

# Health Biotechnology Development in Malaysia: Targeting Local and Global Health Needs through Health Technology

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## I. INTRODUCTION

During last few decades, Malaysia has successfully transformed from an agriculture based poor nation to a modern industrial upper middle income country. Since the independence in 1957 till 2005, real gross domestic product (GDP) has grown by an average of 6.5 per cent per annum (9<sup>th</sup> Malaysian Plan 2006). Malaysia is ranked 61 in Human Development Index (HDI) out of 187 countries with the HDI value of 0.761 which is classified as high human development country in 2011(UNDP, 2011).

Biotechnology in Malaysia is identified as one of enablers to accelerate the transformation of the country into knowledge based economy and industrialized country by 2020. The government’s interest in biotechnology as a key tool for development was started since 5<sup>th</sup> Malaysian Plan (1986-1990), nevertheless, more emphasize and support was given during 8<sup>th</sup> Malaysian plan (2001-2005). In 2005, the government boosted its’ support in this industry by launching National Biotechnology Policy (NBP) and set up several leading agencies such as BiotechCorp to enforce this 15-years of master plan (see **Box 1**). In 9<sup>th</sup> Malaysian Plan (2006-2010), government have allocated RM2.0 billion to support the development of all stages of biotechnology value chain and implementation of the policy has comprised three main phases which are capacity building phase (2006-2010), science to business phase (2011-2015) and global presence phase (2016-2020). The NBP has identified nine thrust areas to be focused and outlined three stages of goals to achieve the target of being the biotechnology

<b>BOX 1 The Biotechnology Master Plan (2005-2020)</b>		
<b>PHASE 1 (2005-2010) CAPACITY BUILDING</b>	<b>PHASE 2 (2011-2015) SCIENCE TO BUSINESS</b>	<b>PHASE 3 (2016-2020) GLOBAL BUSINESS</b>
<ul style="list-style-type: none"> <li>• Adoption of policies, plans and strategies.</li> <li>• Establishment of advisory and implementation Councils</li> <li>• Establishment of Malaysian Biotechnology Corporation Sdn Bhd (BiotechCorp)</li> <li>• Capacity Building in Research &amp; Development</li> <li>• Industrial Technology Development</li> <li>• Develop Agricultural, Healthcare and Industrial Biotechnologies</li> <li>• Develop Legal and Intellectual Property Framework</li> <li>• Incentives</li> <li>• Business and Corporate Development through Accelerator Programmes</li> <li>• Bioinformatics</li> <li>• Skills Development</li> <li>• Job Creation</li> <li>• Regional Biotechnology Hubs</li> <li>• Development BioNexus Malaysia as a Brand</li> </ul>	<ul style="list-style-type: none"> <li>• Develop expertise in drug discovery and development based on biodiversity and natural resources.</li> <li>• New Products Development</li> <li>• Technology Acquisition</li> <li>• Promote Foreign Direct Investment participation</li> <li>• Intensify Spin-off Companies</li> <li>• Strengthen Local and Global Brands</li> <li>• Develop Capability in Technology Licensing</li> <li>• Job Creation</li> </ul>	<ul style="list-style-type: none"> <li>• Consolidate Strengths and Capabilities in Technology Development</li> <li>• Further Develop Expertise and Strength in Drug Discovery and Development</li> <li>• Leading Edge Technology Business</li> <li>• Maintain Leadership in Innovation and Technology Licensing</li> <li>• Create greater value through Global Malaysian Companies</li> </ul>

hub in the world. The policy has outlined Malaysian competitive advantages in biotechnology and building blocks required to translate these advantages to tangible results. At each phase, there are indicators that targeted to achieve as shown in **Table 1**. In 2020, the total Investment by private sector and government is expected to reach RM30 billion; 280,000 people are expected to be employed in biotechnology related sectors; expected total revenue is RM 270 billion and 5% of the GDP is expected to be contributed by this industry. The country’s biotechnology industry already surpassed the phase 1 of capacity development stage and there are significant developments in key indicators. Yet, it’s essential to understand the current development and situation to evaluate the achievements and directions, at the same time, it’s crucial to understand the challenges and obstacles that are faced by this industry.

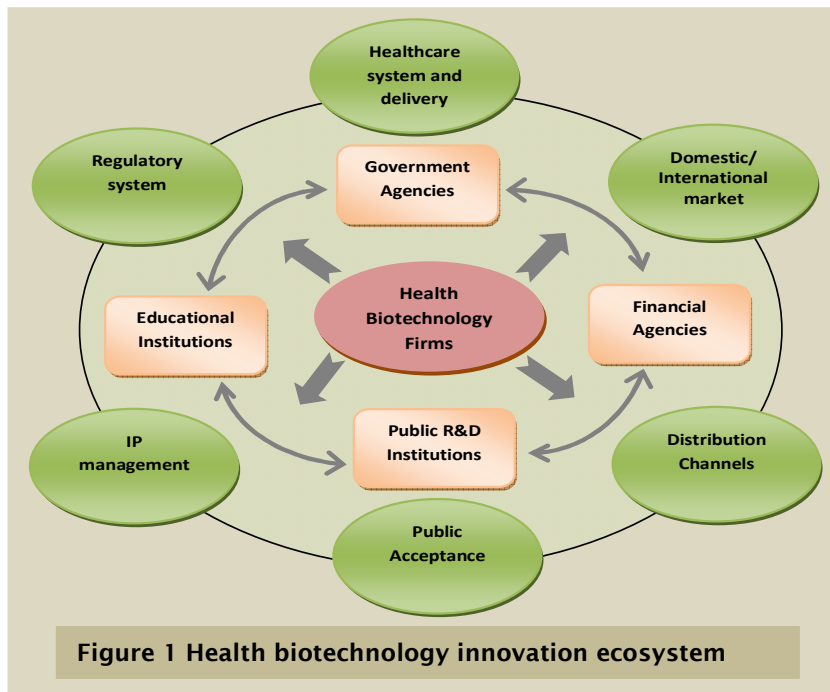
<b>Table 1 Key Indicators for biotechnology industry in Malaysia, 2005- 2020</b>				
<b>Indicators</b>	<b>Phase I 2005 to 2010 “ Capacity Building”</b>	<b>Phase II 2011 to 2015 “Science to Business”</b>	<b>Phase III 2016 to 2020 “Global Business”</b>	<b>Total Phases I to III</b>
<b>Investment by Private Sector and Government</b>	RM6b	RM9b	RM15b	RM30b
<b>Employment</b>	40,000	80,000	160,000	280,000
<b>No. of Companies</b>	25	25	50	100
<b>Total revenue</b>	RM20b	RM80b	RM170b	RM270b
<b>Contribution to GDP</b>	2.5%	4%	5%	5%

In this paper, a situational analysis was carried out for Malaysian health biotechnology industry to examine the capabilities and resources that can be leveraged to address the local and global health needs while ensuring the economic benefit to the country.

## **II. STUDY METHODOLOGY**

Innovation ecosystem is the theoretical framework for the analysis of this study which is made up of various institutions that contribute to the creation, diffusion and use of new, economically useful knowledge. They are held together by a web of linkages and synergies (Thorsteinsdóttir, 2004; Lundvall, 1992). Health innovation system consist of multiple components which operating both public and private sectors, such as education, healthcare system, research, financing, manufacturing, technology management practices, regulatory role, intellectual property management and domestic, international markets, etc. And the system also refers to the technical, financial, legal, social, commercial interactions and interactions between components (Morel, 2005). As illustrated in **Fig1**, biotechnology firms are the heart of the innovation system and it’s essential to understand each sector’s roles in the product development process. The dynamic linkages among sectors and components

contribute significantly to the production of innovative health products and efficient delivery of the products to the end-users (Morel, 2005; Thorsteinsdóttir, 2004).



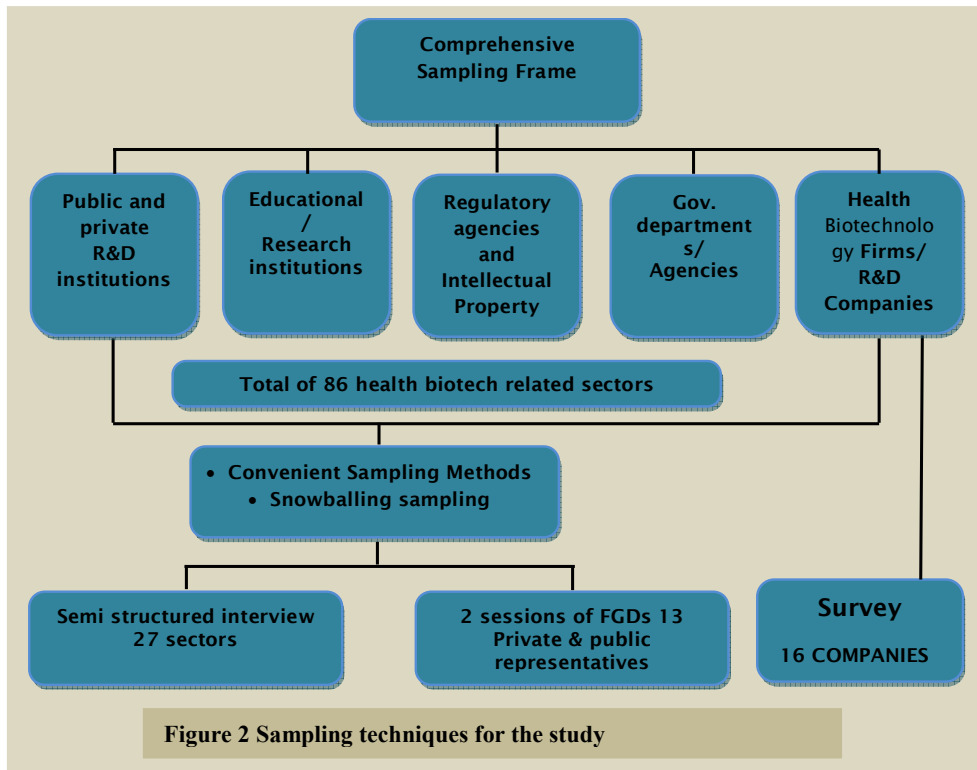
## 2.1 Study design

Case study approach was applied as it can be defined as an empirical inquiry that investigates a phenomenon within its real-life context (Yin 2003?). The main feature of the case study is its' intense focus on the single phenomenon within its real life context. Embedded single case study design is chosen as the most applicable approach for this study which defined as the single case study has more than one unit of analysis where the whole Malaysian Innovation system is the case, and each biotechnology company/Public institutes/Government institutions are the multiple subunits of this case study.

In this study, Biotechnology was defined as *“the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services (OECD, 2005).* Healthcare Biotechnology relates to the applications of biotechnology for medicine and health. For the purpose of this study, we focused on health related biotechnologies and excluded the biotechnologies related to agriculture, environment and the industry. We also included genome-related technologies (such as bioinformatics) and health biotechnology-related contract services (including R&D, clinical development and manufacturing).

## 2.2 Sample selection

A comprehensive sampling frame was developed to include the cases for the study and volunteer participation was requested from the chosen sectors via formal invitation letter attached with the information sheet to the participants (see **Fig 2** for sampling technique). The key informants were in high profile management positions or the founders of the corresponded sectors and they were chosen based on their expertise and experience in specific health related biotechnologies in Malaysia.



They were identified by examining not only background documents describing the health biotechnologies innovation systems in Malaysia, but also information on websites from various sectors. A total of 27 key informants were interviewed and they were from government departments, public and private research institutes, educational institutions, private-sector enterprises, regulatory agencies and intellectual property institutions (**Table 2**).

Recommendations and suggestions were sought from people knowledgeable in this field and ‘Snowball’ sampling technique was used to identify more additional informants by initially interviewed participants. All interviewed health biotechnology companies were requested to fill up the survey questions after the interview session and in some cases, questionnaires were sent and collected via e mail. Participants for the focus group

discussions also were invited from the identified list of key informants who are the main players in the development of health biotechnology in Malaysia.

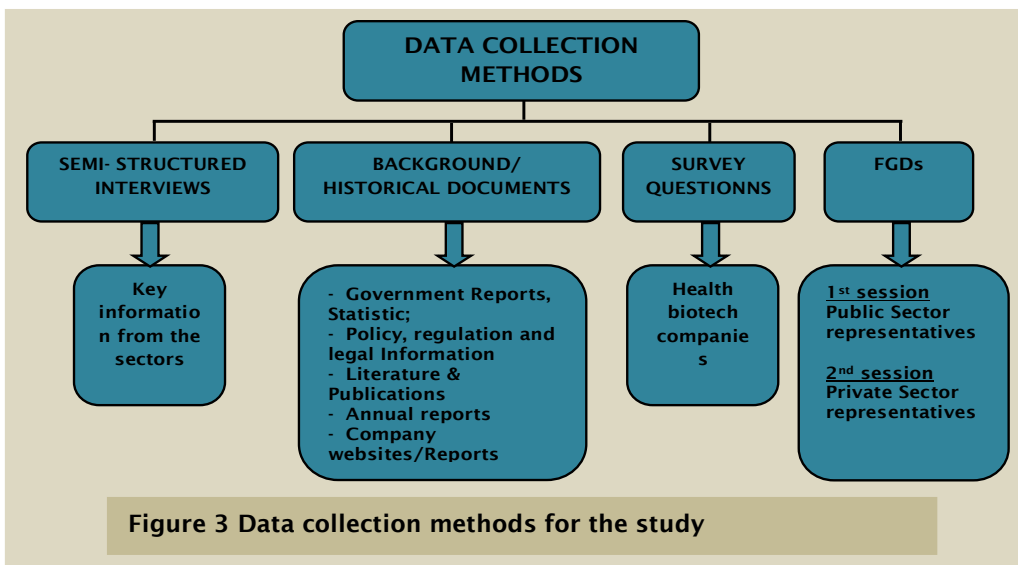
**Table 2. The distribution of interviewed participants for the study**

Organization	Number
Government agencies	2
Health biotechnology companies	16
Regulatory agencies	3
Public educational research institutions	6
<b>Total</b>	<b>27</b>

### 2.3 Data collection

The case studies collected through several sources such as background/historical documents, Semi-structured interviews with key informants and focus group discussions with the representatives from the various sectors. Survey questionnaires were used to gain some specific supplementary data from health biotech companies (Fig 3).

**Background/Historical documents:** The documents gathered and analyzed were included a variety of published papers and books on different aspects of the health biotechnology sector, governmental reports and other official documentations (for example, policy briefs and descriptions of the legal and regulatory arrangements), as well as websites of institutions and firms. These government documents were accessed through the official websites of BiotechCorp, MOSTI, BIOTECK, MARDI, ASM, NPCB, and MTDC, ect. Patent data was collected from Intellectual Property Corporation of Malaysia (MyIPO).



**Semi-structured Interviews:** Interviews with key informants were a vital part of the data collection and an interview guide was developed to use in semi-structured face-to-face interviews. The interview guide included 27 questions which were consisted of 5 main parts, which were 1) background/history of the sectors, main activities and product/services; 2) reasons for investing in health biotechnology in Malaysia, such as drivers, incentives, local needs, government policy, target markets, etc. 3) financial issues such as financial capacity, funding availability, and potential sources for funding. 4) Capabilities issues such as number of employees, R&D capabilities, manufacturing facilities, current technologies and number of IPs, ect. 5) Collaborations and partnership experiences such as reasons, outcomes of collaborations, role and contribution for the partnerships and lessons learned from the experiences. Lastly, some policy related questions such as satisfactions, opinions on the current biotech policy/regulations and recommendations to encourage the development.

**Focus Group Discussion (FGD):** To obtain more comprehensive and dynamic information on health biotechnology industry in Malaysia, two separate sessions of FGDs were conducted among representatives from both public and private sectors. The discussions were carried out to achieve three main objectives and were guided through eight questions (see **Box 2**). Total of 13 participants attended the discussions and each session was conducted for a half day. Prior to the discussion, the consent from the participants was obtained to record the sessions via digital recorder and also taken notes manually by the researcher. The recorded information kept confidential and used for analyzing purpose only.

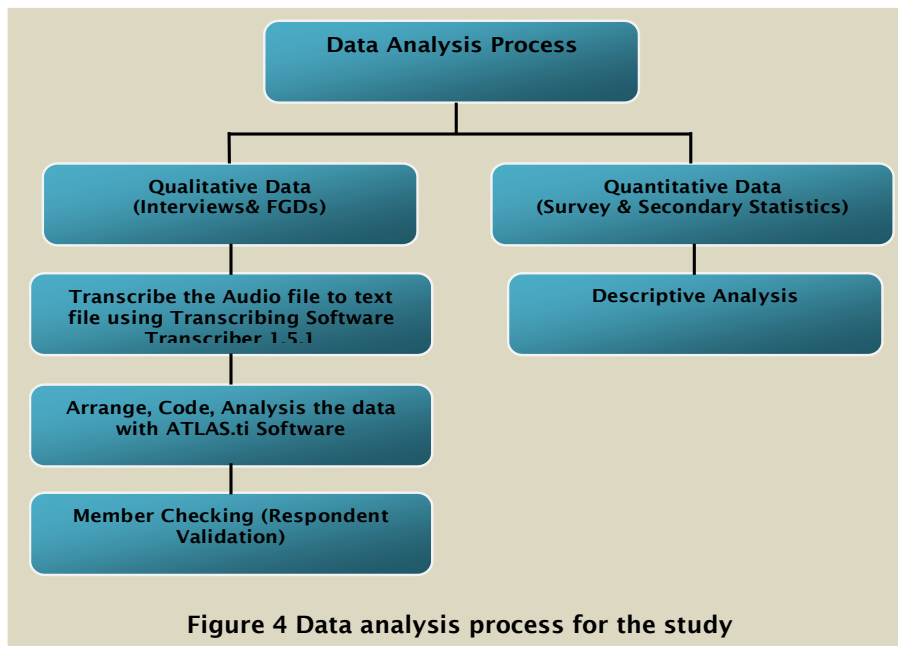
**BOX 2 Main objectives and questions for Focus Group Discussion**

- To identify the main features of the Malaysian health biotechnology sectors;
  - To identify the success stories and reasons for success of the country's HB sectors through comparison with other countries;
  - To identify the main challenges and recommendations to overcome these barriers for HB
- 
- Q1. What are the main features of the country's health biotechnology sectors? List of sectors can affect health biotechnology industry in Malaysia.
- Q2. What are their roles and linkages between them?
- Q3. What are the main HB sectors in Malaysia is moving the industry?
- Q4. What are the success stories in Malaysian Health biotechnology industry?
- Q5. In your opinions, what are the driving factors that encourage the success in the industry?
- Q6. What are the differences of those successes with the similar examples in other developing countries? *Such as India, China, South Korea (developed), etc.*
- Q7. What can we learn from these countries' experiences and what can we adapt to improve the current situation?
- Q8. What you think are the main challenges that biotechnology sectors are facing?

**Survey:** Survey questions were used to gather additional supplementary information on each health biotechnology companies. The questionnaires were consisted of 43 questions related to mainly information on background, financial capacity, ownership, employment characteristics, products/services and partnership/collaboration activities locally and also internationally etc. Key informants were asked to fill up the questions after the interview session or in some cases, were sent via e mail to the company.

## 2.4 Data Analysis

The analysis integrated the in-depth qualitative analysis of the interviews, focus group discussions with the quantitative data and statistics gathered from the survey and secondary data from company websites, government agencies reports and published documents, etc. As shown in the **Fig 4**, audio recorded interviews and discussions were transcribed to text files using software Transcriber 1.5.1, and then organized, coded and analyzed using ATLAS.ti 6.1 software.



The qualitative and quantitative data was integrated and content analysis was carried out to achieve more comprehensive and diverse understanding on the current situation of this industry by drawing the broad picture of each sectors activities and level of involvements in the development. The validation of the findings will be done through member checks, which will be required to obtain the approval and verification of the case studies with key informants for the interview.

## III. RESULTS AND DISCUSSION

### 3.1 Country profile

Malaysia is located in Southeastern Asia, neighboring with Thailand, northern one-third of the island of Borneo, Indonesia, Brunei, the South China Sea and south of Vietnam, total area is 329,847 sq km (World Fact book, 2012). As an emerging Asian country aspiring to move into be one of the knowledge based high technology-driven newly industrializing economies (NIEs), Malaysia has been categorized in the group of countries that

have the potential to create new technologies on their own (MOSTI, 2005; Mun and Su, 2004). Over the 50 years, Malaysia has achieved some successes in diversifying its economy from dependence on exports of raw materials to the development of manufacturing, services and tourism, etc. It is the 19th biggest trading nation in the world, with trade in excess of RM 1 trillion. The country continues to enjoy political stability, with a diverse yet united population. At the same time, per capita income has increased 26 times to RM 22 345 (US\$ 6725.98) and the incidence of poverty has been reduced to less than 6.0% (BiotechCorp, 2008a). Malaysia is home to a vast range of rich natural resources such as the world's oldest tropical rainforest, and it's the 4th mega-diversity nation in Asia and 12th in the world with estimated 15,000 flowering plant species (accounts for 9 percent of world's total) and 185,000 animal species (accounts for 16 percent of world's total) (BiotechCorp, 2008a). The practice of traditional and herbal medicine by its multiracial, multicultural population can be the strength for Malaysia to the lead of its Asian neighbors in the region (BiotechCorp, 2008b).

Malaysia has achieved remarkable socio-economic development and dramatic improvement in health status of its population during the years (Table 3). 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. As illustrated in Table 3, the other major health indicators such as the infant mortality rate, under-five mortality rate and maternal mortality rate are declined significantly from the previous years, shown as results of the overall effectiveness of healthcare in this country (WHO, 2011; Department of Statistics of Malaysia, 2011).

<b>Table 3 Major development indicators of Malaysia (1990-2010)</b>			
<b>Socio economic indicators</b>	<b>Year 1990</b>	<b>Year 2000</b>	<b>Year 2010</b>
Population (millions)			27,468
Annual population growth rate (%)	2.6		2.17
Human Development Index (value/rank)	0.737	0.797	0.805/61**
Gross national income per capita (PPP int. \$)	4,590	8,370	13,710
Total expenditure on health (% of gross domestic product)		3.2	4.6
Adult literacy rate (%ages 15 and above)			95.1*
Unemployment rate (%)			4.5*
<b>Health Indicators</b>			
Life expectancy at birth (years)	71	72	74.2**
Infant mortality rate (probability of dying by age 1 per 1000 live births)	16	9	6
Under-Five mortality rate per 1,000 live births	18	10	6
Maternal mortality ratio (per 100 000 live births)	56	39	31

\*Data for 2009 \*\*Data for 2011  
**Sources:** Asian Development Bank, 2010; World Bank, 2010; WHO, 2011; UNDP, 2011; UNDP, 2009;

According to 2010 CENSUS by Department of Statistics, the population is reached nearly 28 millions, with 2.17 percent of population growth rate during 2000 till 2010, and life expectancy at birth was 74.2 years in 2011 (WHO, 2011). Malaysia's competitiveness lies in the quality and effectiveness of the products it has produced,



political stability, 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.

### 3.2 The success of Malaysian Health Biotechnology sector

During 8th Malaysian Plan (2001-2005) period, Malaysian government has established several initiatives to support the development of biotechnology sector to drive the economic growth and wealth creation of the country. The National Biotechnology Directorate was established and allocated a total of RM95.3 million biotechnology R&D grants for 47 biotechnology research projects in 2001. Out of all, 25 of them were health related biotechnology projects and consisted of more than 62% (RM59.2 million) of the total R&D grant. Among these R&D projects, 27 patents were filed locally and 1 was filed internationally (MOSTI, 2005).

Government has set up few institutions, laboratories such as Malaysian agriculture research and development institute (MARDI), genomics molecular biology at the University Kebangsaan Malaysia (UKM), Pharmaceutical and Nutraceuticals at the University Putra Malaysia (UPM) to improve the specialized facilities for biotechnology R&D and training for skilled personnel. In 2001, National Biotechnology and Bioinformatics Network (NBBnet) was established to improve and promote the collaborations and networking among research institutions, universities and industry. It also contains databases and information on local genetic resources, links and major R&D projects. **Table 4** presents the overall expenditure for biotechnology development during 8<sup>th</sup> Malaysian Plan period which is RM574.4 million, mainly focused on biotechnology R&D, business development and infrastructure. These efforts has played major role in laying the basic foundation towards building a biotechnology industry in terms of development of human capital, R&D infrastructure and facilities to foster innovative development.

<b>Table 4 Development expenditure &amp; allocations for Biotechnology, 2001-2010 (RM Million)</b>		
<b>Programme</b>	<b>8MP Expenditure</b>	<b>9MP Allocation</b>
<b>Research and Development(R&amp;D)</b>	190.0	463.0
Biotechnology R&D initiatives	190.0	363.0
Biotechnology commercialization Fund	-	100.0
<b>Biotechnology Acquisition program</b>	-	100.0
<b>Biotechnology Business development</b>	216.8	529.8
Technology & IP management	69.9	100.0
Entrepreneurship Development	-	50.0
Agro- biotechnology Projects	46.9	79.8
Institutional Support and Equity	100.0	300.0
<b>Biotechnology Infrastructure</b>	167.6	928.5
<b>Total</b>	<b>574.4</b>	<b>2,021.3</b>

*Source:* Economic Planning Unit; 9<sup>th</sup> Malaysian Plan.

One of the main successes mentioned by most of the participants is the launching of National Biotechnology policy and the establishment of BiotechCorp as a leading agency for the industry development and its' BioNexus program which provided for the biotechnology companies. One participant from BiotechCorp highlighted that the BioNexus status has one of the most attractive tax breaks globally as it provides for 10 years of tax exemption to the company from the time it derives profits. As mentioned earlier, In 2005, Malaysian government has launched the National Biotechnology Policy (NBP) which provides comprehensive framework for the industry development by outlined set of goals, priorities and strategies (see **BOX 1**).

The 15- year master plan has three phases with targeted indicators to achieve and encompasses nine thrusts where the healthcare biotechnology is the second thrust areas to be focused on (MOSTI, 2005). As in **Table 4**, during 9<sup>th</sup> Malaysian Plan period RM2 billion has been allocated to develop biotechnology industry in all aspects. Out of total, 45.9% is allocated for physical infrastructure development where the remaining allocation is dedicated for R&D, business development and commercialization. To execute these plans and strategies effectively, Malaysian Biotechnology Corporation (BiotechCorp) was established to act as a lead agency to implement the policy and promote development of local biotechnology industry. One of the initiatives by BiotechCorp was to set up special status called BioNexus which is awarded for qualified international and local biotechnology companies to facilitate them to start up and grow continuously (see **BOX 3**) (BiotechCorp, 2010).

This plays a major role in achieving the objective of create a network of biotech companies and organizations that build on the existing infrastructure of universities and research institutes throughout the country. There are three major centers of excellence, namely, the Institute of Agricultural Biotechnology, the Malaysian Genome Institute, the National Pharmaceutical and Nutraceutical Institute which are the results of

### **BOX 3 The BioNexus Status and the BioNexus Bill of Guarantees**

The BioNexus is a special award for qualified local and international biotechnology companies in Malaysia and the status endows financial incentives, grants and other guarantees to assist growth. Since the establishment, BiotechCorp has facilitated the development of 207 BioNexus-status companies in Malaysia with total approved investment of RM 2.118 billion. Apart from the general benefit and support, BioNexus companies enjoy following list of privileges contained in the BioNexus Bill of Guarantees:

- Freedom of ownership
- Freedom to source funds globally
- Freedom to bring knowledge workers
- Eligibility for competitive incentives and other assistance
- Eligibility to receive assistance for international accreditation and standards
- A strong intellectual property regime
- Access to supportive information network linking research centres of excellence
- Access to shared laboratories and other related facilities
- BiotechCorp as the one-stop agency for all biotechnology assistance

BioNexus programs and each of these research centers focus on particular areas of biotechnology research and development in healthcare and agriculture (BiotechCorp, 2010; Scott, 2007). BioNexus Status companies receive continuous support and assistance from BiotechCorp on immigration related matters, IP advisory and regulatory services and employment related matters. BiotechCorp also provides a wide range of capacity building programs covering a variety of subjects to assist biotechnology entrepreneurs in managing their business locally and internationally (BiotechCorp, 2010). The Malaysian government has also allocated \$3 billion in its budget, 2008 to enhance healthcare, increase the supply of medicine, intensifying research and enforcement activities and strengthen healthcare biotechnology (Sachin and Krishna, 2010).

During last 5 years, there has been remarkable development in biotechnology industry in terms of key indicators such as investments by private & public sector, number of biotechnology companies, revenues, employments and number of patents (**Table 5**). According to BiotechCorp 2010 report, there are total of 349 biotechnology companies. Out of all, 143 (41%) were involved in the agricultural biotechnology sector followed by the healthcare biotechnology sector with 134 (38.4%) and the remaining 72 (20.6%) were in the industrial biotechnology sector. Total investment of healthcare biotechnology companies was USD 235.1 million (RM 822.8 million) and it represents about 28.7% of total investment for the biotechnology industry in 2009. Total investment of USD 122.3 million (RM 428 million) have been approved for BioNexus Status companies.

**Table 5 Malaysian Biotechnology Sector Overview**

Sector	Number of Companies*	Revenue		Investment	
		USD million	RM million	USD million	RM million
Agricultural	143	57.9	202.7	287.5	1,006.3
Healthcare	134	47.4	165.8	235.1	822.8
Industrial	72	44.8	156.9	297.6	1,041.6
<b>Total</b>	<b>349</b>	<b>150.1</b>	<b>525.4</b>	<b>820.2</b>	<b>2,870.7</b>

Of the 134 healthcare biotechnology companies in Malaysia, 51 companies (38.1% of total companies) have obtained BioNexus Status which generated a total revenue of about USD 24.9 million (RM 87 million) in 2008. According to BiotechCorp latest report (2010), BioNexus companies related to health care biotechnology has the RM 604.6 million investment (~30%) out of total investment which is the lowest compare to other biotechnology sectors and growth rate also the lowest with 15% where agriculture and industrial sectors are higher with 25.40% and 62.40% respectively in 2010. And healthcare sector has the highest percentage of knowledge workers compare to other sectors which is 47% of total workers in all biotechnology industry.

As we can see, **Table 6** illustrates the targeted key indicators for biotechnology industry and actual achievements during first five year from 2005 to 2010. In 2010, the number of BioNexus companies and number of employments are outnumbered the targets with 188 companies and by creating 54,766 job in this industry.

<b>Table 6 Key Indicators for the Biotechnology Industry at Dec 31, 2010</b>					
Indicators	TARGETS				Achievements in 2005-2010 period
	Phase 1 (2005-2010)	Phase 2 (2011-2015)	Phase 3 (2016-2020)	Total (2005-2020)	
Investment by Private Sector and Government	RM 6 billion	RM 9 billion	RM 15 billion	RM 30 billion	RM 5.4 billion*
Number of BioNexus companies	25	25	50	100	188
Employment (at end period)	40,000	80,000	160,000	280,000	54,776
Annual Revenue (at end period)**	RM 20 billion	RM 80 billion	RM 170 billion	RM 270 billion	RM 13.5 billion
Contribution to GDP	2.5%	4%	5%	5%	2.2%

However, the investment by public and private is lesser than the expected which is RM5.4 billion and it includes RM 2.2 billion from the private sector and RM 3.2 billion from the Government (BiotechCorp,2010). Annual revenue for this period is RM13.5 billion which is RM7 billion lesser than the expected revenue. At the end of this period, the contribution of biotechnology industry to the GDP is 2.2% which is also smaller than the expected target.

### 3.3 Main features of Malaysian health biotechnology industry

Malaysian health biotech industry is mainly dominated by the sub sectors such as medical devices, natural products, and generic drugs and so on (see **Table 7**). The mentioned focus areas are paralleled with the emphasized areas by the Malaysian government in biotechnology industry (MOSTI, 2005; Frost & Sullivan, 2009).

According to the respondents, those are the areas that companies are focusing on to produce health biotech products as its more easier, feasible and effective due to various favorable factors such as requirement for less investment, less risky, easier to pass through the regulatory system, easier to penetrate the local market, shorter time period of production process and faster to gain revenues, etc. Because of all these factors, development of novel drugs and vaccines are not the focus areas to invest for private biotech companies as One of the participants has demonstrated concern on this point by mentioning that “...*There are some Issues with novel drug development in Malaysia. It’s easy for the generic drugs get the approval from government regulatory*

agencies, but for the novel drugs and vaccines is difficult to get the approval, need to get the data from outside the country, to do the clinical trials outside or need to get approval from other country first before apply locally...” Similar issues regarding regulatory approval and registration procedures for health biotechnology products are stressed by few participants as the procedures and requirements are not clearly explained to the companies during their application.

These concerns are in line with the finding from other studies as it stated as “*Its difficulty in securing funds from local financial institutions because this industry is considered a “high risk businesses. 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”* (ASM, 2010). This shows the urgent necessity of support for the local companies to grow by create a conducive environment for them to develop, produce, register and commercialize their products in local as well as in international market. It was suggested that the clear application pathway and approval procedures need to be developed and provided to assist the biotechnology companies to develop more innovative health products.

<b>Focus areas &amp; Activities</b>	<b>Main players</b>
<ul style="list-style-type: none"> <li>• Medical Devices</li> <li>• Natural products</li> <li>• Generic drugs</li> <li>• Orthopedics</li> <li>• Contract Research Organizations (CROs)</li> <li>• FDI on manufacturing &amp; Commercialization</li> <li>• Being a clinical trial site for big pharmaceutical companies</li> </ul>	<ul style="list-style-type: none"> <li>• Ministries: MOH; MOHE; MOSTI; MITI; MOF</li> <li>• Implementing agencies: PEMANDU; BiotechCorp</li> <li>• Regulatory bodies: NPCB; myIPO</li> <li>• Venture Capital companies: MTDC; MLSCF</li> </ul>

As expressed by the representative from BiotechCorp, there is an increasing trend in foreign direct investments recently and it has been their focus to bring more Foreign Direct Investment (FDI) to invest on manufacturing and commercial activities to reach the NBP phase 2 targets by obtaining the tangible results. However, the discussions again lead to the major question of “are those strategies able to sustain the development of health biotechnology in long term as the basic fundamental research is very weak in this country?” The areas of CRO, CMOs are also becoming the focus sectors in health biotechnology as there is increasing number of companies involving in contract manufacturing and service activities (MOSTI, 2005; Frost & Sullivan, 2009).

Respondents have mentioned that these sectors are building a base for Malaysia to become one of the clinical trial (CT) sites to attract the big pharmaceutical companies from overseas. However, it has also been stressed that conducting clinical trials remains as a huge issue as local companies, institutions and even government agencies having lack of adequate knowledge on clinical trials, available local resources and how to make use of own local assets and resources effectively to gain sufficient skill sets along with the revenue generation through clinical trials. Few examples are given on conducted clinical trials which failed due to lack of knowledge, lack of policy/regulatory protection, lack of transparency & shortage of skill sets to carry on CT.

### 3.4 Main Challenges and weakness of Malaysian health biotechnology industry

There are numerous challenges and obstacles have been identified by the participants as presented in **Table 8** which can be summarized into four major aspects such as the issues related to policy/regulations, niche areas, funding and human capital.

#### **Regulatory issues**

As mentioned earlier, lack of clear pathway for the registration, evaluation and application process for health biotechnology products become a main challenge for biotech companies to register their products locally and commercialize in local market. Participants have stressed that there is no proper guideline or established policy regards to the cutting edge health biotechnologies in the country yet and it takes long time to establish health related regulations/acts. One participant has described the situation with by saying that “...*In Malaysia in order to pass an act, it will take average 8-10 years to even get to the parliament, like medical devices act, human reproductive technology since 2002, , human tissue act 1974 while in UK, they have revised in 2004 and have a second edition in 2006. I think somebody should champi on this as lots of areas in biotechnology haven’t been covered yet, such as in the areas of tissue engineering, gene therapy etc. There is still need a lot of work to do as though we need a body just to look at this gap in the next ten years time...*”

Table 8 Challenges & weakness in health biotechnology industry in Malaysia			
Regulatory Issues	Niche Areas in HB	Funding Issues	Human Capital
<b>BiotechCorp:</b> there is no official qualifying activity guideline for almost all the biotech sectors	Not clearly defined, lack of focus	Minimum Funding, but lots of focus areas	Still remains as the main issue for most of the sectors in Malaysia
<b>NPCB:</b> - There is an international standard regulatory guideline, but the application procedures, pathways are not clear. - Lack of consultation services - Difficulty for local products to get approval	There are no novel drugs or vaccines developed locally yet	Research funding has been cut and there is gap between the health needs and fund defined research niche areas.	In NBP, capacity building phase has been passed, the question is “do we have the required skill sets yet, in terms of quality and quantity?”
<b>MOH:</b> There are no guidelines for cutting edge technologies such as stem cell, tissue engineering, generic medicine, reproductive technology and so on.	Lack of Knowledge, understanding and skills in conducting clinical trails	Funding will be remaining as a main issue in this sector as it requires consistent funding and involve high technology.	Still shortage of skill sets for drug development, clinical trials and vaccine development areas, etc
- <b>MOH</b> is handling all health related activities, so “to much too Handle”. - Lack of transparency - Beucracy in the system	Lack of transparency in conducting Clinical Trials, e.g. usage of resources, end results, etc	Lack of knowledge and understanding on biotechnology among investors	

### ***Niche areas***

It has been strongly pointed out that the niche areas in health biotechnology are poorly defined as it's very broad and focus on all health biotechnology areas at the same time with limited funding by government. One explained the situation as “...*One of the challenges is probably lack of focus; I don't think we can do everything such as medical devices, pharmaceuticals, biopharma, natural products and so on. Because we haven't yet proven that we are strong in even one area and resources are limited...*” As mentioned before, conducting clinical trials have been the attractive field for CROs, however, the various challenges and weaknesses also have been discussed above with regards to clinical trials in Malaysia.

### ***Funding issues***

Funding has been the main obstacle for biotechnology industry to growth since years (MOSTI, 2005). The group has the common opinion as the funding will be remaining as a main issue as the advance of biotechnology industry requires consistent funding on R&D and human capital development in this knowledge based industry. It was pointed out that there is a weakness in the procedures of research grant approval in related filed such as the gap between the local health need and defined niche areas for fund application.

Some stressed that it's difficult for small medium health biotechnology companies to get investments as the reason was explained as “...*at this point of time, the biggest challenge is that there is lack of understanding of investors on health biotechnology. So it's very difficult to get financial assistance when they don't understand likelihood for them to fund, support and give good rates for those companies...*” Thus, BiotechCorp is advocating the biotechnology industry in Malaysia to improve the awareness and knowledge of people regarding this industry.

### ***Human capital***

Even after the human capital development phase of NBP, shortage of skill sets and knowledge workers remain as a challenge, not only for biotechnology sector, but to most of the sectors in Malaysia. One of the apparent examples is the shortage of skill sets in the areas of novel drug and vaccine development, skill personnel to conduct the clinical trials. Development of human capital is long term process and it requires consistent funding, opportunities and time. BiotechCorp is emphasizing the strategies to implement the NBP by focusing to get tangible results such as investment, GDP contribution, and employment/jobs and so on. Whilst also focusing on human capital development. It has been explained by the participant from BiotechCorp as such “.... *Since we established, some of the things that we embarked on is actually based on NBP. The capacity building is getting people to have necessary skill sets and we need to have the players in the industry to play during this period. It's the mixture of the established players and mixture of the going to be established and start ups...*”

## **3.5 Recommendations and Opportunities for Malaysian health biotechnology industry**

There are a number of valuable recommendations for each aspects specified by the participants as seen in **Table 9**. The most emphasized point was to take stake holders approach in decision making. As explained by one of the participant, “...*stake holders approach is very important, every time when we embarked on something, we must think who are the most relevant people here and make sure they all come either in terms of developing guidelines, collaboration, even in terms of defining what the trust areas are.*” There are lots of suggestions to fill the gaps between companies operations with regulatory guidelines and procedures, to increase transparency and availability of funding for niche areas related to local health problems which is dominated by non communicable diseases in recent years.

In terms of niche areas, it was suggested that Malaysia should leverage its advantages in rich natural biodiversity by focusing on Natural products and related areas. The basic research should be given much bigger attention in terms of funding and human capital as biotechnology is a knowledge driven industry, therefore, the fundamental research should be the main focus in order to be able to produce innovative, novel health products. The necessity of defining the specific niche areas was stressed by participants as “...*We really need to define where the niche areas are and discuss the policies. We also need to look at globally, for example India and other places where successfully ruled out their health care biotech what is actually always driven by industry. So key thing that we need to do is to create a very conducive environment in Malaysia and to encourage these parties to try and operate effectively here no matter how big or small they are...*” The industry is the heart of innovation system and also in biotechnology development in a country (Thorsteinsdóttir, 2004). The private firms and companies are the main players in the whole product development chain, especially transferring the knowledge into tangible health products and deliver them to the market (Thorsteinsdóttir, 2004, Sarah *et al.* 2006). Thus, it’s important to Malaysia give emphasize in development of small medium enterprises in health biotechnology by providing them clear guideline, incentives and investments.

By involving all related agencies, experts in the process of defining niche areas can be resulted in less biased and more convincible targets that all the sectors can work towards to achieve the goals. Clinical trials can be the focus of development with complete, standard guidelines, skilled personals, and expertise in this area to exploit the advantages of multiracial population and resources.

It was mentioned that there are some promising improvements have been achieved in the number of CT in the country; however, there are lots of issues should be considered to push this sub sector forward. As one participant emphasized the point as “.... *It’s about really study what our resources are. I think three ethnic groups; the richness in this should be an asset. But if you look at the trend of clinical trials market in Asia, we are not even in top 5. So in a sense, where is the problem? Is it our management of trails? Is it our database of patients that we are lacking? Is it the way we manage our results? Or is it the delay in approval? this kind of issues should be considered...*”.



**Table 9 Recommendations & Opportunities for health biotechnology development**

<b>Regulatory aspects</b>	<ul style="list-style-type: none"> <li>- Clear guidelines, acts and regulation should be set for all HB sub sectors.</li> <li>- Existing guidelines should be followed by clear pathways and procedures.</li> <li>- Must have stake holders approach in decision making. All related experts should be included in the decision making process, not only one or two agencies.</li> <li>- Regulatory bodies should act as consultant to these companies and let them understand the procedure, requirements.</li> <li>- Should increase the transparency and reduce the bureaucracy in the operation.</li> </ul>
<b>Niche areas</b>	<ul style="list-style-type: none"> <li>- Should focus on one or two areas that Malaysia has its strength, such as biodiversity, natural products.</li> <li>- Supported areas should reflect the health needs of the nations, such as infectious diseases as well as non communicable diseases.</li> <li>- Country' assets such as multiracial population and resources should be protected and effectively utilized.</li> <li>- Should be focus on basic/ fundamental research</li> </ul>
<b>Funding</b>	<ul style="list-style-type: none"> <li>- Fund review procedures and process should be transparent, should avoid favoritism.</li> <li>- Should encourage more private sector involvement and investment on the sub sectors</li> <li>- Should attract more Foreign Direct Investments and big multinational companies to invest and set up their company</li> <li>- Collaboration/partnership between public private can be useful in sharing investment, risk and also share of output of the research, such as IP, revenues etc. It could also help to improve human capital development.</li> </ul>
<b>Human Capital</b>	<ul style="list-style-type: none"> <li>- Education system should be modified to suit the industry and niche areas of research and development.</li> <li>- More specific training and support programs should provide to improve the skill sets.</li> <li>- Should consider placing science and technology as a main subject since primary school education.</li> <li>- Provide funding and programs for students to pursue further studies, like masters, PhDs according to the needs of the industry.</li> <li>- Regulatory agencies should be formed by experts, knowledgeable personals and continue training should be provided</li> </ul>

There are some valuable recommendations given with regards to the funding in terms of fund application process, increase of private sector investment and encourage the involvement of private entities in the industry. It was mentioned in the discussion that “..., in 2010 the investment from private vs government sector is almost the same. In terms of private spending actually was 10% above target of what was expected for RNK9...” this point was supported by the 2010 annual biotechnology report (BiotechCorp, 2010). Another stressed point is to improve the collaboration between sectors locally and internationally to share the investments, risks and also the outputs of the research, such as IP, innovative technologies and revenues etc. It could also help to improve human capital development in biotechnology sectors.

As one of the major challenges, human capital development is a long term process and needs to be given great attention from various agencies in the country. First of all, education system should be modified to suit the industry needs and niche areas of research and development. Science and technology subjects should be places as the major part of the education system since primary school in order to have generations with innovative, creative mind set. More specific biotechnology curriculums and training, support programs should be provided to develop specific skill sets. Another important point which stressed was the lack of knowledge and experience of the personals in government, regulatory sectors and financial agencies towards biotechnology, business models

and nature of the industry and so on. These factors may delay the process or become the challenges for the biotechnology companies to register and application process. Thus, it's crucial to form the government regulatory agencies with knowledgeable and experienced personals or by providing training programs to increase their knowledge and awareness in order to assist and guide the private biotechnology companies with the correct directions and consultancy services.

#### **IV. CONCLUSIONS**

This study attempted to examine the overall development of health biotechnology industry in Malaysia to look at the current capabilities and resources which can be leveraged to address the local and global health needs. At the same time, the success in biotechnology industry as well as the challenges, obstacles and recommendations are indentified for the further development of this particular industry. From the results and discussions, we can see that there are significant developments in this newly emerging industry in Malaysia in terms of number of companies, investment, and revenue and so on. However, as it is still in the infant stage of development phase, there are lots of limitations and weakness in HB sector in Malaysia and enormous work need to be done in all aspects to reach the nation's 2020 targets. Lack of regulatory guidelines for most of the health biotechnology activities, poor identification of niche areas for the industry to growth, lack of skilled workforce and fewer numbers of researchers have been the remaining challenges for the development of this sector with limited funding availability and accessibility.

The main message of this paper emphasizes is that the basic/ fundamental research areas should be given stronger attention and focus by adjusting the education system to provide the necessary skill sets for the industry development and to become the knowledge based economy in the near future. For such a knowledge driven, cutting edge high tech industry, it's vital to have the basic/fundamental strength to invent novel products. South Korea is the typical example to prove this point by strengthens its basic research and encourages private sectors involvement in this industry. It's well known fact that mimicking others work wouldn't work in long term, especially in biotechnology industry where requires to be innovative, creative and open minded.

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