboratory has subscribed to the RCPA QA program. The slides are distributed to the participating laboratory for analysis The participating laboratory is expected to correctly identify all positive and all negative slides.
	1.3 TRANSFUSION INDICATORS		
6.	External qa blood banking : A) abo and rh grouping B) antibody screening C) antibody identification	Correctness	Performance: ABO & Rh grouping Antibody Screening Antibody Identification Crossmatching
7.	Neqap in haematology	Correctness	Performance in:- Full blood count Differential Count Morphology
8.	Performance in immunophenotyping: t cell subset enumeration	Correctness	Performance for t cell - cd8
9.	External qa for haemostasis	Correctness	One vial of patient's freeze dried plasma is sent. Lab analyse the sample for basic coagulation tests.
10.	Rate of laboratory error in hbsag testing	Less than 1.0%	Initial reactive – repeat reactive x 100% Total no. Of sample – repeat reactive
11.	Rate of laboratory error anti hcv testing	Less than 0.5%	Initial reactive – repeat reactive x 100% Total no. Of sample – repeat reactive
	1.4 HISTOPATHOLOGY INDICATOR		
12.	Adequacy of histopathology report on colectomy specimen for ca colon	100% should be acceptable	Acceptable: score of 22 and above Unacceptable: score of 21 and below
	2.0 TIMELINESS OF THE REPORT		
	2.1 CHEMICAL PATHOLOGY INDICATORS		
13.	Turnaround of urgent test	-90% of the urgent test request for Renal Profile (BUSE & Creatinine/ BUSE) and - Total Bilirubin (Pediatric) should achieved TAT ≤ 90 min	1. Percentage (%) achieved for TAT : No. Of URGENT/STAT tests requested TAT < 90 minutes x 100 % Total number of URGENT/STAT test requested

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
		and LTAT ≤ 45 min.	2. Percentage (%) achieved for TAT : No. Of URGENT/STAT tests requested LTAT < 45 minutes x 100 % TOTAL NO. OF URGENT/STAT TEST REQUESTED
	2.2 MICROBIOLOGY INDICATORS		
14.	Tat motion study of csf – bacterial meningitis	TTAT - 3 hrs after collection, LTAT - 1 hr after arrival to the lab	Total turnaround time for reporting the specimen CSF is monitored
	2.3 HAEMATOLOGY INDICATORS		
15.	Tat of urgent full blood count	90% should be reported within 60 minutes	Total no. Of urgent full blood count reported within 60mins x 100% Total no. Of urgent full blood count
16.	Tat of urgent pt and aptt	90% should be reported within 60mins	Total no of pt/aptt results informed/dispatched within 60 minutes x 100% Total no. Of requests for ap/aptt
	2.4 HISTOPATHOLOGY AND CYTOLOGY INDICATORS		
17.	Tat of urgent small biopsies	Tat for the report for 80% of urgent biopsies should be within 72 hours from the time the specimen is received in the laboratory	Total no. Of urgent biopsies reported within 72 hrs x 100% Total no. Of urgent biopsies
18.	Tat of hysterectomy specimen	80% of non-urgent hysterectomy specimen be reported within 14 days from the time it is sent to the laboratory	Total no. Of hysterectomy specimen reported within 14 hrs x 100% Total no. Of hysterectomy specimens
	3.0 EFFICIENCY OF SERVICE		
	3.1 TRANSFUSION INDICATORS		
19.	Cross match: transfusion (c: t) ratio	No greater than 2.5:1	Total no of units of blood transfused No. Of units of blood cross matched
20.	Expiry rate of red cell	Less than 5% of the total collection	Total no. Of expired blood x 100% Total no. Of blood collected per

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
			year
21.	Transfusion error rate (0 [zero defect])	0 [zero defect]	No. Of transfusion errors x 100% Total no of request for transfusion
	3.2 HISTOLOGY/CYTOLOGY INDICATORS		
22.	% Of cin diagnosed by histology in all the colposcopic biopsies done	90% of all colposcopic biopsies should show evidence of cin on histology	No of cin diagnosed on histology x 100% All colposcopic biopsies for cin
23.	Accuracy of reporting gynaecology smear: % of cytology-histology correlation	For all colposcopic biopsies, a minimum of 65% agreement must be achieved	no of smear diagnosed as hgsil x 100% Total no. Of colposcopic biopsies done
24.	Histo-cytopathology correlation for fnac of breast lesion	≥ 90% agreement	No. Of correct fna confirmed by histology x 100% Total no. Of fnac

5. TRAINING SERVICES

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
1.	Percentage of student that passes in every examination	85 % of students in every examination (not inclusive of repeat examination	No. of student passes x 100% Total no. of student
2.	Period of trainer-student meeting sessions	20 hours a week for each tutors	Total no. of contacts hours with students Credit hours for programme (didactic)
3.	Ratio of trainers to students	1:20 for basic training 1:10 for post basic courses	Total no. of contact hours Total no. of trainers
4.	Preparation of lesson plan	100% preparation of lesson plan for all scheduled topic	100%
5.	85% of students passing all OSCE station fixed		No. of OSCE station passes Total No. of OSCE station fixed

6. ENGINEERING SERVICES

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
	KMAM, CAWANGAN KEJURUTERAAN ALAM SEKITAR, BAHAGIAN PERKHIDMATAN KEJURUTERAAN		
1.	Residual Chlorine (RCl) < 2.8% (NC)	< 2.8% (NC)	(Number of samples contravening standard) × 100% (Total number of samples analyzed)

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
2.	E. Coli < 0.4% (NC)	< 0.4% (NC)	(Number of samples contravening standard) × 100% (Total number of samples analyzed)
3.	Combine RCl & E.Coli <0.3% (NC)	<0.3% (NC)	(Number of samples contravening standard) × 100% (Total number of samples analyzed)
4.	Turbidity <2.8% (NC)	<2.8% (NC)	(Number of samples contravening standard) × 100% (Total number of samples analyzed)
5.	Aluminum <10.2% (NC)	<10.2% (NC)	(Number of samples contravening standard) × 100% (Total number of samples analyzed)
	LLS (Linen and laundry Services)		
6.	Accepted Linen Per month	98 %	Total Pieces of Linen Accepted Per month X 100 Total Pieces of Linen Issued Per month
7.	Percent of Linen Issued Against Requested Per month	95 %	Total Pieces of Linen Issued Per month X 100 Total Pieces of Linen Requested Per month
8.	Percent of Compliance To Linen Delivery Schedule Per month	100 %	No. of on Time Linen Delivery Per month X 100 No. of Scheduled Delivery Per month
	CWMS (Clinical waste Management services)		
9.	Collection as per schedule	100 %	Collection not to schedule X 100 Collection as per schedule
10.	Transportation as per schedule	100 %	Trans not to schedule X 100 Trans as per schedule
	CLC (Cleansing Services)		
11.	Percentage of acceptable cleansing quality based on joint inspection	100 %	No. of unsatisfactory items inspected x 100 No. of items inspected
12.	Percentage of general wastes collected to schedule.	100 %	General waste Collected not to schedule x 100 General waste Collectied as per schedule
	KWS, CAWANGAN SELIA, BAHAGIAN PERKHIDMATAN KEJURUTERAAN		
	FEMS (Facility Engineering maintenance services)		
13.	% of PPM schedule completed as schedule per month	100 %	PPM Completed for the month X 100% PPM schedule as per HSIP
14.	% of asset meeting Uptime Target per month	100 %	No of Assets Meeting Uptime Target X 100%

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
			Total number of asset
	BEMS (Biomedical Engineering maintenance services)		
15.	% of PPM schedule completed as schedule per month	100 %	PPM Completed for the month X 100% PPM schedule as per HSIP
16.	% of asset meeting Uptime Target per month	100 %	No of Assets Meeting Uptime Target X 100% Total number of asset

7. PHARMACY SERVICES

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
	PHARMACEUTICAL CARE INDICATORS		
1	QAP1: Proportion of prescriptions intervened to total number of prescriptions received at out-patient pharmacy. (Outpatient & discharge prescriptions)	<2.5 %	No. of prescriptions intervened x 100 % Total no. of prescriptions received
2.	QAP 2: Proportion of prescriptions intervened to total number of Prescriptions received at in-patient pharmacy. (Unit of use/unit Dose prescriptions only)	<2.5 %	No. of prescriptions intervened x 100 % Total no. of prescriptions received
3.	QAP 3: Proportion of prescriptions wrongly filled and detected before dispensing to the total number of prescriptions counterchecked at out-patient pharmacy. (Outpatient & discharge prescriptions)	0%	No. of prescriptions wrongly filled detected before dispensing x 100 % Total no. of prescriptions counterchecked
4.	QAP 4: Proportion of prescriptions wrongly filled and detected before dispensing to the total number of prescriptions counterchecked at in-patient pharmacy. (Unit of use/unit dose prescriptions only)	0%	No. of prescriptions wrongly filled detected before dispensing x 100 % Total no. of prescriptions counterchecked
5.	QAP 5 : Number of items wrongly dispensed (Out-patients and Discharged Prescriptions)	0	No. of item wrongly dispensed
6.	QAP 6: Proportion of total parenteral nutrition requests compounded and supplied to the total number of requests received within the same day.	> 90%	No. of total parenteral nutrition request compounded and supplied within the same day x 100% Total no. of total parenteral nutrition requests received
7.	QAP 7: Proportion of Parenteral Nutrition cases reviewed by the Pharmacist to the total number of TPN cases received)	>80%	No. of parenteral nutrition cases reviewed by pharmacist x 100% Total no. of total parenteral nutrition received

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
8.	QAP 8: Proportion of assays interpreted and recommendations communicated to the requesting units/doctors to the total number of assays received within the same working day.	> 75%	No. of assays interpreted and communicated to the requesting Units/ Dr within the same working day x 100 % Total no. of assays received
9.	QAP 9: Proportion of assays interpreted and recommendations accepted by the requesting Units/Doctors to the total number of assays	>75%	No. of assays interpreted and recommendations accepted by the requesting Units/Dr x 100 % Total no. of assays received
10.	QAP 10: Proportion of toxicology cases interpreted and recommendations communicated within two hours to the requesting Units/Dr to the total number of toxicology cases received	100%	No. of toxicology cases interpreted and recommendations communicated within two hours to the requesting Units/Dr x 100% Total no. of toxicology cases received
11.	QAP 11: Proportion of cytotoxic drug reconstitution (CDR) requests reconstituted and supplied on the scheduled date to the total number of requests received	>90%	No. of CDR requests reconstituted and supplied on the scheduled date x 100% Total no. of CDR requests received
12.	QAP 12: Proportion of unused cytotoxic drug preparation to the total number of cytotoxic drugs reconstituted	<1%	No. of unused cytotoxic drug preparations x 100% Total no. of cytotoxic drugs reconstituted
13.	QAP 13: Annual turnover rate of stocks	3 – 6	Annual value of stocks issued (RM) Value of stock held annually (RM)
14.	QAP 14: Proportion of value of stocks written off to value of stocks held annually.	< 0.5 %	Value of stock written off for the year (RM) x 100% Value of stock held annually (RM)
	PRIMARY CARE INDICATORS		
15.	QAP KA 1: Proportion of prescriptions intervened to total number of prescriptions received at the Pharmacy Counter	< 2.5 %	No. of prescriptions intervened x 100 % Total no. of prescriptions received
16.	QAP KA 2: Proportion of prescriptions wrongly filled and detected before dispensing to the total number of prescriptions counter checked	0%	No. of prescriptions wrongly filled detected before dispensing x 100 % Total no. of prescriptions counterchecked
	LICENSING AND ENFORCEMENT INDICATORS (PILOT)		
17.	QAP E-1 Response to complaint within 2 weeks	90%	No. of responses to complaints within 2 weeks x 100% No. of responses to complaints
18.	QAP E-2: Pre-Operation Intelligence completed within 2	80%	No. of Pre-Op Intelligence completed within 2 months x 100

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
	months		% No. of Pre-Op Intelligence completed
19.	QAP E-3: Successful collection of relevant evidence in a raid	100%	No. of raids conducted successful x 100% No. of raids conducted
20.	QAP E-4: Completion of investigation paper within 4 months	100%	No. of investigation papers completed within 2 months x 100% No. of investigation papers completed
21.	QAP E-5: Proportion of licensed premise inspected to the total numbered of licensed premises	100%	No. of licensed premises inspected x 100% No. of licensed premises
22.	QAP E-6: Percentage of follow-up actions taken compared to the total number of follow-up action suggested	100%	No. of followed-up actions taken x 100% No. of followed-up actions suggested
23.	QAP E-7: Percentage of new licenses issued within 3 weeks as compared to the total number of new licenses issued	100%	No. of new licenses issued within 3 weeks x 100% Total no. of new licenses issued
	REGULATORY INDICATORS		
24.	QAP N-1: Percentage of prioritized category of medicinal products with complete dossier evaluated within 6 months	100%	No. of applications evaluated within 6 months x 100% Total no. of applications with complete dossier received
25.	QAP N-2: All registration samples analysed within 4 months	90%	All registration samples analysed within 4 months x 100% Total no. of registration samples analysed
26.	QAP N-3: All market surveillance samples received and analysed within 6 months	90%	No. of market surveillance samples analysed within 6 months x 100% No. of market surveillance samples analysec
27.	QAP N-4: All licensed manufacturing premises inspected according to planned schedule	90%	No. of manufacturing premises inspected x 100% No. for manufacturing premises targeted for inspection
28.	QAP N-5: Proportion of registered pharmaceutical & traditional product sampled under the surveillance programme	10%	No. of product sampled for surveillance x 100% Total no. of products for surveillance
29.	QAP N-6: Percentage of complaint received on registered products investigated and resolved within 6 weeks	80%	No. of complaint investigated and resolved within 6 weeks x 100% No. of complaint received
30.	QAP N-7: Regulatory actions taken on registered products with serious issues within 48	100%	No. of products taken action on within 48 hours x 100% No. of registered products with serious issues
31.	QAP N-8: Dissemination of all important information regarding safety issues of registered products to the public	100%	No. of products where important information has been disseminated x 100% No. of product involved with

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
			safety issues

8. PLANNING AND DEVELOPMENT

No.	Name of Indicator (Standard Set)	Standard (Optimal Target)	Formula
1	Percentage of Medical Brief of Requirement (MBOR) completed within 3 or 6 months from directive for project implementation.	(95 %)	Within 3/6 Months of receiving Directive x 100% Total No. of Projects Requiring MBOR

ANNEX 9

Malaysian plants and herbs with therapeutic values

Scientific name	Local name	Therapeutic indications	Research and development (R&D)
Calophyllum lanigerum	Bintangor	HIV/AIDS	Collaboration between University of Illinois at Chicago/ National Cancer Institute (NCI) U.S.A. and the Forest Research Division, Sarawak 1987-1991 resulted in the discovery of **Calanolide A** which is in phase II clinical trials at NCI
Aglaia stellatopilosa	Rukang	Major types of cancer cells, including lung, breast, prostrate, leukemia and brain tumors	As result of collaborative research between Government of Sarawak and AMRAD Natural Products Pty. Ltd. Australia (later Cerylid Biosciences) **Silvestrol** was isolated, now undergoing preclinical tirals at NCI
Centella asiatica	Pegaga	To enhance skin cleansing and the elimination of impurities, accelerate skin healing, reduce inflammation and to improve venous circulation	FRIM in joint venture with the Massachusetts Institute Technology (MIT) to develop bio-active products
Eurycoma longifolia	Tongkat ali	To improve male vitality, sexual function and increased resistance to stress	FRIM in joint venture with the Massachusetts Institute Technology (MIT) to develop bio-active products
Andrographis paniculata	Hempedu bumi	Diabetes, analgesic, antimalarial, anti-inflammatory, antineoplastic, antiulcerogenic, antibacterial, febrifuge, antiplatelet, antidiarrhoeal and antithrombotic properties, also possess protective activity against various liver disorders.	Local collaborative research projects between (MARDI, UPM), USM, and (USM, IMR), on development and clinical studies as commercial preparation for the treatment of Diabetes
Labisia spp	Kacip Fatimah	To induce and facilitate childbirth as well as post-partum medicine	Local collaborative research projects between (FRIM, UMS), UKM, (IMR, PPUKM), (IMR, USM), and (IMR,

			PPUKM, MOH, HUSM, UH) for estrogenic and androgenic activities
Gynura percumber	Sambung nyawa	Hepatoprotective	
Mitragyna speciosa	Ketum	Antimalaria properties	
Morinda spp	Mengkudu	Antioxidant and help support the immune system	
Orthosiophon spp	Misai kucing	Relieve joint stiffness and inflammation, enhance the removal of acids and wastes and assist in the treatment of arthritis, gout and rheumatism	

Source: IMR, Forestry Sarawak, Cragg et al (1999), Frost & Sullivan (2009)

ANNEX 10

Definition of Criteria and Indicators for STI score rating

1. Economics

1.1 Market value: Malaysian share of the global market/pie

Status	Scoring
Small (less than $500 million)	1
Medium ($500 million to 1 billion)	2
Large (more than $1 billion)	3

1.2 Revenue: Current revenue for Malaysia

Status	Scoring
Small (less than $500 million)	1
Medium ($500 million to 1 billion)	2
Large (more than $1 billion)	3

1.3 Expected growth: Annual growth rate for Malaysian share of the market (refer to 1.1)

Status	Scoring
Less than 10%	1
Between 10% to 19%	2
More than 20%	3

2. Research and development infrastructure

2.1 Level of investment: Current amount of US$ invested in the STI area

Status	Scoring
Low (less than $100 million)	1
Medium ($100 to $500 million)	2
High (more than $500 million)	3

2.2 Availability of specific physical infrastructure for research and development

Status	Scoring
No infrastructure	0
Yes, but not adequate	1
Yes, adequate (local lab)	2
Well established infrastructure (Research and testing facilities locally and/or internationally)	3

2.3 Networking

Status	Scoring
No networking (work within the institution)	0
Local networking (national level)	1
Regional networking	2
Global networking	3

3. Human capital

3.1 Trained/skilled researchers

Status	Scoring
Grossly inadequate (no highly trained researchers)	0
Inadequate (less than 10 highly trained researchers; PhD and above)	1
Adequate (more than 10 researchers, and established post-graduate programmes)	2
Well developed human capital (Highly trained researchers with established post-doctoral program)	3

4. R&D policy

4.1 Supporting policy

Status	Scoring
No policy document or guidelines	0
Guidelines are available	1
Policy document in preparation	2
Well established policy document and/or legislation	3

5. R&D outputs

5.1 Research publication

Status	Scoring
No publication	0
Published in local publication with no impact factor	1
Published in local and/or international publication with impact factor	2
Published in local and/or international with high impact factor (3 and above)	3