# The Roles of National and Local Policy and Practices in Support Knowledge Transfer and Commercialisation of Biotechnology in Malaysia

A Thesis Submitted for the Degree of Doctor Philosophy

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**ABSTRACT**

Malaysia has made a major commitment to developing biotechnology since 2005 through the implementation of a comprehensive National Biotechnology Policy (NBP). The NBP was delivered in three phases, each lasting five years and describing the commitments and strategies for biotechnology to reach 5% of Malaysia's Gross Domestic Product and create 280,000 jobs. Despite major state support focused on knowledge exchange and commercializing agro-biotechnology, there has only been limited success in growing the domestic industry. One of the reasons for this has been a lack of successful translation of central policy to the local level, especially within research universities, with few spin-off companies created. This thesis therefore aims to examine the reasons behind the slow development of biotechnology commercialization among the research universities in Malaysia. To achieve this, the study will explore the value of the Triple Helix model of innovation as a conceptual framework to understand how research universities, industry and government interact in practice in implementing the NBP. It will focus on the gap between policy aims and the experience of these key actors and add to the critical literature on university-industry collaboration in knowledge sharing activities in Malaysia.

Adopting a qualitative methodology, this study is based on document analysis and semi-structured interviews with 41 respondents from national biotechnology agencies, research universities and start-up companies. A number of findings were drawn from the analysis of the empirical data. First, both the government agencies supporting the sector and the research universities responded positively to the NBP. However, this was achieved a through top-down governance style and command and control culture common within the Malaysian state. Although the government agencies and the research universities adhered to the NBP, there was poor coordination and a fragmented response in pursuing commercialization. At the national level, the control culture and large number of competing and overlapping agencies and programmes limited

the interaction between government, research universities and industry. These interactions were made more difficult as policies promoting innovation had to cross institutional and political boundaries. Secondly, at the research university level, the nature of bureaucracy and top-down government administration significantly restricted the autonomy of local managers in pursuing knowledge transfer. This resulted in difficulties in improving university policies and practices and in meeting the needs of academic researchers working with industry. This included problems with workload, incentives, and inflexible support programmes. Thirdly, the policies at national and local level were poorly designed and implemented when supporting commercialization activities among start-up companies. This included only funding firms above a certain size and not covering all the costs of working with the university. These difficulties were made worse by the small size of the Malaysian biotechnology industry, a lack of demand for its products and the inexperience of company managers. Conceptually, these findings can be understood as resulting from the Statist model of the Triple Helix related to Malaysian biotechnology, where the government dominates, influences and closely controls the institutions involved in knowledge transfer and commercialization. These were made harder by the inflexible and restrictive administration styles embedded at the national and local level. This study has significant implications for policy and practice. It offers new evidence that stakeholders can use in assessing and/or redesigning government policies to enhance the exploitation of biotechnology research by academics and start-ups companies. It makes a series of recommendations to improve the design and delivery of policy.

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# Chapter 1

# Overview of the thesis

## 1.1 Introduction

This chapter explains the thesis structure by providing the background and context of the research. The discussion addresses important components that frame this study's empirical focus. This includes framing the inquiry with the concept of the Triple Helix The purpose of Chapter One is also to provide a background to the field of research concerning biotechnology commercialisation in Malaysia, specifically in university settings. This chapter also outlines the goals, objectives, and conceptual approach of the thesis, followed by the theoretical and practical arguments for conducting this study. Finally, it explains when, where, and how this research was carried out, and it finishes by presenting the organisation of the thesis.

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## 1.2 Background of the research

In the past few decades, science and technology have influenced society as never before. Scientific achievements and knowledge-sharing activities are increasingly contributing to technological progress and influencing the way people live and work (OECD, 2004). Realising the potential of science and technology as a push factor for achieving high-income nation status, Malaysia launched its first National Biotechnology Policy (NBP) to achieve this target. It is believed that implementing this policy together with the national innovation strategy can be the vehicle for the nation to become a high-income country (Govindaraju, 2010). The NBP was launched to fully utilize the rich natural resources found in Malaysia and provide a favourable setting for their industrial exploitation (MOSTI, 2005).

The NBP was announced in 2005 and was expected to become the key driver of economic growth for Malaysia (Ministry of Science Technology and Innovation, 2005). The biotechnology sector was envisaged to generate new wealth and income for both the urban and rural populations, thus improving the socio-economic status of Malaysians as a whole. Being blessed with rich biodiversity, a pool of cost-competitive labour, ICT infrastructure, and good transportation along with strong support for research and development, Malaysia provides a promising destination for foreign biocompany investment.

The second phase of the NBP specifically focuses on bringing science to business and on the creation of start-up companies to commercialize new scientific discoveries in the university. To achieve this aspiration, the government has become the major funder for R&D&C activities in university and public research institutes. With the establishment of a dedicated group of Research Universities (RUs) the government has focused more resources on exploiting R&D up to the commercialisation stage. The RUs are therefore closely integrated with the aims of the second phase of the NBP implementation.

The establishment of research universities in Malaysia in 2003 was based on the view that a university's role is not limited to producing graduates for the workforce but also acts to create new intellectual capital, new knowledge, and innovative technology. Therefore, it can be seen that universities are experiencing an evolution in the education system. This evolution is important as more countries are shifting toward a knowledge-based economy (Ministry of Education Malaysia, 2013, pg.5).

This is where many see science, technology and innovation (STI) and the National Biotechnology Policy playing a strategic role. There is clear evidence to show that countries which invest heavily in STI do very well in the new technology-driven global economy (Wong, 1999, Furman and

Hayes, 2004). With increasing pressures from governments for universities to generate income, they have started to be more entrepreneurs and create spin-off companies (Hajar and Kamariah, 2010). University spin-offs company are capable to contribute to the regional economy by providing employment and generating sales revenue (Son, Chung and Yoon, 2020). For instance, Stanford's Cohen-Boyer patent which is regarded as a role model of university research commercialisation (Li and Morgan, 2010) in the United States has generated over USD 50 million from DNA cloning technology (Leute, 2005). In the United Kingdom, university commercialisation activities took off in the late 1990s, while in Europe, governments have invested increasing amounts of money in universities to encourage them to form spin-off companies as one way to generate income for themselves and for the nation. Japan, for example, amended its intellectual property laws to enable the spin-off company creation process, and in this period, there was an increasing number of university spin-off companies in Asian countries (Shane, 2004).

Although the formation of university spin-off companies has been increasing since 2000, there is very limited study on the factors influencing their formation in Malaysia. Therefore, this study will explore the role of policy at both national and local level in enabling the creation and sustainability of university spin-off companies (Chandran et al, 2009).

### 1.3 Context of research: the role of biotechnology as a focus of study

Biotechnology can be defined as "the use of science and technology to living organisms, as well as their components, products, and models, to modify living or non-living materials for the production of goods, services, and information" (OECD, 2006). Biotechnology has various applications and it has developed into a major global industry. The biotechnology industry is using biological techniques to generate products and services that meet the demand of human needs in healthcare, animal health, agricultural productivity, food processing, environmental affairs, and the area of renewable resources (Ernst & Young, 2000). The significance of biotechnology as a driver of economic progress is undeniable. Developing the bioeconomy as a whole will contribute significantly to efforts to reduce climate change, offer global food security, enhance nutrition and public health, and make industrial processing clearer and more efficient. By increasing product quantity and quality, biotechnology has recently revolutionised industrial and agricultural processes. For example, biotechnology applications play an important role in the agriculture and agribusiness industry by boosting production, adding value, and diversifying the products made from agricultural produce while lowering environmental effect. Therefore, biotechnology offers distinctive potential for the advancement of sustainable industry. Utilizing the right technology during processing and manufacturing will facilitate commerce and international development collaboration in addition to increasing production efficiency and product quality (Lokko *et al.*, 2018).

Some 20 years ago Malaysia recognised biotechnology as a major 21st century's engine of growth for life sciences (BIOTEK, 2001) by building platforms for new products and markets (Ernst & Young, 2000). According to former Malaysian Prime Minister, Abdullah Badawi, "Malaysia boasts the richest biodiversity on the earth. It is a gift; a God-given competitive advantage that we must exploit to the best of our abilities” (Badawi 2003, p.3). During the sixties, Malaysia's economy was dominated by agricultural operations and commodities. Now, it is securely placed to become an export-driven economy, propelled by high-tech, knowledge-based, and capital-intensive businesses. Malaysia has been named the fifth most competitive economy in Asia, after Singapore, Hong Kong, Taiwan, and China, and the nineteenth most competitive economy in the world (Schwab & Porter, 2008). Malaysia has increasingly created and capitalised on the biotechnology industry's competitive advantages.

Gomez (2005) identified five competitive advantages of biotechnology in Malaysia: Malaysia's rich diversity of flora, fauna, and people; existing agriculture-based biotechnology; an increasing number of government grants and venture capital funding; the existence of an ICT infrastructure and experience in the high-technology industry; and the government's unwavering commitment to biotechnology.

According to Gomez (2005), Malaysia has approximately 4.06 million hectares of agricultural land distributed across its 14 states, with approximately 75% of this land dedicated to primary crops such as palm oil, rubber, cocoa, coconut, and pepper, and the remaining portion dedicated to agro-food production. Malaysia transitioned from an agricultural-based economy in the early 1960s to an industrial economy with the manufacturing and service sectors being dominant in the 2000s. According to agricultural sector's actual worth increased from USD 674,000.00 in 2003 to USD 9 billion in 2008, producing a total of 7258 agricultural business owners (Gomez, 2005). Realising this opportunity, Malaysia established the National Biotechnology Directorate or BIOTEK, a division of the Ministry of Science, Technology and Innovation in 1995 with the aim of building capacity, developing expertise in the discovery and development of new drugs based on natural resources and ensuring the strategic positioning of Malaysian companies globally. Malaysia has been dealing with agrobiotechnology activities since 1985 (Abu Bakar, 2007) nevertheless, the concerted efforts on this area only started in 2000 without any significant results (Ismail *et al.*, 2012).

Malaysia has a lengthy history of being at the forefront of tropical plantation technology. Although agriculture remains the backbone of the Malaysian economy, the country has shifted from a traditional to a modern perspective on the sector. Agricultural biotechnology fulfills Malaysia's need for an abundant food supply and sustainable food production (BiotechCorp, 2009). Taking an example of rice, this crop is the most important staple food in Malaysia. By 2030, it is estimated that there will be increasing demand for rice with declining supply in the country (Rajamoorthy, Abdul Rahim and Munusamy, 2015). Statistics from Department of Statistic, Malaysia also shows that there were increases in import commodities in crops such as fruits and vegetables, livestock such as beef, mutton, pork and poultry meat and fisheries such as tuna and crab (Department of Statistics, 2015). These statistics show important indicators about the national agricultural situation particularly in determining sufficient food supply security.

Compared to Malaysia in 1970, rice productivity has been slowing down in terms of the annual rate of change after its success implementation of Green Revolution. By 1990s, the chemical intensive culture introduced by the Green Revolution has started taking a toll. The soil fertility and water quality has declined. Malaysian's farmers remain using conventional ways in operating their activities without realizing the long-term effect of using chemical fertilizers. The reduction of soil fertility and water quality have caused the low yielding in crops, fruits and fisheries. Therefore, a gradual transition to bio-fertilisers, funding for R&D for the development of high yielding hybrid rice and increasing cropping intensity hold the promise of productivity enhancement (Bala et. al, 2014). Biotechnology has the potential to increase crop and animal productivity; improve nutritional quality; broaden tolerance of crops for drought, salinity and other environment related stresses and increase resistance of crops to pest and diseases. This is where the establishment of a national biotechnology policy is seen as the right mechanism to increase agriculture production.

### 1.4 Research problem

The starting point of the analysis is that institutions and public goods organizations have an important role to play in supporting firm-level R&D activities. Universities are considered important bases of R&D activities whose knowledge embodied in graduates, R&D labors or simply interaction have often been tapped by firms to generate new products and services. (Rasiah and VGR, 2009). Furthermore, the government significantly increased the allocation for R&D and commercialisation of technology to RM 1.4 million in 2016 compared to RM 1.1 million in 2009 as part of the strategy to innovate and commercialise research findings (MASTIC, 2023). In order to accelerate commercialisation activities, special grant programmes such as ScienceFund, InnoFund, TechnoFund, and Commercialisation of R&D Fund (CRDF) were established (Ng *et al.*, 2019).

Because Malaysia's government has great expectations for the development of this industry, biotechnology was a top priority in the country's national strategy for the ninth Malaysia Plan (2006–2010). As a result, it got substantial financial support from the government for the growth of its infrastructure, research and development, and human resources. Malaysian research universities with a history of somewhat successful research and development could potentially advance biotechnology. (Yaacob *et al.*, 2003). The commercialisation and innovation development among universities has been regarded as 'Niche 1' by the MOHE which implies an emphasis and urgency under the Tenth Malaysian Plan (Aziz, Harris and Norhashim, 2011) (see figure 6.3).

Despite all these initiatives, the progress of biotechnology commercialisation is still slow. For example, previous scholars discovered biotechnology policy in the country is weak (Amin *et al.* (2011); Abuduxike, Aljunid and Sulong (2012); and Sahrom, Tan and Yahya (2016). The policy also seems unfriendly (Saad and Zawdie, 2011) and unsupportive for the biotechnology players (Ahamat, 2013). However, there are limited literature review found on poor coordination and fragmented response in pursuing commercialisation activities. This is resulted by the top-down governance style practiced by Malaysia. The command-and-control culture has made interaction difficult between government agencies at the national level and as a result has made the policy development process become difficult. Therefore, it is important to identify what are the issues associated with commercialisation at the national level although the NBP are already in action. In the university setting, the allocation for R&D activities were reportedly increasing for almost every year.  For example, the government allocate RM 6.041 million (USD 1.8 million) in the year 2016 compared to only RM 1.2 million (USD 365,000.00) in 2008 (MESTECC, 2018).  This showed that the government is committed in encouraging the university to involve in R&D&C.

Despite of all these investments, the revenue earned by research universities as solution providers to industry is not that impressive (Ali Hassan, 2012).  As cited in ‘R&D Products of Universities in Malaysia 2012’ report, the commercialisation of R&D goods by research institutions has a poor return (about RM 10 million – USD 2.8 million) as compared to MRU as solution providers to industries, which amounted to RM 759 million (USD 216 million). Overall, the MRUs produced RM1.25 billion (USD 355 million) in revenue from 2007 to 2012 as solution providers (Kementerian Pendidikan Malaysia, 2014), so biotechnology is a very small part of this.  On top of that, previous studies have also discovered that the academics face a workload that is disproportionate to the benefits they earn. This entails completing a lot of research projects and publications, as well as teaching and learning, administrative work, and program management (for some)  (Basarudin *et al.*, 2016). These difficulties have demotivated academics, who are now struggling to participate in the university's third goal. Therefore, it is important to understand the roles of the universities in translating the National Biotechnology Policy into local practices and how these local practices support knowledge transfer and the commercialisation of biotechnology in Malaysia.  At this point, the university faces problems of workload, incentives and inflexible support program.  The nature of bureaucracy and top-down government administration significantly restricted the autonomy of local manager in pursuing commercialisation.  This has resulted difficulties in improving university policies and practices in meeting the needs of academic researchers.  By understanding this, the policy makers able to make improvements to the current NBP.

While in industry setting, it is discovered that most biotechnology firms have their own in-house R&D, lowering the need for university-industry collaboration (Subramonian and Rasiah, 2016). Malaysia also evidences a weak industrial base, as investors refuse to understand the complexity of the biotechnology industry and want a quick return on investment (Mokhtar and Mahalingam, 2010), resulting in lower industry uptake of technologies originating in universities (Nordin *et al.*, 2016). Bakar, Sulaiman and Osman (2013) believe that the biotechnology industry is still underdeveloped and new in Malaysia (Subramonian and Rasiah, 2016), thus resulting in low collaboration among university and industry.  Inadequate connections and interactions between the public and private sectors are also contributing to a significant gap in knowledge creation and dissemination across sectors, and serves as the root of the conflicts in identifying niche markets (Abuduxike, Aljunid and Sulong, 2012). Insufficient funding for biotechnology R&D is another major problem; therefore, financial support is also reported as an obstacle to biotechnology commercialisation activities due to the lack of private sector presence and participation in this sector (Arujanan, 2016). Despite having a small number of private sector investors, it was also reported that the funding procedures are complicated and overly administrative (e.g., involving cumbersome paperwork) when it comes to applying for public grants (Rahman and Mohd, 2015). Although there are many reasons were discovered by the previous researchers as mentioned above, it is discovered that there are limited further research is conducted to understand the reasons behind the factors.

To sum up, there are various issues contributing to the slow development of biotechnology commercialisation in Malaysia which can be categorised in policy development and implementation of the biotechnology policy.  In the bigger picture, it can be said that these factors have contributed to the systemic failure of the biotechnology system in Malaysia. These issues are rooted at the level of government, universities, and industry. Researchers previously raised attention to these issues and for added value in this research, I attempt to view the issues from the perspectives of government, universities, and the company managers of start-up companies, as fixing one stakeholder is unable to improve the slow progress of knowledge exchange and biotechnology commercialisation in Malaysia. One thing in common between these three stakeholders is that they are expected to respond to the National Biotechnology Policy (NBP). Therefore, the issue of commercialisation practices in Malaysia is worth investigating given the dearth of understanding regarding the hurdles to commercialisation, particularly as they relate to policy and the university-industry-government interaction. The purpose of this research is to determine why policy has partially failed and what impediments exist to the commercialisation of biotechnology in Malaysia.

### 1.5 Research objectives

The first objective of this study is to examine and analyse issues associated with commercialisation in the research university resulting from the NBP in Malaysia. The study aims to understand the roles of policy at the national and local level in enabling the creation and sustainability of university spin-off companies in Malaysia. Generally, the NBP is part of the science, technology and innovation agenda. This national agenda contained 81 policies, involving 458 entities and 13 state governments (Academy of Sciences Malaysia, 2015). The NBP contained goals, guidelines and a plan for how Malaysian could become a high-income nation through biotechnology. The formulation of this policy involved various stakeholders such as the academia and private sectors (MOSTI, 2013) to ensure inclusiveness of all actors involve in spurring biotechnology. In terms of implementation, the government through its agencies carried out all the initiatives in the policy.

One of the main agencies is the Malaysian Biotech Corporation (BiotechCorp) which was established as a one stop-center to coordinate all biotechnology industry activity. This also include enhancing collaboration between domestic and foreign companies (Ahn and York, 2011).

Despite of all the efforts taken to spur the sector, the rate commercialisation remains low with few start-up companies in this area.  Therefore, this study will facilitate an understanding of the support and opportunity offered by the government to encourage the commercialisation of indigenous products resulting from R&D activities.

The second objective is to understand the roles of the universities in translating the National Biotechnology Policy into local practices and how these local practices support knowledge transfer and the commercialisation of biotechnology in Malaysia.  This will help understand how the university have responded to policy at the national level and adapted it. Among the initiatives at university level are the enhanced roles of research management and the establishment of innovation centres to deal with commercialisation activities.  With the implementation of the NBP, the RUs also have to align their research agenda in accordance with national policy. Furthermore, engagement with the third role of the university shows that the university must balance its roles as a place to disseminate knowledge, conduct research, and participate in commercialisation. However, these initiatives were unable to attract the academic researchers to engage in exploiting their R&D. This could be related to the insufficient funds, the university governance, the size of market or maybe due to the product itself.  By understanding this objective, this will provide a more in-depth explanation of why and how the university institution will balance duties and generate possibilities. The third objective is to investigate the consequences of this study, particularly in the biotechnology industry, in assisting entrepreneurs to promote better and more productive ventures.

## 1.6 Justification for the research and contribution to scholarly Knowledge

The study was driven by normative, contextual, and scholarly concerns. It seeks to improve social scientific understanding of the development of biotechnology in developing countries using

Malaysia as a case study., and the role of universities in this process. It is based on grounds for scepticism about the loosely-based assumptions about the role of universities and their relationships with industry in current Triple Helix literature that universities may actively participate in localised interactive processes to promote biotechnology commercialisation development. It seeks to advance theoretical contributions to the Triple Helix concept by furthering an understanding of how universities and other stakeholders interact in practice. This research is framed at the outset in terms of public policy and university reactions to it, and it focuses on the gap between policy aims and the actual response and interactions of universities. In practice, this research adds to critical analyses of university-industry collaboration in knowledge-sharing activities in Malaysia.

In general, with a knowledge-based economy, universities' roles in territorial development have been re-evaluated by taking into account the localised interactive learning processes. Furthermore, the Triple Helix concept is extensively used in understanding and identifying innovative development that emphasises interacting mechanisms amongst actors. Although there has been significant accumulated knowledge in these areas, there is a dearth of critical perspective and less micro-analytical effort.

Previous studies have focused on the normative role of universities' participation in their communities (Chatterton & Goddard, 2000; Lundvall, 2002). At the theoretical level, there is extensive research on both the function of universities and the development of RIS (Mowery & Sampat, 2005). There is little examination of how they might, and do, interact in practice. There have been some exceptions with a critical viewpoint on the roles of universities, but these lack a micro-analytic foundation in analysing the relationships of universities with other stakeholders (Gunasekara, 2004). Therefore, this research will use the Triple Helix concept to examine the dynamic interaction between the government, university and industry. Choosing to use this model will hopefully answer all the research questions and contribute to the commercialisation practice in the Triple Helix Model.

## 1.7 Conceptual framework

In order to help undertake this study a robust conceptual framework will be used to guideline the analysis. Among the core concepts used in this project are i) Model of innovation, ii) the Triple Helix model of innovation, iii) Knowledge transfer and iv) Roles of university and industry in commercialisation activity.

In order to explore the concept of the innovation model, one must understand what it means. Among the well-known models are the National System of Innovation (Nelson, 1993; Lundvall, 1992), the National Innovation System approach (Godin, 2009), Regional Innovation System (Breschi and Malerba, 1997), the Sectoral System of Innovation (Malerba, 2002), and the Triple Helix (Etzkowitz, 2007, Etzkowitz et al. 2002; and Etzkowitz 2002). Taking the definition from Edquist's point of view, a system of innovation consists of all economic, political, social, organizational and other factors that affect the diffusion, development and use of innovation (Edquist, 2001).

In terms of operating the model, the concept of knowledge transfer is vital. Knowledge transfer is related to the process of transferring information to the other actors. In the university setting, knowledge transfer can occur in many ways such as transmission, presentation, talks, spin-off companies, visits, consultation, licensing, joint research collaboration etc. (Tang, 2007; Landry et. al. 2006). For knowledge transfer to take place, the roles of the university in the creation and sustainability of knowledge are highlighted. Recently, many scholars have shown how universities have shifted their mission and become entrepreneurial organisations and playing a much more active role in wealth creation (Dooley and Kirk, 2007). This mission can be accomplished by creating spin-off companies. University spin-off companies have played a major role in contributing to the economy by generating sales revenue and providing employment (Son, Chung and Yoon, 2020).

The main focus of the study will therefore be how national biotechnology policy is shaped by the structure of the relationships between universities, government and industry in support the commercialisation of biotechnology with an emphasis on the creation of spin off companies. To help understand this, the Triple Helix model will be used as a conceptual framework.

### 1.8 Research questions

There is abundant literature on commercialisation activities in research universities. However, as stated earlier, studies of the roles of national and university policies in supporting commercialisation in Malaysia have been very limited. Therefore, this research will attempt to investigate the roles of the National Biotechnology Policy and university policy in the process of knowledge exchange and commercialisation. In doing this it will answer four research questions.

I. What are the issues faced by biotechnology actors at the national level in enabling knowledge exchange and commercialisation of biotechnology in Malaysia?

II. How do universities translate the National Biotechnology Policy (NBP) into local practice?

III. How do these local practices support knowledge transfer and the commercialisation of biotechnology?

IV. How might the successes and limitations of national and local policy be conceptualized in terms of the Triple Helix model of innovation?

It is very important to know how the design and implementation of policy is able to enable the exploitation of knowledge in the research universities and how these activities could help Malaysia in escaping the upper-middle country dilemma. This research is expected to help all the organizations such as the government, universities and SMEs involved in the process of commercialisation to improve their effectiveness in generating wealth from biotechnology knowledge. The fourth research question will reflect the nature of Triple Helix in shaping the commercialization activities. The background literature and methodology to do this will be discussed in detail in Chapter Two.

## 1.9 Methodology

The research design that will be employed in this study is descriptive and evaluative and based on a national study of Malaysia. I chose it because it describes the characteristics of an existing phenomenon and focuses on events that occur in the present (Salkind, 2009). Evaluative research is concerned with the question of how well an intervention – such as a national policy works. This kind of research is also useful in providing information for improving or changing the identified programmme or policy.

This methodological approach is also well suited to the type of data obtained through semi-structured interviews and the analysis of secondary sources, and to the types of questions addressed relating to particular contextual conditions concerning various government institutions, universities, innovation systems and groups of companies (Saad, Zawdie and Malairaja, 2008). It presents the broadest possible view of the problem by exploring many perceptions and interpretations provided by the various stakeholders involved (Hartley and Muhit, 2003).

## 1.10 Strategies adopted in obtaining the data

To begin with, the research project was broken into four work packages. Each of these addressed the research questions outlined above.

Work package 1 addressed the role of biotechnology actors at the national level in enabling knowledge exchange and the commercialisation of biotechnology in Malaysia. To obtain the information, document analysis and interviews were conducted with policy-makers involved in the formulation of NBP.

Work package 2, aimed to obtain information on how national policies were being translated into local practice. It focused on the policies and processes involved in spearheading commercialisation activity. To obtain the information, commercialisation policies were collected and interviews were conducted with the management of these RU.

The third work package was concerned with how the academic scientists feel about the translational of the NBP at faculty level. To obtain this information, interviews were conducted with academic scientist who were in involved in commercialising their research.

The last work package collected the view of the managers who ran start-ups company involved in commercializing academic scientist's invention. This aimed to understand the type of support provided by the university and government agencies to company managers, and the managers views on the effectiveness of the support.

There are many ways of conducting research but in this study, qualitative methods are best suited to the nature of the study. Ritchie and Lewis suggested that qualitative research is a powerful tool in exploring, understanding and revealing a phenomenon. By adopting the qualitative method, we can obtain and understand various kinds of information from a range of different perspectives and consider the larger function of investigation in the social world (Ritchie and Lewis, 2003 in Siti Hajar, and Kamariah, 2010). Due to a lack of information on the performance of biotechnology-related university spin-off companies, this method is believed to be the most suitable and appropriate tool to address the research objective.

In the process of recruiting the interview respondents, four different groups of actors were identified each with important experience and perspectives on the commercialisation of biotechnology:

I. Policy-makers involved in the NBP
II. Top management of RU
III. Academic scientists in the RU
IV. Company managers of start-up companies

Data from the document analysis and interviews was carefully collated and analysed to address the research questions stated above and also used to make a series of recommendations to improve policy.

## 1.11 Thesis structure and content

Chapter Two presents the concepts and context of the research. It contains the literature that helps the researcher to deeply understand the background of the study, and develop a conceptual framework. The literature also helps in identifying the gap that exists in current knowledge concerning the commercialisation of biotechnology in Malaysia. The chapter discusses the concepts of innovation and knowledge exchange and provides an exploration of these concepts in an attempt to understand how the innovation system works and how it supports university's commercialisation activities. It also discusses the roles of universities in the growth of the knowledge-based economy, as well as the benefits of a localised learning process and the interactions within it. In particular, it will outline the idea of the Triple Helix model of innovation as a framework for the study.

The methodology of the empirical work is presented in Chapter Three. This discusses the methodological foundations of this thesis and how the data is being collected and analysed to answer all the research questions set out in Chapter One. This chapter also explains the challenges faced by the researcher while completing the thesis. The fieldwork for the research was undertaken in 2014 and this explains the slightly historical feel to the study. This involved extensive document analysis and over 41 semi-structure interviews in Malaysia. Due to very adverse personal circumstances (see page 76), it has taken many years to complete writing the thesis. Despite this, the study still fully meets the requirement for a PhD at the University of Sheffield both as a piece of research training and as an empirical study in its own right.

Chapter Four provides the background of Malaysia in the context of this study. This includes the role of RUS and micro, small and medium enterprises in supporting the economy of Malaysia. This chapter is divided into two sections. The first part provides the background of research universities including their structure and role. The later section explains the roles of RUs and MSMEs in supporting economic development through biotechnology.

In Chapter Five, the background of biotechnology in Malaysia and the roles of government agencies at the national level to support biotechnology related activity are explained. This chapter presents the government approach in implementing the NBP. This is used to analyse biotechnology policy and various mechanisms supporting biotechnology development. In particular, it will explore what are the challenges faced by the government in encouraging biotechnology development and commercialisation activity in Malaysia.

Chapter Six explores the question of how the universities adopted the NBP in order to accelerating biotechnology commercialisation activities. This aims to understand and explore the challenges faced by the universities' top management in translating the NBP into local practices. It also includes how the academic scientists responded to this policy and the difficulties in pursuing these activities.

Chapter Seven outlines the challenges faced by the company managers who have collaborated with academics in pursuing commercialisation activities. This explores to what extent the policy at the national level and university level impacts the commercialisation activities of start-ups companies. It also explores the company managers' view on the effectiveness of the NBP and the implementation of university local practices and policies.

The last chapter combines the empirical findings and the theoretical perspective to address the research questions.  It draws out conclusion and addresses the issue of generalising the research findings to the development of an existing theoretical understanding of the Triple Helix. This chapter also attempts to reflect on the efficacy and limitations of the national and local approaches used, as well as identify areas for further research.

# Chapter 2

# Literature review

## 2.1 Introduction

This chapter examines the literature underpinning this study and discusses the concept of innovation and knowledge exchange. Among the themes covered are the National Innovation System (NIS), Regional Innovation System (RIS), Sectoral System of Innovation (SSI), and the Triple Helix Model of Innovation and Knowledge Exchange. Each of the innovation models leads to an understanding of the innovation system and how it supports research universities' commercialisation activities. The information acquired in this chapter serves to clarify the background of the thesis and increase the scope of the investigation, particularly in Malaysia.

## 2.2 Models of innovation

Innovation models abound in the literature on science and technology studies (STS) and science, technology and innovation (STI), as stated by Godin (2015). They are regularly invented and achieve success one after another. Innovation models include the NIS, the RIS, and the SSI. In this thesis, innovation models are utilised to describe how the various system components work together to foster knowledge exchange and commercialisation at the institutional level. These models also serve as a framework for knowledge exchange and the commercialisation of biotechnology operations in Malaysia. The subsequent sections will discuss the aforementioned Innovation models.

### 2.2.1 National innovation system

This subsection will explain the National Innovation System that is extensively used to analyse the country's economic development performance. The national innovation system tradition of research has highlighted the importance of economic development of institutions' idiosyncratic and interrelated nature within particular countries (Hung and Whittington, 2011).

Decades ago, Porter (1990) demonstrated that firms are heavily influenced in their choice of technological strategies by the conditions of their home countries. According to Lundvall (1995), NIS are comprised of all parts and aspects involved in economic structure and the institutional set-up which affected searching, exploring and learning activities. The elements involved in the system components include the following: inter-firm relationships; the internal organisation of firms; the public sector; the financial sector of the institutional set-up; R&D organisations; and the intensity of R&D in the country (Lundvall, 1995: pg.12).

Gu (1999) and Sutz (2000) provided useful insights regarding national innovation systems in emerging nations. These studies concurred that the NIS is an 'ex-ante' notion in the sense that relatively few patterns of socio-economic behaviour related innovation at the national level can be considered as functioning in a system-like manner, in contrast to industrialised countries, where the concept of NIS is 'ex-post'. This asserts that the inventive strength of enterprises in developing nations "remains isolated and contained" and that there is a dearth of institutions that contribute to innovative activity. Gu (1999) stated that the NIS in developing nations possess five features. They are: (i) the technological and institutional properties necessary for modern growth; (ii) the connectedness level of economic structural and institutional development with the level of NIS development; (iii) the absence of 'extraordinary intensive learning' among citizens; (iv) the underdevelopment of market mechanisms; and (v) the fact that capital accumulation rather than intangible assets and learning is the primary contributor to technical progress in developing countries (Gu, 1999). These are the factors that determine the NIS level in each country.

Looking at the bigger picture, Patel and Pavit (1994) recognised a wider range of institutions that helped the general process of creating, spreading, and adapting knowledge in order to improve the NIS. These include universities and research institutes (which undertake basic research and train future researchers), a wider range of public and private institutions (that provide general education and vocational training for the workforce), business firms (which are actively involved in innovation-related activities), and the government (which finances the innovation process and provides the necessary infrastructure, including public funding) (Naser et al., 2018). For instance, weak engagement between a university and industry discourages the occurrence of R&D activity. This has limited the ability for knowledge exchange to happen between universities and industry, thus resulting in fewer discoveries and less knowledge exploitation. As less information sharing takes place, the likelihood that a product will be sold on the market is reduced. This makes clear how important R&D operations are. The government needs to provide the right infrastructure, grants, and policies to make it easier for people to come up with new ideas in the first place.

The NIS framework has been utilised to assist in identifying the unique characteristics of the growth of individual nations. By analysing Taiwan's national innovation policy in fostering biotechnology innovation networks, Dodgson et al. (2008) discovered that the government made significant investments in R&D, human capital, and infrastructure to strengthen its innovation capabilities. Despite these efforts, biotechnology sales remain relatively modest. In Taiwan, research institutes frequently play a central role in biotechnology, and the Industrial Technology Research Institute (ITRI) coordinates interactions between university-based research teams and corporations. However, the sector's comparatively poor performance may be attributable to the fact that biotechnology networks are separate within the system and global engagement is minimal. This demonstrated that industry did not play a large part in the system (Dodgson et al., 2008).

Using the NIS framework, Wu, Zhuo, and Wu (2016) examined rural economic growth in China. They discovered the connection between the adoption of new technology and NIS facilitation during the innovation process with the improvement of rural economic growth in China. Common infrastructure, clustering, and connectivity all demonstrated a positive and significant relationship with rural production and incomes. The Chinese government fosters productive entrepreneurial activity by allocating more resources to R&D activities and supporting regional labour mobility. The study recommended that policymakers comprehend the demands of the various regions and apply an appropriate plan to enhance economic development in each area (Wu, Zhuo and Wu, 2016).

The notion of a NIS has been extensively examined by Lundvall (1992), Nelson (1993), Porter (1990), Gu (1999), Sutz (2000), and Naser et al. (2018) among others. Studies in the extant literature have asserted that the market conditions in a developing country are distinct from those in a developed nation on account of the distinct composition and characteristics of the respective innovation processes. Additionally, the literature served to illustrate the evolution of research on national innovation systems. In the early stages of establishing the concept the emphasis was placed on the functions of the institutions comprising the NIS's constituent elements, before gradually shifting to the investigation of their interrelationships. This highlights the role for the government in aiding the innovation process in developing countries, which frequently lack strong institutional structures. In addition, evaluation of earlier literature indicated weaknesses in the interaction between the elements composing the NIS (Dodgson et al., 2008; Naser et al., 2018). These components are essential since they provide the basis for comprehending how NIS concept will be implemented in this study.

To ensure that innovation occurs at the national level, key aspects must be aligned and on par to ensure that the system operates efficiently. These include the participation of the university, the private sector, and the government. The university is obliged to prepare human capital with a high capacity for absorption and to actively engage in R&D. In turn, the R&D activities could pique the industry's interest, for example, in collaborating on product commercialisation. Additionally, industry must comprehend the character of the institution while collaborating with them, and government must establish a conducive environment for the innovation system to function. This includes the method used to stimulate industry and university partnerships, such as providing incentives. A well-functioning NIS is a critical element to a knowledge-based economy because it establishes connections and fosters ties among the three key stakeholder groups, namely government, university, and business (Chung, 2002). The relationship of these three stakeholders describes the functions and how the NIS operates to create new knowledge and innovative outputs.

In summary, the center of this framework is firm and their channels of obtaining sources of learning, which can be different firms, investigation foundations, or the scholarly world in provincial, national, or worldwide.  This model primarily focuses on wealth creation at the national level by connecting all parts and aspects involved in economic structure.

### 2.2.2 Regional innovation system (RIS)

The RIS is the second model connected with understanding innovation. This approach focuses on examining a country's regional and economic geography. This system emphasises the roles of innovation players and institutions in a specific region that collaborate together to generate, disseminate and allocate technical innovation in their interrelationships (Gao and van Lente, 2008). According to previous academic literature, knowledge, learning, and innovation are essential economic competitiveness and development factors for enterprises, regions, and nations. Until the 1990s, the linear model of innovation policy was the most common. This led to a focus on R&D infrastructure, financial support for companies' innovation, and the transfer of technology (Todtling and Trippl, 2005). Researchers such as Cooke (2002) focused on clusters of knowledge-based industries, Audretsch and Feldman (1996) on knowledge spillovers, and Keeble and Wilkinson (1999, 2000) on high-tech areas. This led to questions arising about why these industries tended to cluster in certain places, what kinds of links and networks existed, and to what extend knowledge spillovers could be seen.

Breschi and Malerba (1997) have further argued that regional level innovation activities will be able to stimulate cluster and potentially improve the economic balance of state development. Universities, industrial enterprises and public research organisations are among the main actors involved (Gao and Van Lente, 2008). Su and Chen (2015) defined the “regional innovation system as the institutional architecture that supports innovation within a region's industrial structure”. All regional innovation actors are integrated into sociocultural contexts under this framework, and many factors contribute to a successful RIS. Su and Wu (2015) investigated RIS using three biotechnology clusters in Taiwan as case studies: the Nankang RIS of novel drug discovery; the Hsinchu RIS of medical electronics; and the Southern Taiwan RIS of medical devices. In the case of Taiwan, the central government plays an important role in developing the industry. This includes the allocation of public financing, private financing, and regional and technology policy supporting the biotechnology industry.

Using the same perspective, Zhang (2015) described the evolution of biotechnology in Shanghai, concluding that there are three important components to developing the RIS. These are land, human capital, and the regional system. Key to the success of Zhangjiang High-tech Park (ZJHP) are the government's role and its ability to adapt top-down and bottom-up approaches. The development of ZJHP has been accomplished through the operation of land development, which has been assisted by both national and local policies to attract talent, provide a skilled labour force, and create settings that are distinct but constructive to the establishment of biotechnology capacities. The role of Zhangjiang High-tech Park Development Corporation and its land development is its capacity to attract foreign and domestic investment into the region. This new method of market-driven land development was the driving force behind the creation of the Zhangjiang High-tech Park in China. In term of human capital, the government, through its central and local policy, successfully attracted returnees from overseas to work in this region. These returnees possessed critical talents needed to fill the gap between business development and scientific research. In terms of its regional system, then, ZJHP has extensive subcontracting networks and platforms. To reduce the cost of brand promotion of these huge networks and platforms, Zhangjiang rebranded all under one name. This action helps to increase the visibility of ZJHP.

Using biotechnology clusters in Belgium and German as a case study, Segers, (2016) demonstrated that the BioRegions led to an increase in the number of new biotechnology companies. This resulted from the regional policy plan targeted at fostering the growth of robust and competitive biotechnology clusters. Active collaboration between universities, research institutes, existing companies and financiers has resulted in many university spin-offs (Segers, 2018). In Belgium, they relied heavily on large strategic partners, particularly for marketing outlets and manufacturing resources when they reach the commercialisation stage and for continuing product development efforts (Segers, 2016). This included relying on milestone payments and licensing agreements. Such strategic partnerships allowed smaller firms to survive in the biotechnology industry which is very high-cost and risky. The findings by Sergers (2016) demonstrated that the development of a domestic biotechnology industry or new biotechnology firms are largely influenced by the policies of regional government and larger company.

Asheim et al. (2012) state that the main fortes of the RIS concept are its robust policy agenda and its ability to articulate essential elements and directions of regional innovation policies which are tailored to meet the conditions and needs of various types of regions. Failure to identify the current condition of the country could result in RIS failures. One example of system failure in RIS can be found in (Tödtling and Trippl, 2005). According to them, there are three main types of system failures in RIS, namely ‘organisational thinness’, ‘fragmentation’ and the ‘lock-in’ problem. First, organisational thinness refers to a situation where there is a low level of clustering that will lead to a weak endowment with the relevant institution. Second, fragmentation refers to a lack of interaction and knowledge flow between the organisations in an innovation system, resulting in low levels of systemic innovation activities. Third, the ‘lock-in’ problem refers to innovation problems related to over-embeddedness and overspecialisation leading to a decline in industries and outdated technologies.

A number of similarities can be found from the above discussion. The previous researcher agreed that policy is important to develop a successful RIS. Findings by (Solleiro and Gaona, 2012; Luis and Gaona, 2012) stated “the key feature of the concept is that an economy’s (regional or national) ability to generate innovations does not only depend on how individual actors (including firms, universities, organisations, research institutes, governmental institutions) perform, but rather on how they interact as part of a system” (pg.112). This interaction is highly influenced by policies formulated at the national level to govern the interaction of the stakeholders in developing a specific region. In developing the RIS in Mexico, the government implemented a project to upgrade the competitiveness of small and medium-sized enterprises (SMEs) in the country. In order to define the agenda, a series of consensus building workshops were organised. The most striking factors constraining the success of this initiative were bureaucracy and lack of technical knowledge among the staff of firms, universities, R&D centres and government institutions. This included their lack of understanding of technological and organisational innovation and their role in industry competitiveness, and a limited knowledge concerning innovation, competition and market behaviour. However, companies were also reluctant to share their problems and areas of opportunity due to the fear of losing confidential information. This obstacle would affected the process of formulating a robust agenda (Solleiro and Gaona, 2012).

The RIS highlights the critical criteria required to develop a region. The most striking evidence in developing a region lies in the relevant policies. Robust regional policy has the capability to develop the region into a developed area when the policy(s) are formulated in accordance with the strength of the region in question. Further, the relationship between the industrial knowledge base, human capital, and institutional structures of the players in the region also affects its development. The current condition of the region's institutional structure, system failure and the industrial knowledge base can also be affected by the successful implementation of the RIS. Instead of formulating the relevant policies, it is also important to identify the current condition of the country that could contribute to the system failures in the RIS. The organisational thinness, fragmentation and the lock-in problem are the failures that found in the RIS. This failure seems to happen in others model of innovation such as the Triple helix. Therefore, it is important to acknowledge this while exploring this topic.

### 2.2.3 Sectoral system of innovation (SSI)

This subsection will explain the third model of innovation system which is sectoral innovation system. Understanding sectoral differences across sectors is relevant for any analysis that aim to foster innovation in firms. It is also important for a country to understand what are the factors that need to be taken into consideration in order to develop specific technology in the country.

The Sectoral System of Innovation (SSI) consists of a set of products and a set of agents who engage in market and non-market interactions in order to create, manufacture and sell product. SSIs have specific technologies, inputs, knowledge base and demand. They interact through processes of communication, exchange, competition, co-operation, and command which are shaped by institutions. The sectoral system undergoes change and transformation as a result of the alterations of its constituent parts. (Malerba, 2002). The SSI concept developed by Malerba has seven elements: (i) firms in the sector; (ii) other actors (in addition to firms); (iii) networks; (iv) demand; (v) institutions; (vi) knowledge; and (vii) the basic processes and coevolution (Malerba and Mani, 2009).

The first element is the firms in the sector. The firms are characterised by their specific learning process, organisational structures, capabilities, expectations, beliefs and goals. This element includes the key actors in innovation and production in the SSI. The second element regards the other actors, referring to the agents involved in the interaction of the firm above. 'Other actors can consist of organisations or individuals. The organisation may refer to suppliers, users, government agencies, universities, financial institutions and others while the individual may refer to consumers, scientists or entrepreneurs. These agents are also characterised by specific learning processes, objectives, competencies, beliefs, behaviours and organisational structures. The third element refers to networks. The firms in the SSI are connected through market and non-market relationships that can involve processes of exchange, competition and command. In more recent findings, it was found that the interaction can occur by tacit or explicit collusion, formal R&D cooperation or a form of hybrid governance. At this point, it can be seen that the relationship between firms and non-firms' have been a source of innovation and change in some sectoral systems.

The fourth element is demand. Demand may be domestic or international where it consists of heterogenous agents who interact in various ways with producers. The next element is institutions, which refers to norms, routines, common habits, rules, laws and established practices and so on which could shape the agents' cognition, actions and interactions. In all sectoral systems, institutions play a big role and have significant impact on the rate of technological change, the organisation of performance, and innovative activity.

It is essential to recognise that certain sectoral systems become prominent in a country because the existing institutions provide a more favourable environment for certain types of sectors over others. The sixth component is the base of knowledge. Knowledge is crucial for innovation and influences the forms of learning and the capabilities of businesses. The knowledge and technology domain raises the issue of sectoral borders at the centre of analysis, which are typically not set but change over time. At the firm level, knowledge is extremely idiosyncratic, does not spread instantly and easily among firms, and must be absorbed by firms through their accumulated differential expertise. The analysis of sectoral systems involves a thorough comprehension of interaction, cooperation, and competing processes. In a sectoral system, innovation is viewed as a process involving systematic interactions between a large number of players for the development and sharing of innovation-relevant information and its commercialisation. The sectoral system undergoes change and transformation processes as a result of the coevolution of its many components. This includes technology, demand, the knowledge base, learning processes, businesses, non-business groups, and institutions (Malerba and Mani, 2009).

The SSI focuses on learning processes and the development of capabilities, both of which are essential for middle income countries in the catch-up process of economic development. This model can be used to identify areas of institutional failure particularly in middle income countries and prompting action against such failures (Mehrizi and Pakneiat, 2008). In the industrial environment, an industrial cluster is made up of public and private stakeholders who communicate, coordinate actions, and collaborate on joint R&D activities as well as commercial initiatives. Managing the cluster entails providing an equally targeted and open communication platform, hence facilitating open innovation methods (Kircher et al., 2018).

Intarakumnerd and Chaoroenporn (2013) explored the roles of intermediaries in Thailand's automotive sector and determined the way in which institutional context influences the performance of innovation intermediaries. According to the study, intermediaries play a critical role in compensating for the lack of social capital that impedes the functioning of innovation systems in developing nations. Due to the low technological capabilities and dependency of the international joint venture partners or licensors, local employees were unable to absorb the transferred technology due to a lack of skilled labour (Brooker Group, 2002). As a result, the automotive cluster including the Thai Automotive Institute (TAI) and Thai Auto-Parts Manufacturing Association (TAPMA) acted as the intermediaries to improve the low absorptive capabilities among local suppliers in the automotive sector. Both TAI and TAPMA performed the role of the mediator where TAPMA is excellent at resolving disputes between its members (parts suppliers) due to trust among them and its understanding of private firms while TAI held more authority to foster collaboration between foreign automakers and local suppliers. These two combinations of intermediaries have successfully translated into producing a public good consisting of formulating policy (sectoral master plan), creating new possibilities and system dynamics by connecting actors, and providing important but costly training in critical skills and knowledge that local firms cannot access privately. Additionally, they also provided testing facilities and initiated R&D upgrade programmes in industry value chains critical for survival (Intarakumnerd and Chaoroenporn, 2013).

Hu and Hung (2014) contributed to understanding the failure of the SSI in their research on the pharmaceutical sector in Taiwan. Despite considerable state assistance, the pharmaceutical industry has been unable to achieve international competitiveness. The study's findings revealed that intellectual property regimes such as patents and publication play an important role in connecting innovation actors. The research concluded that Taiwan's pharmaceutical/biomedical sector's poor market performance is related to misalignment between and within its sectoral innovation infrastructure, industrial clusters, and the links between upstream and downstream innovation processes (Hu and Hung, 2014). For instance, public research institutes excel in upstream research activity but the private sector does not show its significant number of activities in terms of patenting or publication. This showed that the interaction and network mechanism in Taiwan sectoral system is weak. Moreover, due to the nature of SMEs and family-run enterprises, R&D operations in Taiwan's pharmaceutical sector are mostly sponsored by the public sector, which explains the conservative attitudes of family-run SMEs regarding the creation of riskier new pharmaceuticals and worldwide market expansion. Family-owned SMEs also limit their open innovation network and the industrial cluster's structure. In addition, Taiwan's national industrial policy emphasised the development of indigenous technical capabilities, mandating that any research outputs generated by its public research institutes must be licensed or disseminated to local firms before worldwide market demand is considered (Hu and Hung, 2014). The imbalance of innovative capability between the public and private sectors, combined with conservative venture capitalism, has thus served to stifle innovation and close cooperation, resulting in a 'chasm' in Taiwan's pharmaceutical value chain (Dodgson et al., 2008; Hu and Hung, 2014).

In regard to the thesis, the researcher will focus on the roles of the government in furthering knowledge exchange and commercialisation activities in Malaysia. This includes the relationship between the public and private sector in biotechnology policy. This section provides the readers with the functions of intermediary and the importance of specific knowledge in developing specific technology. These two factors are important as this research exploring the roles of intermediary of specific knowledge which is agro-biotechnology. The next section will discuss the Triple Helix concept to elucidate the relationship of the university, industry and government in-order to understand the innovation system in Malaysia.

## 2.3 The Triple helix model of innovation

This section highlights the most important concept that binds the whole thesis. The concept of Triple helix emphasized the sharing roles of three stakeholders namely government, university and industry. The discussion will also include three different models of Triple helix.

Numerous research studies have been conducted using the Triple Helix concept (Etzkowitz, 2007; (Leydesdorff and Etzkowitz, 1998); (Ranga and Etzkowitz, 2013). These include: Triple Helix in the technology transfer office (TTO) (Debackere and Veugelers, 2005); Triple Helix based on systems theory (Ranga and Etzkowitz, 2013); the transformation of innovation systems in the Triple Helix (Ivanova and Leydesdorff, 2014); Triple Helix in an open innovation system (Corona-treviño, 2016); Triple Helix in technology transfer activities (Osabutey and Croucher, 2018); and Triple Helix in relation to game theory (Mêgnigbêto, 2018). The Triple Helix model has also played a significant role in influencing analysis of NIS (Munshi Naser et al., 2019; Iqbal et al., 2015), RIS (Leydesdorff, 2018; Puangpronpitag, 2019), and the Open Innovation System (Yun et al., 2020; Leydesdorff and Ivanova, 2016).

The Triple Helix model of innovation refers to the link between universities, industry, and government. The Triple Helix is considered a spiral model of innovation that encompasses many reciprocal interactions at various stages of the knowledge capitalisation process (Brink and Madsen, 2016).Furthermore, the Triple Helix framework is utilised to examine the processes of invention within networks of trilateral and bilateral relationships entrenched in collaboration (Yoon, 2015). Although these three actors operate independently, they also partly share each other's roles in terms of the responsibility to stimulate innovation in a knowledge-based society (Etzkowitz et al., 2007). Engagement is a term that has only recently been applied to universities as a way to broaden the idea of what universities can do to help with their third mission (Davey, 2017). In the past, the third mission was seen as a one-way transfer of knowledge from the source of knowledge (universities) to the users of knowledge (business and society) (Mitton et al., 2007). But this one-way model has been replaced by a two-way and multi-channel knowledge exchange between universities, businesses, and the government that works symbiotically for all three (Mars et al., 2012).

In promoting knowledge capitalisation as one source of generating wealth for the nation, the Triple Helix model has gained recognition as an important new concept for developing countries to advance (Irawati, 2006). According to (Etzkowitz, 2016), government, universities and firms will take the roles of the other actors in the Triple Helix interactions whilst maintaining their main responsibilities and identity (Penksa, 2010). The university takes the role of industry by encouraging the development of new firms derived from their research, introducing 'the capitalisation of knowledge' as an academic goal and becoming an entrepreneurial university (Zhou and Etzkowitz, 2015).

Firms develop training to the highest level and share knowledge through joint ventures, thus emulating the role of universities. Government acts to regulate markets, but also operates as a public venture investor. Unlike other models that emphasise the role of government or corporations in innovation, the Triple Helix emphasises the university as the source of entrepreneurship, technology, and critical inquiry (Etzkowitz, 2008, pg.14). Many researchers have used this model to examine the key factors behind successful commercialisation activities in universities. Pique, Berbegal-Mirabent and Etzkowitz (2018) and others have used this model to examine how this relationship could impact problem solving in specific areas of technology such as IT (Puangpronpitag and Phongsiri, 2012), biotechnology (Chen and Lin, 2016) and disaster management (Agus et al., 2012).

The first component and central discussion of the Triple Helix focuses on the entrepreneurial university. Within universities, it can be seen that the quality of research, training and human capital are the important criteria in boosting entrepreneurial activities (Iqbal, Khan and Senin, 2015). Furthermore, it includes recruiting expertise and improving current commercialisation policies (Saad and Zawdie, 2011). In terms of facilitation, the establishment of science parks or incubators could assist university start-up companies to enhance their performance. However, Malaysia's indigenous R&D institutes have been inefficient in aiding local businesses to improve their technological capabilities (Malairaja and Zawdie, 2008). Wonglimpiyarat (2016) highlighted the importance of utilising a university business incubator as a way to encourage the formation of start-ups and entrepreneurial ventures, and noted that this required close interactions among the actors. Effective commercialisation of university inventions requires robust linkages between academics, industry, and government-supported policies and stimuli (such as grants, subsidies, tax incentives, and tax credits for innovative activities). In addition, Wonglimpiyarat (2016) stated that the majority of university research remains in its infancy and hence cannot be commercialised. University researchers are also hampered by a lack of government financing, support, and continuity of operations as a result of frequent policy shifts.

Further studies have revealed the importance of education in influencing student entrepreneurship. (Davey, Hannon and Penaluna, 2016) contended that better entrepreneurial leadership is currently required in universities. Entrepreneur training and education in universities can be divided into four categories: (i) entrepreneurial sensibilisation; (ii) entrepreneurship education; (iii) education for entrepreneurship; and (iv) education in entrepreneurship. The university can develop interest in entrepreneurial activity in both students and academics, as well as in business-related graduate career routes, via entrepreneurship education programmes (Davey and Galan-Muros, 2020). For example, the Carnegie Mellon Institute has integrated entrepreneurial education programmes into their MBA curriculum. The effectiveness of university technology transfer programmes has been improved considerably by entrepreneurial education. The role of entrepreneurship education programmes is to teach and support entrepreneurs in the academic setting, as well as to develop ties to outside community  (Boni, Emerson and Model, 2015). A study conducted at the University of Pretoria discovered that entrepreneurship education was unable to optimise entrepreneurial performance if graduates lacked exposure to non-traditional experiential learning methodologies (Botha and Ras, 2016). Students in rich countries see less of a need to understand entrepreneurial principles without the motivator of needs-based business, and hence student interest in entrepreneurship is reduced (Davey et al., 2011). As a result, universities must generate talent that meets the needs of industry. This can be seen in how talent is the main driver contributing to the growth and success of Silicon Valley (Pique, Berbegal-Mirabent and Etzkowitz, 2018).

There is also the notion that all public universities must adhere to the system mandated by the Malaysian department of public service, despite the fact that work specifications vary from institution to institution. For instance, the teaching burden at research institutions differs from the teaching load at research universities. These concerns have resulted in disparities between the teaching load of academic staff and their compensation (Basarudin *et al.*, 2016). Academics are burdened with a workload that is disproportionate to the effort expended and advantages received in obtaining each component of the necessary marks, including the number of research projects and publications, teaching and learning, administrative labour, and managing the programme for others. These challenges have diminished academics' motivation, as they now struggle to engage in the university's third goal (Basarudin, 2016).

Many universities rely heavily on government money to finance their running expenses (Ridzwan, Nik Muhammad and Ab Rahman, 2017) making funding one of the greatest obstacles to continued commercialisation efforts. As a consequence, the government wants research and innovation operations in research universities to operate efficiently. University funding is required to support ongoing R&D and daily operations. The move from research and development to the commercialisation phase demands substantial resources. (Munari, Sobrero and Toschi, 2018) therefore proposed the development of a proof-of-concept (POC) programme to determine the financial gap for this activity. The design of the POC includes: (i) financing size; (ii) selection criteria; (iii) a strict control and milestone-based structure; and (iv) extra support. External factors include: (i) university research excellence; (ii) TTO expertise; and (iii) public support.

Yusof and Jain, (2010) categorised university-level entrepreneurship research into three groups. These are the entrepreneurial university (EU), academic entrepreneurship (AE), and university technology transfer categories. AE is a component of the EU that is the end result of the research university initiative (RU). The more a university places emphasis on academic entrepreneurship, the more technology transfer activities will occur. To achieve the decision to collaborate, (Ramli *et al.*, 2013) suggested that institutions' missions for information diffusion and industrial revenue must be balanced. If this is not accomplished, the missions of universities may be impeded. Different motives, university management, conflicts over intellectual property ownership, and problems in generating local innovations through local expertise are obstacles to collaboration (Ibne Afzal *et al.*, 2017).

The second component of the Triple Helix is industry. Research by Virick (2015) found that investors are more likely to invest in companies that have prior start-up experience. There is further evidence that entrepreneurs with past startup experience are more positive about their venture's performance than rookie entrepreneurs (Cassar, 2014). Knowledge stock is measured by R&D expenditure and staffing levels are highly predictive of VC investment. Although VC engagement is more prevalent in newer companies, venture funds appear to invest more frequently in larger companies than smaller ones. This outcome resulted from understanding firm size as a metric of investment risk, with extremely small firms often being more opaque than bigger ones (Lahr and Mina, 2016).

According to research by Vanderford and Marcinkowski (2015) industry's reluctance to invest in academia is primarily attributable to inadequate infrastructure, a lack of emphasis by the university on the importance of research commercialisation, a low to nonexistent entrepreneurial culture on campus, inhibitive policies, and a lack of business and commercialisation knowledge among faculty. In accordance with this, investors are frequently hesitant when it comes to funding equipment, and even more so when it comes to investing in shared equipment. Shareholders seek a high return on investment, and equipment tends to depreciate over time, thus investing primarily in equipment is unappealing. In addition, entrepreneurs report that it is frequently challenging to convene shareholders between investment rounds to debate the distribution of shares because it is time consuming (Hulsink and Scholten, 2017). Investors are also more attracted to invest in companies with high-performance projects (Honjo and Nagaoka, 2018). These factors help explain why industry is often reluctant to collaborate with universities, thus influencing how the Triple Helix functions.

The third element of the Triple Helix is government. Government policy also influences the collaboration of commercial activities. Although government intervention is one way to correct market failures, government should always carefully analyse the potential unintended effects of new policies before implementing them (Lee and Kim, 2016). For example, although the Thailand government has implemented several entrepreneurship policies and programmes to help SMEs, these state innovation schemes are viewed as inefficient and bureaucratic, impeding the commercialisation of university research. The primary issue was a lack of policy coherence across government departments working with SMEs. In addition, the limited availability of VC funds and private equity investment impedes the financing of SME enterprises (Wonglimpiyarat, 2016).

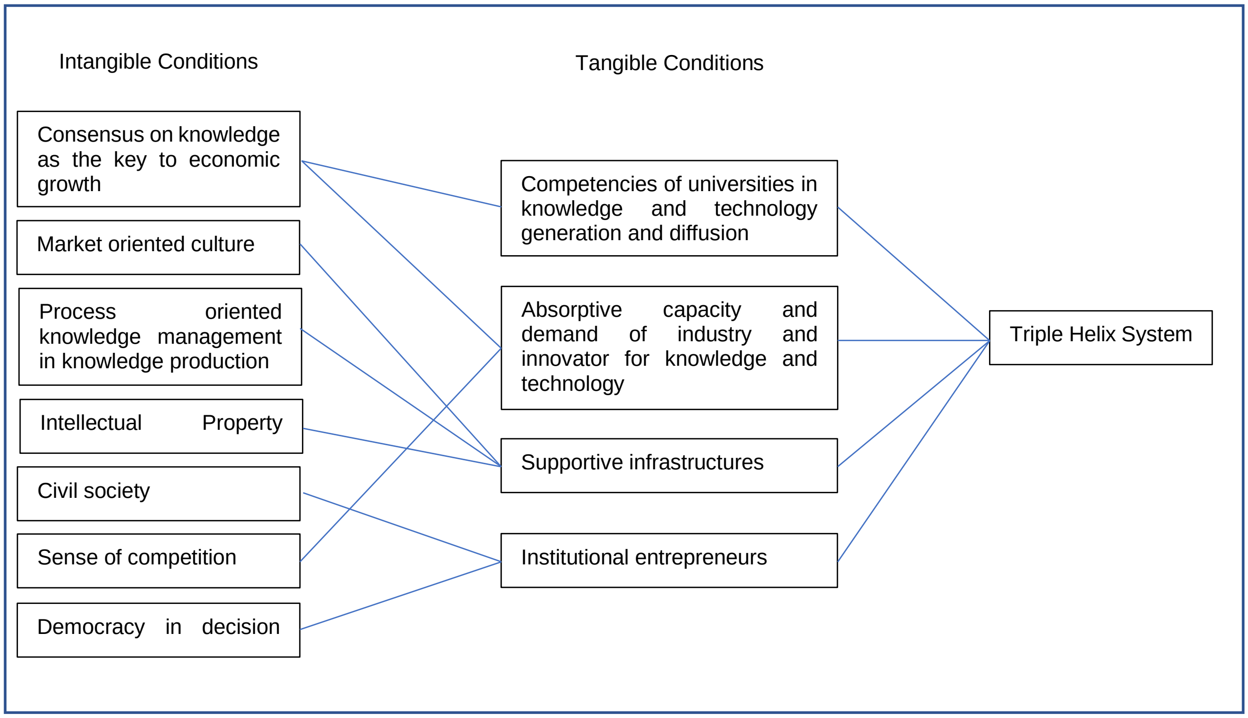
In another example, in Japan the government is very flexible in adapting policy changes, regulations and other organisational activities depending on their economic situation. In the 1970s, collaboration among government-universities and industries was statist: the government collaborated with industry or the university collaborated with industry, with no direct collaboration between the three. This situation was the result of the Antimonopoly Act, which forbade joint research between major firms and industries, as well as between the government and national industry. The Triple Helix was incomplete during this government-led model because university participation was hampered by severe constraints. Following deregulation in 2000, university-industry collaboration resulted in the establishment of a hybrid Triple Helix, as the scope of industry-government collaboration decreased.  The industry-government collaboration decreases as it is replaced by the university (Yoda and Kuwashima, 2019). This example demonstrates the necessity for flexibility in laws, regulations, and the operations of other organisations in order to facilitate collaboration among the Triple Helix actors.

In order to effectively allocate innovation resources and maximise the role of university-government-industry collaboration, the government should encourage efficient use of external resources by industries through policy guidance, knowledge spillover, and scientific research (Zhuang, Zhou and Li, 2021). To date, the development of technology transfer capacity in Malaysia has been mostly driven by the government in a top-down fashion. Some outcomes are encouraging and can be expanded with continued government intervention. Moreover, to maximise policy impact and improve the innovation and entrepreneurship culture in universities, the government's top-down approach must be met with bottom-up efforts from the universities themselves at multiple levels, including academics, students, TTO staff, and university managers (Ranga *et al.*, 2016).

The top-down method and the bureaucratic model of governance are closely related. The bureaucratic model considers the role of front-line employees in policy execution. Staff members who interact directly with people and other stakeholders have a crucial role in the successful implementation of policies, according to this theory (Khan and Khandaker, 2016). In addition, Khan and Khandaker (2016) argued that policy implementation requires job clarification in terms of goals, mission, objectives, detailed planning, appropriate job assignments, effective monitoring and evaluation, and comprehensive and efficient operating procedures and techniques to assist implementers in defining the scope of their responsibilities in accordance with the policy objective (Bock et al., 2018).

Multiple factors have been found that contribute to the successful implementation of the Triple Helix. In the development of a RIS, Ranga and Etzkowitz (2013) revealed four enabling conditions of the TH method. This was subsequently expanded upon by Cai, Pugh and Liu (2015) who discovered another seven enablers. The enabling conditions consisting of tangible and intangible logics are demonstrated below in Diagram 2.1.

**Diagram 2.1: The enablers of the Triple Helix system**




Adapted from Cai, Pugh and Liu (2015, pg.22)

Diagram 2.1 shows the 11 factors that underlie the success of the functional ability of the TH system. Each of these logics has its own role in shaping how the system works. These can be considered as enablers in promoting networks and interactions between university, industry and government as depicted in the balanced Triple Helix model which will be discussed in the next section. While the circumstances supporting RIS's are varied and complicated, the four tangible and seven intangible elements listed in Diagram 2.1 are the most important. The tangible circumstances are concerned with the Triple Helix system's specific performance referring to its technical environment, whereas the intangible conditions are concerned more with general contextual issues such as the institutional environment (Cai and Etzkowitz, 2020). Although this model was constructed to analyse regional innovation, it can be generalised to all settings.

In sum, this section provides the information about components of Triple helix. The concept of Triple helix showed the process of inventing new knowledge that have resulted from the interaction of government, university and industry. In this concept, the role of university is emphasized as the source of knowledge production, and therefore, university are expected to have strong foundation of entrepreneurial orientation and more responsive policy towards entrepreneurial activities. The industry plays an important role in supporting entrepreneurial activities by collaborating with university through R&D activities. The government have the biggest responsibility in formulating and implementing policy to encourage such innovation to happen.

### 2.3.1 Different models of the Triple Helix

The Triple Helix consists of three principal actors: the university; industry; and government. In some research, the actors are referred to as Science (university), Business (business), and Government (government) (Ivanova and Leydesdorff, 2014). There are three types of Triple Helix model that have been identified: the statist model; the laissez-faire model; and the hybrid model.

#### 2.3.1.1 Statist model.

In the statist Triple Helix model, the government plays a crucial role in propelling academia and industry. The government also plans, regulates, and oversees initiatives that promote innovation (Saad, Zawdie and Malairaja, 2008) . Under this approach, the knowledge generated by universities is not fully harnessed because the output product generated by the university are unrelated to industry needs. Furthermore, it can be said that no or few incentives are offered to universities and businesses, thus demotivating the academics and industry to further explore this area (Leydesdorff, 2013; Sarpong, Abdrazak, *et al.*, 2017).

In this model, both industry and universities are active in specialising and objectifying problems, while the government is responsible for project development and resource provision. This indicates that the university is primarily focused on education and the production of graduates for industry, with minimal intention of conducting research for commercialisation. Therefore, cooperation between universities and businesses is poor and requires significant government direction and leadership (Etzkowitz, 2008). Furthermore, according to Mohd Yusof (2013), bureaucracy is the primary impediment to the flow of ideas from the bottom to the top. Through this model, it can be seen that each of the actors are disconnected and work in silos.

#### 2.3.1.2 Laissez-faire model

This laissez-faire model depicts distinct institutional spheres with rigid boundaries and minimal interaction between them. These three institutional realms operate independently and lack close connections. The laissez-faire policy, which emphasises the loosening of government control, reflects the laissez-faire model to a large extent (Etzkowitz and Zhou, 2017).This The model is also focused on the productive force of industry as the prime mover of economic and social development (Etzkowitz, 2008). Through the production of usable knowledge in the form of scientific articles and trained staff, the university is indirectly linked to industry. The institution has begun to provide basic research to industry, although it primarily serves as a teaching and learning centre with no plans to collaborate or apply its basic research in the market (Yusof, 2013). The lack of a synergistic relationship between these institutional spheres demonstrates that the government's role in harnessing innovation is limited to addressing market failures. Enterprises are set apart from each other in an intensely competitive environment but interact modestly in the market relationships of buying and selling. The role of government and industry in the statist model is indeed reversed in the laissez-faire regime (Yoon, 2015).

In the laissez-faire relationship model, the role of government is reduced to a minimum and limited to being either a customer or regulator (Etzkowitz, 2003). With the role of regulator and source of funds, the government is actively involved in lobbying activities related to industry and universities. The networks between these three as a result of lobbying has become an important arena for building private-public relations. Research from Larsen, Nesse and Rubach (2018) in Norway determined that the role of government (referring to lobbying activity) differs according to the growth of the companies. The Laissez-faire model is found when companies are small and independent and have little experience with lobbying at a national level.

#### 2.3.1.3 Hybrid model

As a result of the evolution of the statist and laissez-faire models, the hybrid model emerged. This paradigm allows for the hybridisation of actors' roles while preserving their duties, basic roles, and identities (Saad, Zawdie and Malairaja, 2008). This illustrates that universities and industry have greater autonomy with substantial interaction and connections amongst participants of the Triple Helix (Yusof, 2013). At this stage, all actors play a role in creativity and economic activities that lead to the formation of new creative organisations in their own capacity. Strong social relationships among participants encourages knowledge transfer activities and the emergence of new or inventive concepts, products, or applications resulting from the fusion of organisational innovation and technological aspects from the institutional realm and technological system (Yusof, 2013). This paradigm emphasises the development of overlapping and interdependent links between the three domains. It serves as a network that promotes links and mutually beneficial ties between the three major institutional realms and other various organisations and disciplines in which innovation policy is the result rather than government directives (Sarpong, Abdrazak, *et al.*, 2017).

In this section, the Triple Helix has been explained in detail. Based on the literature, two striking distinctions can be made. First, the components needed to ensure the good function of the Triple Helix. including tangible and intangible conditions. Second, the Triple Helix can be divided into three types. In developed countries, the hybrid model and Laissez-faire model are common as these countries are less dependent on government support. In contrast, for a developing or underdeveloped country, the Statist model is commonly spotted as economic development is more dependent on government support. This literature can help the research to frame the condition of Malaysia in terms of commercialisation activities.

This subsection highlights three different models of Triple helix. Statist model signifies the government's taking lead and controlling the university and industry collaborations, while the laissez-faire model is in contrast of statist model where every entity in this model is separated from one another and the role of government is limited. The hybrid model represents the ideal interactions of the three stakeholders whereby organisations, institutes and government are taking each other's roles and responsibilities in technology development and innovation. It is important to identify the characteristic of these three models as it will be used in determining the innovation level of biotechnology commercialisation activities in research universities in Malaysia.

### 2.3.2 Reflection on Triple helix

Triple helix stresses the interaction of government-university-industry. The Triple helix is an analytical and normative concept that arose from the government's evolving relationship with academia and industry. The notion emphasises the need for interaction among government, university, and industry as relatively separate yet interdependent institutional realms in improving the conditions for innovation and sustainable growth in a knowledge-based society (Dzisah and Etzkowitz, 2008).

A debate exists concerning whether the Triple helix model plays a different role in developing and developed countries (Dzisah and Etzkowitz, 2008). For example, Williams and Woodson (2012) claimed that patterns of innovation in less economically developed countries differ from those in developed countries. Prior to that, Lorentzen (2010), Metcalfe and Ramlogan (2008) and Mytelka (2000) stated that innovation in underdeveloped nations faces different capital and infrastructural obstacles compared to developed nations. Moreover, developing countries frequently lack a cohesive plan for integrating the essential components required for socioeconomic growth (Dzisah and Etzkowitz, 2008). Therefore, it has been argued that Triple helix concept is unable to fully explain innovation in developing countries (Williams and Woodson, 2012).

Nonetheless, innovation studies are crucial for low-income countries. According to Fu *et al.* (2014), only technological advancement and innovation are able to provide significant solutions to the major challenges faced by low income countries (LICs) including poverty alleviation, resource depletion, and sustainable development. Due to an absence of innovative ability, knowledge creativity, and diffusion institutions in developing countries, policy formulation in these countries will typically be geared towards the establishment of the foundational technology infrastructure. In contrast, policies linked with innovative clusters in industrialised countries are likely to emphasise information sharing, such as network building, increased cooperative R&D, and strategic alliances (Irawati, 2006).

According to the science and technology studies (STS) perspective, the Triple helix concept is unbalanced because it fosters the “accumulation and concentration of capital through science and technology-based innovation”, measures development through economic growth, and establishes techno-scientific regimes without adequately addressing socioeconomic ills (Amir and Nugroho, 2013, p. 6). Despite these objections, many industrialised and emerging nations consider trilateral cooperation between their university, industry, and government sectors to be crucial for fostering innovation and achieving endogenous economic development (Choi, Yang and Park, 2015).

In fact, there are a number of examples of the Triple helix being used in both industrialised and developing countries. For example, in Singapore, the National University of Singapore, Singapore Management University and Nanyang Technology University have joined to start an agency that encourages the sharing of knowledge, the commercialisation of knowledge, and cooperation. In South Korea, the government of President Park Geun-Hye has pushed for a ‘creative economy’ that stresses the value of trilateral cooperation, especially between government, universities and businesses.

For developing countries, William and Woodson (2012) provide four survey cases of agriculture, banking, biomedicine, and information and communications technologies in less economically developed countries to explain the innovation theories applicable in Less economically developed countries (LEDCs). William and Woodson (2012) state that there are four source of innovators that have influenced innovative development in LEDCs. The innovators can come from international non-government organisation (INGO) and non-government organisation (NGO), individual funding, public private partnerships, and the government, whereas the Triple helix model emphasises the roles of government, university and industry (G-U-I) and their interactions (Choi, Yang and Park, 2015). Although the example above does not have the clear cut of Triple helix elements, it exemplifies how the initiative (of the NGOs and government as innovators) have connected the government-university-industry relationship. To comprehend the Triple helix paradigm from the viewpoint of a developing nation, it is necessary to understand the narrative of developed nations, including the risks and pitfalls that have already occurred during the implementation phase. Subsequently, it may be advantageous for developing nations to use these lessons as benchmarks in order to improve the emergent Triple helix embryo(s) in some developing nations (Dessy, 2007). Consequently, there are no issues of adapting Triple helix model or any innovation model into LEDCs.

Understanding the innovation system is essential and valuable because, if properly implemented, it can analyse the context in which innovation is embedded, including universities and government (Lundvall, 2010), for example; Malaysia and India. In Malaysia, the government has provided financial incentives for universities and businesses to work together and some universities have set up investment arms and business units to market and use their skills and knowledge (Saad et al., 2008). Inspired by the MIT model of the United States, the India Institute of Technologies (ITTs) seeks to cultivate a technical elite (Etzkowitz and Dzisah, 2008). Innovation should therefore not be viewed as a result of development, but as a means to attain it. Consequently, the central issues are the synergy between the three distinct actors in societies with diverse traditions of political economy, as well as the different levels and types of economic development, including the macro- and micro-economics of each country (Irawati, 2006). Innovation, then, is not a result of development; rather, it is a means of development. In other words, there will be no transition from low income to middle income without innovation.

### 2.4 Knowledge transfer and exchange activities

This section will demonstrate types of knowledge transfer and exchange activities. Understanding how knowledge transfer and exchange activities is important as this research will look at how government, university and industry exchange their knowledge in pursuing commercialisation activities.

Knowledge transfer and knowledge exchange are frequently used synonymously. Knowledge exchange reflects a two-way process in which participants share their knowledge, ideas, and experiences. Knowledge transfer is often seen as a more one-way process and has been identified as a key component of innovation, generating economic advantage in increasingly knowledge-based economies. According to Tangaraja *et al.*, (2016), knowledge transfer and information sharing are misunderstood. Based on a review of the relevant literature, knowledge sharing is a component of knowledge transfer.

Other sorts of knowledge, such as expertise and talent, are challenging to codify. This information is typically embodied in human experience and is transferable alongside personnel (Kang, 2016). Knowledge transfer is established during the collaboration and mutual interaction of different stakeholders such as government agencies, firms and universities. This multi-level process of research commercialisation involves interactions between university, researchers and the external environment (Guerrero and Urbano, 2012).

In a university setting, the activity of information exchange from one member to another will add value to the academic's annual performance, which will ultimately result in individual career achievement (Rasdi et al., 2012). Knowledge transfer and knowledge sharing among researchers are not new in the area of knowledge management. Knowledge transfer can occur in a variety of ways in university settings, including collaboration in R&D, academic mobility, student mobility, commercialisation of R&D results, curriculum development and delivery, lifelong learning, entrepreneurship, and governance (Davey, 2017). The study by Fernandez-Esquinas et al. (2016) classified university-industry ties into five latent dimensions:

knowledge generation and adaptation; participation in new organisations; training and exchange of human resources; intellectual property rights; and facilities and equipment. All are primarily based on exploitation or exploration activities. Similar to the previous study, a firm's absorptive capacity (AC) is crucial in among university-industry interaction. although the spectrum of exploration and exploitation activities is not definitive (Fernández-Esquinas *et al.*, 2016).

In mapping the knowledge exchange relationships of Sussex University, Martinelli et al. (2008) determined that different faculties evidenced differing ways in engaging with university-industry collaboration. In Sussex University, there are seven types of knowledge exchange, namely transmission, presentation, effort, consultation, use, and business activities. Martinelli et al. (2008) also noticed that university staff without external links held prejudices about these collaborations. They also discovered that faculty awareness concerning the university's codes of practice was low, thus limiting their involvement in entrepreneurial activities. Furthermore, the 'standard' university codes of practice on intellectual property, commercial exploitation, financial benefits and consultancy seemed ill-suited to the needs of all faculties in the university.

According to Rasdi et al. (2012), enormous focus has been given to develop knowledge sharing. Knowledge transfer explains the movement of information and ideas from a knowledge source to its potential users (Fogg, 2012). Knowledge has a unique character in that it is sticky (stickiness), meaning it is so specialised that it cannot easily be transferred from one actor to another (Fier and Pyka, 2014). When knowledge is too sticky, its transfer becomes difficult. Cohen and Levinthal (1990) coined the phrase absorptive capacity (AC) to encapsulate the idea that organisations may have varying aptitude to innovate and to perceive the value of new knowledge, digest it, and apply it to the creation of economic opportunities.

In a similar vein, Zahra and George (2002) offered four dimensions for firms' AC: acquisition; assimilation; transformation; and exploitation. These dimensions can be used to precisely explain the processes a SME must take to assimilate new external knowledge in order to achieve a competitive edge. In addition, two subcategories of AC were identified: potential absorptive capacity (PAC); and realised absorptive capacity (RAC). PAC facilitates a firm's openness to external knowledge (the acquisition and assimilation of new knowledge). RAC refers to the capacity of a company to capitalise on acquired knowledge. Increasing RAC should be a fundamental element of any knowledge exchange programme. However, it is believed that brief training programmes and one-time events, which are frequently supplied by universities to SMEs, only help to boost PAC (George, Zahra and Wood, 2002).

Zahra and George (2002) also suggest that the following four conditions should be paid attention to in order to absorb new knowledge: unaware or passive; reactive; strategic; and creative. The 'unaware or passive' condition is where SMEs fail to recognise the need for change and thus were unaware of what to improve. The second condition is reactive. Here, SMEs acknowledge the need for change but are unsure of how to do it effectively. The third condition is strategic, in which SMEs recognise the need for change and have strong implementation skills. The final stage is creative, when SME competencies are fully developed and they can function and lead effectively on an international scale. Fogg (2012) argued that this typology could assist in categorising diverse SMEs and determining which knowledge exchange programmes should be tailored to the organisation's stage of development.

However, successful knowledge exchange is tough to accomplish and maintain as it involves development processes (Szulanski, 2000) in which academic personnel share their expertise with others to build innovative projects and long-term partnerships. Participation in industrial activity has a less well-established legacy of scholarship and is frequently considered less relevant than research within HEIs. This has been a result of the research assessment exercises set by universities and higher education funders which only values publication activities compared to commercialisation. However, the practice has changed and universities are offering financial and reputational incentives when engaged in knowledge-based partnership activity.

Technology transfer from university to industry is not a simple process as it needs co-production (Rossi, Rosli and Yip, 2017). For a firm to engage in technology transfer, it is important to educate the staff, identify resisting employees and include everyone in the change process. First, the employees should be informed why the change is happening. If a person does not understand the reasons for change, this is likely to increase resistance and the risk that technology transfer will fail within a company. Second, employees who are resisting should be encouraged to understand that the changes are necessary and important. Here, the role of the knowledge expert in the university is important to remove the occurrence of any internal prejudices or biases. Third, people in the organisation should be actively involved to ensure the process is understood across the whole business, not just those employees directly involved with the process. From this research, it can be seen that the roles of top management are crucial in ensuring the technology transfer process (Jones and Coates, 2020).

The growing popularity of university-industry collaboration has raised some crucial challenges, such as how to ensure success in knowledge transfer (Hanid et al., 2019). Lakpetch and Lorsuwannarat, (2012) discovered that the primary enablers of efficient knowledge transmission are partner qualities. Private partners must comprehend the multifaceted mission and sophisticated culture of universities. This comprehension and subsequent adaption will help to connect university and partner aims and strategic priorities. While pursuing the university's interest in fostering an entrepreneurial spirit within the university, management should recognise the importance of staff members gaining mutual benefit and a win-win agreement in order to avoid an actual or apparent conflict of interest between their obligations to the university and outside interests.

The university is suggested to promote an innovative culture, and that ethical considerations and management justice in allocating research projects will boost the motivational and absorptive ability of researchers in sharing knowledge. Universities have a culture that is often confined by laws and regulations that conflict with the operational procedures of private organisations. Although university leadership support commercialisation, peers undertaking the peer review process may not support the point that commercialisation fulfils the research purpose of the university. This is connected to the university's practice of rewarding researchers based on the publication of refereed (peer-reviewed) articles rather than the commercialisation of products deriving from their published research efforts. The corporate sector should contribute to strengthening and supporting the cooperation. This involves the ability to adapt to the university's culture in order for the relationship and subsequent commercialisation process to be successful Lakpetch and Lorsuwannarat (2012).

The technology transfer office (TTO) is also involved in knowledge transfer activities. In their study to determine the roles of TTO in helping commercialisation, Belitski, Aginskaja and Marozau (2019) determined that the TTO was unable to fulfil its roles in the institutional framework which is unfriendly in transition countries. This occurs in countries with highly bureaucratised rules and practices. In addition, the TTO they studied were extremely bureaucratic, with the decision-making process dependent on university administrators and government interests rather than business requirements. This highlights the significance of co-ownership of inventions and direct industrial participation (Boardman and Ponomariov, 2009). Indeed, university scientists frequently view innovation as a public good (Slaughter and Rhoades, 2004).

Fernández-Esquinas, Pinto, Yruela and Pereira (2016) discovered that corporations connected with universities through a range of channels, including collaborative research initiatives, patents, spin-off developments, consulting and specialised training, and informal contacts. Although the degree of knowledge exchange activity is related to knowledge management and revenue production, it also depends on the individuals who own and participate in the shared activity and are enabled by their organisation to do so (Davis, 2009). For example, Handoko, Bresnen and Nugroho (2018) made an attempt to understand the impact of social capital on knowledge exchange within supply chain. Comparing two companies, Handoko, Bresnen and Nugroho (2018) found that the company with flexible control tended to be more involved in knowledge exchange activities. In other words, this company is capable of making the best use of social capital within the company to facilitate knowledge exchange within and across the organisational level. At this point, it can be seen that a strong bond between innovators, shared understanding, supportive company culture and shared values provides positive impact to knowledge exchange between staff in the company as well as with the customers (Handoko, Bresnen and Nugroho, 2018).

This section provides the readers with the differences between knowledge transfer and exchange. Knowledge transfer can easily be transferred as it is codified and often seen as a one-way process while knowledge exchange reflects two-way process in which participants share their knowledge, ideas and experiences. The knowledge can be categorized depends on its stickiness. The more stickiness of the knowledge, the more difficult the knowledge can be transfer. At the university level, knowledge transfer is frequently occurred as university values research publication rather than commercialisation of R&D activities.

Commercialisation activities are considered as knowledge exchange as it reflects a two-way process in which participants share their knowledge, ideas and experiences. It is important to understand how knowledge transfer and knowledge exchange happened as this research will look at how the university transfer and exchange the knowledge with the government and industry.

### 2.4.1 Knowledge transfer in the biotechnology industry

The previous subsection describes the differences of knowledge transfer and knowledge exchange activities happen at university and organisational level. In this section, discussion will be continued with knowledge exchange activities in the biotechnology industry. As a late comer in biotechnology industry, biotechnology is new to Malaysia, therefore this subsection will explore the essential factors to support knowledge exchange in the biotechnology sector.

The bioeconomy has been around for a long time in agriculture and forestry, wood processing, textiles, paper, chemicals, food, and pharmaceutical industries, as well as bio-fuels and other types of biomass-derived energy. Driven by a range of factors including climate change, innovation in processing and products, and scarce investment, these factors started a real innovation wave. According to Kircher *et al.*, (2018), the innovation wave has not only affected traditional sectors but also bio-based products such as those chemicals that enter industrial practice.

To advance the industrial potential of the bioeconomy, several biotechnology-related institutions and stakeholders with distinct responsibilities and interests must collaborate. All technological, commercial, and administrative entities and competencies must be accessible. Open innovation, a concept popularised by Henry Chesbrough, operates on the belief that firms can generate value by commercialising internal ideas through channels outside of their existing business (Chesbrough, 2006). An open innovation strategy necessitates collaboration with parties outside the organisation, including academia, suppliers, customers, and even competitors. Crucial factors that determine the successful collaboration include: finding the right partners; having good knowledge of the product or process; and trust. The latter factor, trust, is also an essential factor in a successful open innovation approach (Caulfield and Ogbogu, 2015).

A high level of uncertainty characterises cooperative research projects, which also include competitors or models like cross-licensing and patent pools. This uncertainty can be overcome to a certain extent by mutual trust built on long term relationships. Crucial factors to successfully manage a bioeconomy cluster include: sharing a joint vision; creating a culture of cooperation; and the level of participation by active members in the cluster. It is important to have a collective vision because it affects the cluster's goal and strategy.

A study undertaken by Subramonian and Rasiah, (2016) to investigate knowledge transfer barriers in Malaysian automotive and biotechnology industries discovered that while firms' perceptions of universities was positive, collaboration between them was low. This is due to the two organisations' distinct cultures. According to Kehrel, Klischan and Sick (2016), knowledge exchange is difficult to achieve when organisations are unable to communicate on a technical level with one another. The benefits of a partnership can only be realised when the partners communicate effectively. This research demonstrated that strategic collaborations are especially important for organisations in research-intensive industries like medical biotech (Kehrel, Klischan and Sick, 2016). In a more detailed study of knowledge exchange in the biotechnology sector, Adham, Kasimin and Said (2011) highlighted the roles of ministries, government agencies and public policies in implementing Malaysian Biotechnology Policy. Using the Open System theory becomes a powerful tool in explaining how these institutions operate within the system via realising the goals in the NBP. It is discovered that the NBP consists of all subsystem needed for the policy to operate but missing in terms of monitoring and intelligence absence in operating the subsystem as each of the subsystem has its own complexity. The missing of these two functions limiting the policy to works appropriately.

This section has identified the essential factors that determine knowledge exchange activities in the biotechnology sector. Previous research has suggested that knowledge transfer activities will occur when there is coordination of the same goal among different stakeholders and mutual trust. Networking also affects knowledge exchange activity in the biotechnology sector. Using the Triple Helix framework can help this study unveil the reasons for poor knowledge exchange activity among university and industry in biotechnology in Malaysia.

**2.5 The roles of university and industry in commercialisation activity**

The previous subsection explain how knowledge exchange occurs at the university and organisational level and how biotechnology can be exchange among the Triple helix stakeholders. In this subsection, discussion will continue in understanding the roles of the university and industry in supporting biotechnology commercialisation activity. As mentioned in section 2.3, the main strength of Triple helix lies in the function of the university. Therefore, this subsection will illustrate how university and industry able to support this activity.

Scholars have realised that the function of university is not simply restricted to knowledge production, dissemination and perpetuation (Stephens *et al.*, 2008). Instead it has gone beyond traditional roles by being transformed into a wealth generator institution (Dooley and Kirk, 2007) . According to Martinelli et al. (2008), universities nowadays are entering a third mission by engaging in knowledge sharing and exchange activities. The connection between university and industry always involves knowledge transfer activities. The potential for knowledge exchange and transfer activities to occur between the entities (entrepreneurial university and industry) exists due to the potential for wealth generation (Irrawati, 2007).

According to Landry, Amara and Oumit (2002), knowledge exchange activities can operate both formally and informally, and are often seen as a seed-bed for more formal and contractual knowledge transfer and exchange activities between the university and industry. This can lead to spin-out firms and licensing arrangements with external organisations. The universities that engaged with entrepreneurial activities such as the creation of startup companies can potentially create jobs in the local region or state but at the same time, the startup strategy entails higher risk. This is due to the relatively high probability of failure of new companies. However, startup companies are able to generate high returns if they are taken public (Siegel and Phan, 2005).

It is also acknowledged that educational institutions have made significant progress in shifting their focus in creating and commercialising intellectual property and engaging with the third mission of the university to become one of the promoters of economic development (Lawton-Smith, 2007). Entrepreneurial activities will improve the university's financial statement and, at the same time, will improve regional or national economic performance (Etzkowitz et al., 2000). Apart from that, the university is engaging in these activities due to a lack of financial support for their R&D. In a study on the governance of knowledge transfer, (Rossi, 2010) discovered that firms were likely to collaborate with universities because they could gain access to new knowledge in terms of database infrastructures, the opportunity to become temporary researchers or scientists in universities, and the opportunity to gain new experience in learning and research activities (Rossi, 2010).

In this new mode, the system of knowledge production is more sophisticated as it involves specialists from a variety of disciplines to collaborate on problem-solving guided by cognitive and social practices. Due to the rise of the knowledge-based economy, global competition, and IT in contemporary society, the university's original functions of preservation and knowledge transfer have been expanded to include the production of new knowledge and, more recently, knowledge exploitation for innovation (Etzkowitz and Dzisah, 2008; Sam, 2016). Etzkowitz and Leydesdorff (2000) also noted that universities play a crucial and difficult role in leading innovation initiatives in a knowledge-based society, as the pressure on academic institutions to satisfy this expectation continues to grow. According to Mok (2005), the knowledge-based society is the result of the university's responsibility to adapt to socio-economic and socio-political changes (Sam, 2016). The university's function is not limited to research and instruction, but also encompasses community involvement. In recent years. As a consequence, emphasis has been placed on the evolution of universities' integration into the innovation system of a rising economy (Fischer, Schaeffer and Vonortas, 2018).

Lin (2017) explored the effects of industry collaboration on enhancing academic innovation output in China and discovered that the relationship between the two is used to gain access to technologies, develop innovative knowledge, expand financial resources, and leverage universities' innovative capacities. Industry provides the finances and equipment; hence, the university will commit substantial knowledge resources in establishing a working relationship with companies to develop academic innovation. Academic innovation increases as a result of the university's increased number of industry partnerships (Lin, 2017). Cheng *et al.*, (2018) performed research on the effect of university-industry collaboration policy (UIC) in China. They showed that the policy had a favourable impact on a university's knowledge output and that the policy's impact on patents is greater than its impact on publications. These empirical findings indicate that government support for collaborative input has a greater impact on knowledge output than enterprise funding.

This is due to the fact that most research funding comes from the Chinese government, with limited investment available for collaborative research, and insufficient funding for basic research in China. The study also posits that the UIC policy in China focuses on the problem faced by industry rather than on publishing articles. The finding of this research also determined that government funding of R&D collaboration from the enterprise, government and other resources, has a more significant effect on the number of patent licenses than it does on the number of the articles published by the university. Thus, it can be seen that industry can increase the number of patents invented. However, the UIC strategy has a threshold effect on the connection between enterprise-university collaboration and government-university collaboration. When the UIC policy strength exceeds the threshold, government-university collaboration may replace enterprise-university partnerships (Lin, 2017; Cheng et al., 2018).

In sum, it can be seen that the roles of university and industry are interdependent and have changed over time. From the university perspective, the main role of the university is teaching and research (Etzkowitz, 2004), with further engagement in the third mission of the university which is entrepreneurial activity that demands participation from industry. Etzkowitz (2003) proposed the concept of entrepreneurial activities, arguing that the entrepreneurial university is an extension of the traditional teaching and research missions of the university. The third mission is difficult to follow as it involves complex relationships with industry and special characteristics of skills and requirements to enable collaboration or knowledge exchange to occur. To enable collaboration between university and industry, the university needs to be equipped with high-skilled employees, high levels of absorption capacity, and provide a good ecosystem for the collaboration to take place. This includes the roles of government and university in introducing policies related to commercialisation, including tax waivers and special privileges to further attract participation from the university and industry to collaborate. In short, this section has provided a framework to analyse the complex relationship between the research university and industry in Malaysia in supporting knowledge exchange and commercialisation of agro-biotechnology

# Chapter 3

# Methodology

## 3.1 Introduction

This chapter aims to explain the rationale for the chosen research methodology and research design of this study. Research design constitutes the decision made to decide what, when, where, and how concerning an inquiry or a research study. It is the conceptual structure within which research is conducted. It constitutes the blueprint for the collection, measurement, and analysis of data. As such the design includes an outline of what the researcher will do from writing the research questions and its operational implications to the final analysis of data (Kothari, 2004). Bryman (2008) further explained that a research method is simply a technique for collecting data and may involve a specific instrument.

This chapter examines the methodological approaches chosen for the research and how the research is carried out. The conceptual framework developed in this study helps to examine the issue of commercialisation activities, hence answering the main research question which is: To what extend has the NBP helped the commercialisation of biotechnology and the creation of spin off firms in Malaysia.

The first objective of this thesis is to explore the role of the NBP in further enabling the creation and sustainability of university spin-off companies. This study examines how government agencies help commercialisation activities in research universities. The second objective is to understand what challenges are faced by universities in pursuing biotechnology commercialisation. This is to gain a more advanced understanding of why universities are unable to engage closely with commercialisation activities. The third objective of this thesis is to understand how policies at the national and university level are able to help commercialisation activities among start-up companies. It is important to determine whether the policies have helped the start-up companies or made the situation more complicated. In the context of this chapter, the use of multiple approaches in the data collection and analysis process (i.e. interviews and interpretative analysis) enriches the study and generally allows a better understanding of the current issues being researched.

### 3.2 Research methodology

Before conducting research, it is necessary to understand the research methodology. To adopt the most relevant methodologies and research methods, researcher must first comprehend the underlying philosophy of research. As a new researcher, there is always confusion between methodology and method. The approaches or procedures used to acquire and analyse data are known as research methods. It is a strategy or methodology that is selected for a research endeavour and is linked to the research objectives and data gathering sources. The methodology is driven by certain ontological and epistemological assumptions which consist of research questions, a conceptual approach to a topic, the methods employed and consequently the data sources selected. All of these steps are logically connected. In other words, the methodological component of this study will lead the research design. The methodology of research is guided by the axiological assumptions (values) of the researcher. Values will determine how a researcher will access information and what instruments will be used to collect data. This is referred to as epistemology (Tobi, 2016).

There are various models available which are used to understand the research methodology. For this study, 'The Research Onion' model will be use as a template to explain the research methodology. The Research Onion was developed by Saunders et al. (2007) and has six elements. It constitutes of: (i) research philosophy, (ii) research approaches, (iii) research strategies, (iv) research choices, (v) time horizons, and (vi) research procedures. This model is chosen as it provides a step-by-step guide to conducting the research. The next section discusses each of the components in the context of this research.

### 3.2.1 Research philosophy

Philosophy research is a study of the nature, knowledge, ideals, and causes or principles of reality that is based on logical reasoning instead of direct observation. It makes an appropriate contribution to the body of knowledge. The research philosophy guides the researcher in the creation of new knowledge (Tobi, 2016). Easterby-Smith et al. (2002) provided three reasons for emphasizing the significance of comprehending philosophical issues when conducting research. First, it assists in elucidating the research design. Second, it aids the researcher in determining which research designs will be effective and which will not under various conditions. Thirdly, it assists the researcher in identifying and developing research designs that may be outside his or her area of expertise. Research paradigms are another name for the research philosophy (Maghrabi, 2019).

This can be classified into two groups: classical and contemporary research paradigms. The classical research paradigms are positivism, critical rationalism, classical hermeneutics and interpretivism, while the contemporary research paradigm consists of critical theory, ethnomethodology, social realism, contemporary hermeneutics, structuration theory and feminism (Blaikie, 2010). Accordingly, as the foundation of the research methodological design, research philosophy explains the philosophy that is chosen with the appropriate assumption to classify: (i) what counts as reality in many ways to structure it as a type of knowledge (ontology), and (ii) how the knowledge of that reality is established (epistemology) and what values go into that knowledge (axiology).

In this study the research paradigm is interpretivism in which social reality is viewed as the product of its inhabitants. It is a ‘world’ that is explained and interpreted by the meanings that participants produce and reproduce as a necessary part of their everyday activities together. This ontology requires the use of a different logics of inquiry to that used in the natural sciences (Blaikie, 2010).

### 3.2.2 Research approach

The research approach is the strategy used to collect and analyse data. In this stage, the researcher is required to determine which approach is best suited to the chosen topic. For this research, qualitative research is employed. Qualitative research is the systematic inquiry into social phenomena in natural settings. These phenomena can include but are not limited to, how people perceive aspects of their lives, how individuals and/or groups behave, how organisations function and how interactions influence relationships. In qualitative research, the researcher is the primary data collection instrument. The researcher examines why events occur, what happens and what those events mean to the participants studied (Teherani et al.,2015). In examining the roles of policies related to commercialisation, the researcher attempted to understand what these policies mean and how they affect the government agencies, research universities, and companies.

For the purpose of this study, a combination of deductive and inductive procedures were used, although the main research approach used is inductive. This is because qualitative inquiry is primarily oriented towards exploration, discovery, and inductive logic hence, the inductive method is used as the primary research strategy. Qualitative research is a systematic method for answering inquiries (Saunders et al, 2019). It entails spending a significant amount of time in the field, engaging in the often complex and time-consuming process of data analysis, composing lengthy passages, and participating in an unstructured form of social and human sciences research. As more data is gathered, conclusions continue to change and develop.

The inductive approach works from specific to general foundations. The researcher who uses the inductive approach will work from the bottom-up using the participant's view to build broader themes and generate a theory interconnecting the themes. Inductive research does not start with a theory to be confirmed or refined but with unanswered questions about a particular phenomenon of interest.

The inductive research strategy establishes limited generalisations about the distribution and patterns of associations amongst observed or measured characteristics of individuals and social phenomena (Soiferman, 2010). Trochim (2006) defined induction as moving from the specific to the general while deduction begins with general arguments and ends with specific arguments based on the experience of observation that is best expressed inductively. In contrast, they define an inductive researcher as someone who works from the 'bottom-up, using the participant's view to build broader themes and generate a theory interconnecting the themes.

Qualitative research is often said to employ inductive thinking or reasoning since it moves from specific observations about individual occurrences to broader generalisations and theories (Saunders et al, 2019). In making use of specific observations and measures it then moves to detect themes and patterns in the data allowing the researcher to form an early tentative hypothesis that can be explored. The results of the exploration may later lead to general conclusions or theories (Creswell, 2005). Creswell and Plano Clark (2007) also mentioned that the information gathered from the individuals helps the researcher to categorise themes which allow them to develop theories inductively.

While the deduction approach starts from a theoretical base, it is also used in this study particularly in literature review section. Literature reviews form part of a qualitative review that are used to provide evidence for the study's purpose and to identify the underlying issue that will be investigated (Saunders et al, 2019). The literature review is typically concise and does not normally guide the research questions as much as literature reviews in quantitative research. This is done to ensure that the literature does not limit the categories of information that the researcher will obtain from the participants (Cresswell and Plano Clark, 2007).

In this study, I read materials regarding the commercialisation activities in research universities. The literature review helped me to understand the nature of this research and it was used to identify a number of themes that then shaped the design of the study and the choice of interview topics. This is where I used the deductive technique in my research approach. I chose the concept of the Triple helix to fulfil this research purpose. For this type of approach, the starting points are not grounded in empirical observation but based on a proposed theory that often is as yet not fully validated (Locke, 2007). Cresswell and Plano-Clark (2007, p.23) stated that deductive researcher "works from the top down, from a theory to hypothesis to data to add to or contradict the theory". As data analysis proceeded, I used these themes to undertake the analysis but I also identified other themes and these then guide me to look at other literatures. This is where the inductive technique is employed in this study. This explained how I used both inductive and deductive in my research approach.

### 3.2.3 Research strategies

According to Cresswell (1998), there are five traditions of research design within qualitative inquiry. They are case study, biography, phenomenology, grounded theory and ethnography. For this thesis, a case study approach was used. A case study is an inquiry method to explore a topic or phenomenon in-depth within its real-life setting (Yin, 2008). For this study, research universities, start-up companies and government agencies are chosen to become the informants in exploring the issue of biotechnology commercialisation in a developing country using the case of Malaysia. The ‘subject’ in case study research is not restricted to a person, a group, an association, an organisation, a change process, an event or any other types of case subject. The strategy in a case study has the potential to produce insights through an in-depth investigation into the study of a phenomenon in its actual setting, leading to rich empirical descriptions and the creation of theory (Saunders, Lewis and Thornhill, 2019).

The selection of a case study as a research strategy requires the researcher to identify the boundaries of the study (Flyvberg, 2011). The researcher is also required to have full understanding of the topics’ dynamic. This includes examining the interaction between the case’s subject and its context. According to Yin (2028), this research strategy is frequently used when the boundaries between the phenomenon being investigated and the context within which it is being studied are not clear. Although much is known about the government’s roles in spurring the commercialisation of biotechnology in Malaysia, little is known regarding how it affects start-ups companies. Therefore, this research strategy is seen as a particularly suitable tool to help the researcher to reveal the reason behind slow commercialisation activities among university spin-off companies.

### 3.2.4 Research choices

Research choices can come in three different forms. Quantitative, qualitative and mixed methods. Quantitative research involves numeric data, quantitative involves non-numeric data and mixed method involves the combination of the two. For this research, a qualitative research design was employed. Qualitative research collects data such as texts, words, images, audio recordings, or clips. In qualitative research, words and images bring multiple meanings. Therefore, during the interviews, it was important to explore and clarify these meanings with participants (Saunders et al., 2019). In exploring Malaysian commercialisation activities, the interview questions were designed as semi-structured and emerged during the research process. Since interviews alone were insufficient to answer the research questions, the study also used secondary data to support the findings. This technique of combining interviews and data analysis from secondary sources is known as a multi-method qualitative study.

### 3.2.5 Time horizons

This research was carried out as a cross-sectional study. This type of study is the most convenient design as it only examines a particular phenomenon at a particular time. As a new researcher undertaking a Ph.D. in the UK on biotechnology commercialisation in Malaysia, time constraints were a major factor in choosing this approach. The fieldwork was mainly undertaken during 2014, but the completion of the thesis was severely delayed due to personal circumstances (see section 3.6).

### 3.2.6 Techniques and procedures

For this research, I decided to use purposive samplings because it selects participants with knowledge of the phenomena being studied therefore allowing a deeper understanding of the topic under investigation (Ahamat, 2013). 41 participants were interviewed ensuring the collection of data from a wide range of perspectives. The participants were selected based on a number of criteria that matched the study design. The next section will show how data were gathered to answer each research question in the thesis. To recap, the questions asked were as given below:

**Table 3.1: Table of research questions and group of informants**

| Question | Group | Sources of data |
|---|---|---|
| 1. What are the issues faced by biotechnology actors at the national level in enabling knowledge exchange and commercialisation of biotechnology in Malaysia? | • Policy-Maker<br>• Top management of biotechnology agencies | • Interview<br>• Policy of National Biotech Policy |
| 2a. How does the university translate the National Biotechnology Policy (NBP) into local practice?<br>2b. How do these local practices support commercialisation activities among academic scientists? | • University top management<br>• Technology transfer officer<br>• Academic scientist | • Interview<br>• University policy |
| 3. How do these local practices support knowledge transfer and the commercialisation of biotechnology? | • Manager of start-up company | • Interview |

#### 3.2.6.1 Participants selection

The section explains how the participants were selected. In this research, four different types of groups were identified and chosen based on their involvement and relatedness with the National Biotech Policy.

The first group of respondents were the ministry level policymakers. In this stage, the respondents from the Ministry of Science, Technology and Innovation (MOSTI) were chosen because they were the main actors designing and implemented this policy. Within the Ministry, there was a particular unit on biotechnology known as the National Biotechnology Division (BIOTEK) responsible for steering the national biotechnology agenda through research and development, technology development, and promotion of biotechnology programmes. Therefore, the top-ranking officers were suitable to be taken as the respondents in this project.

The group chosen as the participants for question 2, was top/upper-level university management. The respondents were not restricted to a faculty but were across the university. First of all, the respondents came from the Innovation Unit of all five research universities. It then followed the respondents at the faculty level. Some of the universities did not use the term 'faculty', they used 'school' instead. These informants at top management and faculty level explain how the universities help university members in spurring agro-biotechnology commercialisation activities.

The third chosen group was the informants at faculty level. This group represent the academic scientists who through their research discovered new knowledge and exploited new discoveries. At the faculty level, I only managed to interview informants from the University of Putra Malaysia and University of Technology Malaysia. The highest rate of informants came from the University of Putra Malaysia as this university was historically established to develop the agriculture sector. The University of Technology Malaysia has contributed many however, only one spin-off company from this university fulfilled the requirement of being the informants. Other universities such as the University of Malaya and the National University of Malaysia have no informants as these universities are still developing their bio-agriculture research. There was one potential informant from the University of Malaya but he refused to be interviewed as his company is currently at a dormant stage.

For the University of Science Malaysia, all the inventions made in the universities are commercialised under one university spin-off company namely U-Sains Holdings. I only managed to interview the marketing manager of U-Sains Holding. I could not get the opportunity to conduct the interview with the academic scientist as it is restricted. Thus, the marketing officer unable to arrange any interview with the academic scientist.  This is justification for the third group of respondents in this study being only limited to the University of Putra Malaysia and the University of Technology Malaysia.

The third question is concerned with to what extent policy at the national and university level encourages commercialisation activities among the start-up companies. This question will be answered by the last group of informants. This group represent the company managers who operates the university spin-off companies or company managers who buy the technology from the RU. The company managers were chosen based on their involvement in commercialising their products and managing their start-up company. Most of the universities that were actively involved in the commercialisation of agrobiotechnology product joined the 'Symbiosis' program. The MTDC Symbiosis Programme is a comprehensive programme initiated by the Malaysian Technology Development Corporation (MTDC) to encourage commercialisation activity of public-funded Research & Development (R&D).

#### 3.2.6.2 The recruitment of the participants

The study design required four groups of respondents to be recruited. These were national policy makers, university managers, university scientists and company managers (see appendix B). The total number of respondents was 41 and all of them were recruited using the same procedures. The first step was to identify all potential respondents through websites and the BioNexus Status Company Directory. All emails were attached with the background information of the project, an informed consent form and ethical approval letter. Before the interview began, the researcher read the project description and key information contained in the informed consent form to make sure they understood their rights and were clear about how the data was being handled and the anonymity of the respondents. The researcher also read and clarified the respondent's rights during the interview session. The respondents could choose to terminate the interview session at any stage without having to give a reason and could choose not to answer any question in the interview session. Examples of the documents can be found in the appendix. All respondents were given the informed consent form to sign before the interview started. A copy of the consent form would be sent to the respondent after the interview took place.

### i. Policy-makers

To recruit policy-makers from the Ministry of Science, Technology and Innovation, an email was sent to the particular person in the National Biotechnology Division (Biotek Division) obtain information about the unit. It included information about the function and roles of the division and how it translated policy to the biotechnology committee and universities. However, the response rates at the ministry level were very poor with only one respondent accepting the request to be interviewed. However, I managed to interview the directors and top-management of national biotechnology-agencies such as ABI and NIBM. Although the number of informants in this group is quite low, it is enough to answer the research questions.

### ii. University top management

To approach the university staff, the researcher first emailed the Vice Chancellor of each research university to obtain approval. After that, emails were sent out to all related respondents regarding the research topic. Among the respondents were the directors of research and innovation, directors of research management center, directors of innovation center and deans of the school.

### iii. University scientists

Information regarding university scientists was obtained through the directory of the university's spin-off companies. All interview sessions were held in the office of the university researchers. In some university, there was no specific department as 'biotechnology' in the university except at Putra University Malaysia and Technical University Malaysia, thus this has create a challenging situation in recruiting the informants. Putra University Malaysia focuses on agriculture, making participants easier to find. However, other universities were less focused on agro-biotechnology advancement and there were fewer respondents from these RU.

**iv. Company managers**

In this study, there were two kinds of company managers. The first group was university entrepreneurs and the second was non-university company managers. To contact the university company manager, emails were sent to the identified respondent. However, due to slow response rates, the researcher made follow up calls to set up an appointment. There were ten participants from the group of university entrepreneurs. When the interviews were conducted, there were no representatives from the University of Malaya and Science University of Malaysia. The potential respondent from the University Malaya declined to be interviewed since his product was dormant. While at the Science University of Malaysia, all the inventions made by the academics are commercialised under 'USains' branding. Therefore, there was no representative from a start-up company from this university. The data gathered from the marketing officer of Usain's Holdings was grouped with the university top management.

For the non-university start-ups, information about the companies was obtained through the directory of BioNexus Status Company produced by the Biotechnology Corporation. Only companies related to agro-biotechnology products were chosen to be participants. They were contacted through email and telephone calls call for faster results. There were only three respondents who wished to be interviewed.

## 3.3 Method of data collection

For the study, a qualitative methodology was adopted to investigate each actor's experience of commercialisation activity. This methodological approach was also well suited to the type of data obtained, that being through semi-structured interviews and secondary sources, and to the types of questions relating to the contextual condition. It also provided a 'deeper' understanding of social phenomena than would be obtained from purely quantitative data (Silverman, 2000).

This research combined descriptive and evaluative research to understand the commercialisation activities among the research universities. Descriptive research was chosen because it described the characteristics of an existing phenomenon and focuses on events that occur in the present (Salkind, 2007). This research took place in the second phase of the National Biotechnology Policy, therefore, it fit the characteristics mentioned by Salkind. Descriptive research aims to understand specific events, persons or situations (Salkind, 2007). In this study, the research aimed to understand the commercialisation activities that happen at the research universities during the implementation of the National Biotechnology Policy.

The second method employed in this research is evaluative. As described by Saunders et al. (2019), the aim of evaluative research is to determine how well something works. In the case of this research, the aim is: how well does the National Biotechnology Policy work in encouraging biotechnology commercialisation among start-up companies? The essence of this study is to ask different groups in the biotechnology area about the effectiveness of the policy. By doing this, it allows the researcher to access performance. This kind of research is suitable to provide suggestions to improve a programme or policy.

### 3.3.1 Document analysis

At the early stage of the study, document analysis was employed as a way to provide a valuable background and data on the evolution of policy. Document analysis is a systematic procedure for reviewing or evaluating key texts to gain understanding and to develop empirical knowledge (Corbin and Strauss, 2008). According to Bowen (2009), firstly, document analysis will provide data on the context within which research participants operate and their background. Secondly, it can suggest possible questions that need to be asked and situations that need to be observed. It also indicates the conditions that affect the phenomena currently under investigation. Thirdly, document analysis before the interview phase will provide supplementary research data. These data can add value to the researcher's understanding and interpretation of the interviews. In this research, documents related to the policies, organisation and funding of government institutions, research universities, and the biotechnology industry were collected and analysed. However, the document analysis technique alone was not sufficient to generalise a good understanding of how policy operated in practice, therefore semi-structured interviews were conducted to provide a richer picture of the success and limitation of the NBP. As suggested by Wolff (2004), the document analysis was undertaken before collecting the subjective views of key stakeholders.

Documents collected included NBP document, Government reports on commercialisation, Malaysian Plans, Government Official Websites, and reports on University's Performance on Commercialisation are among the secondary data used in this research. These data not only support the research findings but provide background settings to this research.

### 3.3.2 Interviews

The use of interviews is the most commonly employed method in qualitative research (Britten, 2006; Bryman and Bell, 2007). As mentioned by Seidman (2013), interviews facilitate understanding the lived experience of other people and the meaning they make of that experience. It is a powerful way to gain insight into educational and other important social issues through understanding the experience(s) of the individual(s) whose lives reflect those issues. In order to understand the roles of national and local policy and practices in supporting the knowledge transfer and commercialisation, face-to-face interviews were conducted.

Prior to commencing field work, I emailed all the informants; with a resonse rate of 60%. All of the sent emails were attached with the project background information, an informed consent form, and an ethical approval letter. The remaining balance of the informants were followed up by phone call. Before the interview started, the informants were provided with the explanation once again, stating the purpose of the research, and how the information will be used and stored. The researcher also asked permission to voice record the interview sessions from the informants. Of note, participants were free to agree to be recorded or not. In this case, all of the participating informants agreed to be voice recorded. However, there were three cases where I needed to cut the interviews short due to participants' schedules. Two of them were followed up by subsequent emailing of the remaining questions, and one informant agreed to continue the interview by phone call.

The semi-structured interview technique was chosen because it can provide rich information regarding the subject matter involved in the study. The interview was adopted due to its ability to reach the parts that other methods cannot reach (Wellington and Szczerbinski, 2007, p.79). By using this technique, the 'subjective theory' (Flick, 2006, p.155) which refers to the complex stock of knowledge about the topic can be discovered (Flick, 2006). Studying documents such as websites, brochures and reports would allow the researcher to see the way an organization portrays itself in print but interviewing allowed the researcher to investigate and prompt things that cannot be observed. During the interview, the respondent's views, feelings, perspectives and thoughts can be investigated (Wellington and Szczerbinski, 2007). However, as the interviewer, the researcher must try to be neutral and to ensure that the interviewee do not mix his or her personal view during sessions (Flick, 2006). To get a better picture of how this project would take place, the fieldwork activity was broken down into four discrete but closely related work packages.

**Work packages:**

<u>Work package 1 (WP 1) – What are the challenges faced by the biotechnology actors at the national level in enabling knowledge exchange and commercialisation of biotechnology in Malaysia?</u>

This work package aimed to obtain background information on the structure and context of the biotechnology industry in Malaysia. The information would provide a broad understanding of the sector and how it fulfils the national aim to become a highly developed nation. This work package would describe the role of policy, ministries and agencies in supporting the knowledge economy and the biotech sector.

a) Data analysis of government publications – e.g.: Knowledge Economy Master Plan, National survey of research and development financial year, Malaysian Science and Technology Indicators Report, National Survey of Innovation, National Biotechnology Policy, Malaysian Biotechnology Country Report, published by Ministry of Science, Technology and Innovation, Ministry of Finance

b) Semi-structured interview with the policymakers involved in the formulation of the policy and top management officers from government biotechnology agencies

The findings of this work package would provide a broader context for the researcher to understand the structure and setting of biotechnology development in the country and also as a background for conducting policy analysis. It would not only provide the context on how this policy fits the nation but also a detailed analysis of the national policy itself. The second work package would explore how these policies could be implemented at the local level.

Work package 2 (WP 2)- How does the university translate the National Biotechnology Policy (NBP) into local practice?

This work package aimed to obtain information on how national policies were being translated into local practice. This work package focuses on the decisions of the university's top-level management in spearheading commercialisation activity.

By analysing this information, the researcher would be able to identify the compatibility of policy at the national and local levels. From here, it could be seen whether the universities' policies regarding R&D and commercialisation especially in the creation of start-up companies support biotechnology development in Malaysia. It would also assess the role of national policies regarding research development and commercialisation in biotechnology and its support of the creation and survival of spin-off companies.

To obtain this information, policies regarding this commercialisation activity particularly in the creation and sustainability of spin-off companies will be collected from the five selected research universities in Malaysia (Science University of Malaysia, National University of Malaysia, Technology University of Malaysia, University of Malaya and Putra University of Malaysia). At this point, interviews with the top management of these universities will be conducted. The chosen interviewees are those who are directly involved in the governance of the university.

Work package 3 (WP3) - How do these local practices support practices support commercialisation activities among academic scientists?

This work package aimed to understand how the policies and practices work at the university, especially at faculty level, and are able to support knowledge transfer and exploitation of R&D. This work package explores how the academic researcher adapts and processes the policies and practices in the university.

By analysing this information, the researcher is able to understand the challenges faced by the academic in pursuing R&D activities and later on into exploiting knowledge. This phase is referred to as 'bringing science to business'. This stage will reveal how the academic scientists feel regarding how current policies are being practiced at the university. It is important to get data from this group as these informants would explain whether current practices are able to support their development in commercialisation activities or not.

Work package 4 (4WP) How do these local practices support knowledge transfer and the commercialisation of biotechnology?

This work package is aimed at getting information on the type of support provided by the university and government agencies to company managers, and the managers views on the effectiveness of the support. It focuses on identifying the support given by university and government agencies – directly or indirectly such as lab facilities, staff transfer, lab space or building soft skills. In particular, it aimed to collect information regarding the factors that enable start-up companies to grow. This research focuses on the views and experiences in the creation of start-ups from the perspective of company managers.

To obtain the information, semi-structured interviews were conducted with the managers of start-up companies at all stages (restricted to the biotechnology area only). At this stage, each manager from these companies was interviewed (university start-ups and non-university start-up companies) to discover what are the challenges they have been facing while doing commercialisation.

### 3.4 Analysing the data

This section will explain how the data were analysed. There are many recognised procedures for analysing qualitative data (Yin 1994; Silverman, 2013). Graue (2015) listed four key steps in analysing qualitative data while Cresswell and Cresswell (2018) suggested five sequential steps. It is important in this stage to describe how the data were classified and processed. These procedures greatly helped with the processing the large volume of data obtained during the collection stage. Although the software application such as Nvivo, ATLAS.ti and MAXQDA available for analysing the data, I choose not to use software to help me doing analysis. I believed software cannot discover themes as it remains the responsibility of the researcher. Furthermore, it can be time consuming to expert the skills. Therefore, I used Microsoft Word processing to organise and analyse my data. However, if I have time and access to the software, it will be a great opportunity for me to learn and use the software. For this phase, I used the thematic analysis approach. According to Braun and Clarke (2006, p.78), ‘thematic analysis serves as a foundational method for qualitative analyses. This involves coding activities of the qualitative data to identify specific themes or patterns related to the research questions. Saunders, Lewis and Thornhill (2019) outlined a set of guidelines involves in thematic analysis. These are explained as follows.

#### 3.4.1 Familiarise with the data

In this first step, all interviews were listened to and transcribed. As mentioned earlier, the interviews were audio recorded. Through listening to the recorded audio, I also cross-checked the important points that I previously jotted down during the actual interview. This is important to ensure I did not miss any important points, quotations or expression. Each interview took between 60 to 90 minutes per session. However, it took more than 90 minutes to interview informants from the national level group. This is because they had a more in-depth understanding and a wider view of how NBP should work at the national level.

Transcribing activities can be very tiring as I need to transcribe all 41 interviews by myself. I did the initial analysis in Malay and after coding, I translated all relevant extracts related to a particular topic into English to form the outline of each section. Although tiring, I believe this is an effective way to become familiarised with the data. While transcribing, I emersed myself with the informant's situation to gain a better understand of their feelings and analysed the meaning of their response.

Feedback collected from the informants obtained through sharing the recordings via email enabled the accuracy of the translations be assessed. Given that informants had nothing to comment, the assumption was made that the transcriptions were accurate. I also made phone calls to the respondents to clarify the points which were not clear during interview sessions. In regards observation notes, these were written in a 'fieldwork notebook' as soon as I finished each interview session and the transcribed audio recording were transcribed and saved to Microsoft Word files. Each transcript was saved with the informant's coding number and their real name. This is to ensure that these could be easily traced back the informants. All transcripts were stored in a different folder in accordance with the groups they belonged. Storing the data comprehensively and systematically is important so that it can easily be retrieved and analysed (Pickard, 2013).

### 3.4.2 Coding the data

The next step involved analysing the data for coding. Coding is used to group data that shares similar meanings. ‘Coding involves labelling each unit of data within a data item with a code that symbolises or summarises the extract’s meaning’ (Saunders, Lewis and Thornhill, 2019, p. 653). In this step, meaning was attributed to the information given by the informants. To give meaning to the data, I read the interview transcript several times to truly understand their experience and become more familiar with the data. After that, an initial list of ideas was created to increase the chance of identifying patterns related to the research questions. Repetitive patterns arising from the data were searched for, as a qualitative data set may involve big data such as actions, beliefs, behaviours, conditions, ideas, interactions, events, outcome, relationships, strategies and policies. Without assigning coding to the data, it might be difficult to comprehend all of the meanings therein and any meanings might be lost in the big data. Therefore, coding is important in managing the data so that it can be rearranged and retrieved under the relevant codes. I gave coding to all the data that was believed to be related to the research question. This was done to enable the identification of anything and everything relevant from the entire data set and help answer the research questions with rich insight. This process was repeated for all data sets. See appendix for a worked example of coding.

### 3.4.3 Searching for themes and recognising relationships

The search for themes began after the completion of dataset coding. A theme, according to Saldana (2015), is a result of coding that captures and brings the characteristics of the phenomenon under study together into a coherent whole. A theme should have the ability to describe the whole data (Joffee and Yardley, 2004) and has ‘a central organising concept’ (Braun and Clarke, 2013, p.224) in which codes are merged to form themes. The themes were categorised into overarching themes, themes and subthemes. The overarching themes represent specific ideas encapsulated in themes and sub-themes (Braun and Clarke, 2013).

The below table illustrates the example the themes identified in the second research questions.

**Table 3.2: Example of Coding**

| Data extract | Coded for |
|---|---|
| **R24 Technology Transfer Officer**<br>*Sometimes it looks like this commercialisation thing is a burden for the researcher. There is no support (from the university).* | The support system given to the academicians in term of work burden is inadequate |
| ***R20: Senior lecturer, Scientist***<br>*we need to groom the person on how to become a good researcher. So, I think it is the same in this case. You need to identify who is the person that is the best in this area, and you need to continue to monitor them and provide help if the person is stuck in the middle or needs help. Then you monitor the progress. That is why I said; we are left alone.* | The university lack in enhancing the human capital development |
| **R21, Associate Professor**<br>*I don't think the university has the facilities. We are talking about manufacturing facilities, the Bottling plant. So, what we did was, we came out with the capital and built our own.* | University is unable to cater the needs of all researchers. |
| **R13, Professor, Head of Department**<br>*So, when they work together and build trust between them, they will ask the researcher to run this particular project. This is what we are doing actually. It is very important to build trust if not, it will be difficult to get the money/funding. Once they know how you work, how they can get the result and only then they are willing to invest the money.* | Building trust is important in attracting the industry to invest the money. The university must project a good image that they could provide the best solution for industry |

The process of coding was deductive and concept driven as I created a preliminary code (Miles and Huberman, 1994) before reviewing the data which emerged from the literature and my initial observation. The preliminary codes were helpful as they integrated already known concepts from the literature (Bradley, Curry and Devers, 2007). The themes emerging from the data analysis were guided by theoretical assumptions, but at the same time other responses mentioned by the informants were coded as new themes. The semi-structured interviews have allowed themes to be discovered by using both inductive (driven from data) and deductive (driven from concept) approaches.

### 3.4.4 Refining themes

This stage is a very important part of the overall analytical process. The themes discovered in the previous stage refer to searching for themes and recognising relationship. These themes need to be arranged to be part of a coherent set. By doing this, it will provide a well-structured analytical framework to pursue the analysis. In developing the themes, the coded data extracts were reorganised me under relevant themes and sub-themes. It is important to reorganise coded data under the correct headings as it helps to evaluate whether these coded data are meaningful to one another within their theme and how these themes are meaningful in relation to one another in relation to the data set (Saunders, Lewis and Thornhill, 2019, p.658). This process required a re-reading and reorganisation of the data. As the data set was further examined, these themes were finally refined in order to answer the research questions. In doing so, I separated, combined and discarded the initial themes. This process helped to evaluate whether these data supported the continuation of the theme or whether there was insufficient data to sustain it. Table 3.3 provides an example of theme categorisation in order to answer the second research question.

**Table 3.3: Example of theme categorisation**

<table>
<tr><td colspan="2">Second RQ: How do universities translate the National Biotechnology Policy (NBP) into local practice?</td><td colspan="2">Overarching theme: Support system in the university</td></tr>
<tr><td>Data extract</td><td>Coded for</td><td>Subthemes</td><td>Themes</td></tr>
<tr><td>R24 Technology Transfer Officer<br>Sometimes it looks like this commercialisation thing is a burden for the researcher. There is no support (from the university).</td><td>The support system given to academic in term of work burden is inadequate</td><td></td><td></td></tr>
</table>

| | | | |
|---|---|---|---|
| ***R20: Senior lecturer, Scientist*** *we need to groom the person on how to become a good researcher. So, I think it is the same in this case. You need to identify who is the person that is the best in this area, and you need to continue to monitor them and provide help if the person is stuck in the middle or needs help. Then you monitor the progress. That is why I said; we are left alone.* | The university lacks in enhancing the human capital development | 6.2.1.1 Lack of University Support | 6.2.1 Lack of Support Mechanism |
| **R21, Associate Professor** *I don't think the university has the facilities. We are talking about manufacturing facilities, the Bottling plant. So, what we did was, we came out with the capital and built our own.* | University is unable to cater for the needs of all research | 6.2.1.2 Lack of Financial Support | |
| **R13, Professor, Head of Department** *So, when they work together and build trust between them, they will ask the researcher to run this particular project. This is what we are doing actually. It is very important to build trust if not, it will be difficult to get the money/funding. Once they know how you work, how they can get the result and only then they are willing to invest the money.* | Building trust is important in attracting industry to invest money. The university must project a good image that they could provide the best solution for industry | | |

## 3.5 Ethical Issues

Ethical approval for the research was submitted and granted by the Ethics Committee of the Department of Sociological Studies at the University of Sheffield. This study involved human interaction and participation. Consequently, critical attention was given to ethical considerations to ensure that the study conforms to the ethical principles and values governing research involving human subjects as well as to protect both the respondents and researcher (Habibis, 2006). The main ethical issues raised by this research are protecting participants and ensuring good data management. As a first step, the interview questions were first sent by email with a covering memorandum. The memorandum and the introduction to the interview both assured participants that their responses would be treated in strict confidence and their identity would never be linked to their responses and that no personal details would be made public. Another critical consideration for ethical research is how the data and information gathered from the research would be shared and stored (Cresswell, 2003). For this study, records including interview transcripts in both languages, Malay and English were only shared with the researcher and their supervisor. Completed interview data are kept in a safe place and once the research is completed, they will be destroyed.

### 3.6 Challenges in completing the PhD

The researcher enrolled on this Ph.D. study in February 2013 but only submitted the thesis in 2022. I am aware that I have been granted 'leave of absence' several times previously and being unable to complete my Ph.D. I have been deeply frustrating. This was due to a number of major personal problems I encountered. It all started in the third year of my Ph.D. when I developed a pregnancy complication and consequently delivered a premature baby girl. This caused considerable stress as this was my first time being a mother. At the same time, my family circumstances were difficult and I became depressed and took medication. In late 2016, I went back to Malaysia as my visa had ended and I was pregnant with my second child. During this time, I suffered several health issues. I was diagnosed with gestational diabetes, placenta previa and suffered a severe skin condition. Due to this, I had to visit the hospital frequently. In 2017, my first child was diagnosed with autism and required occupational therapy, speech therapy and paediatric appointments.

In the same year, my father died of pancreatic cancer in November 2017. In 2019, I lost my job and up until now I am still jobless. As I am no longer employed, my husband has had to work in a job in another city that offered a higher salary and we live apart with him only coming home every few weeks. We are currently separated due to the pandemic lockdown and long commute. Due to this, I am left taking care of our two children on my own. During the pandemic period, my daughters and I were affected by Covid-19. Furthermore, coronavirus restrictions also severely limited the amount of childcare I had and I did most of the writing early in the morning or late at night. In addition, my mother has recently been admitted to the hospital with a serious lung infection and I need to support her as she is on her own. These extreme personal circumstances over many years have at times left me devastated. Despite all this, I always told myself never to give up and always keep going. After almost 10 years, I am very pleased to have successfully submitted this thesis.

# Chapter 4

# The role of universities and SMEs in accelerating biotechnology commercialisation

## 4.1 Introduction

The focus of this chapter is to introduce the role of universities and SMEs in supporting the Malaysian economy through the biotechnology sector. This section starts with an examination into the background of research universities with a particular focus on their structure and role. The second section then explains the background of Micro, Small and Medium Enterprises (MSME) and their role in supporting the economy. Finally, the third section highlights the importance of research universities and MSMEs in supporting the government agenda through biotechnology. Therefore, is important to understand university institutions and MSMEs and how they impact the country's biotechnology agenda.

## 4.2 The role of the university in Malaysia

Malaysia strives to create a world leading higher education system. The National Higher Education Strategic Plan 2007-2020, the Malaysia Education Blueprint (2015-2025) and the University Transformation Programme (Ministry of Education, 2015) are among plans and initiatives launched by the government aimed at achieving a high-quality education system. These efforts show Malaysia's commitment to improving their educational quality. Universities are no longer just seen as traditional institutions only engaged in delivering knowledge to new generations of learners. Rather, they are now seen as institutions that have a wider impact on society and economies at both national and local level (Kumar, Kumari and Saad, 2014).

The establishment of a university is the apex of any education system. However, it is also the costliest when compared with other levels of education such as primary and secondary schools. Throughout the world, national governments invest heavily in tertiary education with a strong belief that universities play an important role in national development. As of 31 October 2019, in Malaysia there were 20 public and 446 private universities including branch campuses (Education Malaysia, 2021). Public universities are grouped into three categories: research; comprehensive; and focused universities (Education Malaysia, 2021). Table 4.1 below shows the categories of public universities in Malaysia.

**Table 4.1: Categories of public university in Malaysia**

| Categories | Descriptions | University |
|---|---|---|
| **Research Universities** | Focus heavily on research, as well as teaching and training of undergraduates with the aim of producing highly skilled postgraduates with good soft skills, knowledge, and innovative technology. | University of Malaya |
| | | University of Putra Malaysia |
| | | National University of Malaysia |
| | | University of Technology Malaysia |
| | | University of Science Malaysia |
| **Comprehensive Universities** | Offer courses in various fields of studies for all levels of education including postgraduate, undergraduate, and pre-undergraduate courses. | MARA University of Technology |
| | | International Islamic University of Malaysia |
| | | University of Malaysia Sarawak |
| | | University of Malaysia Sabah |
| **Focused Universities** | Focus on a specific field such as education, management, defense, and technical aspects. | Northern University of Malaysia |
| | | University of Malaysia Perlis |
| | | University of Malaysia Pahang |
| | | University of Malaysia Terengganu |
| | | University of Kelantan Malaysia |
| | | Sultan Idris Education University |
| | | Sultan Zainal Abidin University |
| | | Islamic Science University of Malaysia |
| | | Technical University of Malaysia Malacca |
| | | Tun Hussein Onn University of Malaysia |
| | | National Defense University of Malaysia |

Source: (Hock-Eam *et al.*, 2016)

Table 4.1 sets out the list of public universities in Malaysia as well as their respective categories. Each category has its own focus in regard to supporting the economic development of Malaysia. The contribution of these universities to economic development can be attributed to three functions, namely: (a) producing and accumulating human capital; (b) disseminating and applying knowledge; and (c) innovating and inventing new information and technology (Ministry of Education, 2014). Each institutional category is given its own weightage for core functions such as teaching, research and services. The categorisation of each university is intended to ensure their unique strengths and challenges, specific to each category's niche, are fairly represented (Education Malaysia, 2021). Furthermore, this ensures the quality of higher education is on par with standards set by the Ministry of Higher Education. In the context of this investigation, only the roles of research universities are discussed. Therefore, the next section will provide the background to the establishment of Research Universities (hereafter RU) and their significance in supporting the government's economic development agenda.

## 4.3 Background to research universities in Malaysia

The first Malaysian RU were established in 2006. Consequently, university governance had to change to meet the standards expected of a RU. In the first five years (2007-2012), the government invested a total of RM1.8 billion into Malaysian RU. The impact of RU as engines of growth and nation-building can be seen in terms of: (i) talent development; (ii) research prominence; (iii) wealth creation; and (iv) bridging the grand challenges. As well as driving new technological innovation, the function of a RU is to create and disseminate knowledge. Since Malaysia is moving towards becoming a knowledge-based economy, the role of RU is important in supporting this transition. Another impact of the establishment of RU would be wealth creation by enhancing both government agencies and NGOs in commercialisation activities (Ministry of Education, 2014).

The RU in Malaysia are not new universities. Their roles were expanded from the existing philosophies and good practices of current higher education institutions in the country. Although RU place a heavy emphasis on research, their objectives also include the teaching and training of undergraduates similar to that seen at Harvard University, Stanford University, and Massachusetts Institute of Technology (MIT) in the United States. In achieving these objectives, RU will have to change their governance in matters pertaining to research (Ministry of Education, 2014). Universities were selected to become RU based on their performances as contained over several selected higher educational criteria. The criteria for selection and the weightage are shown below in Table 4.2.

**Table 4.2 Criteria for the assessment of RU performance with MyRA score**

| Selection and Criteria | MyRA marks |
|---|---|
| **A: General information** | - |
| **B. Quantity and Quality of Researchers** | 25 |
| **C. Quantity and Quality of Research** | 30 |
| **D. Quality of Postgraduates** | 10 |
| **E. Quantity of Postgraduates** | 5 |
| **F. Innovation** | 10 |
| **G. Professional Services and Gifts** | 7 |
| **H. Networking and Linkages** | 8 |
| **I. Support Facilities. Lab Accreditation** | 5 |
| **Total Marks** | 100 |

Source: MOSTI (2013)

Table 4.2 lists the criteria and marks allocated for RU using the Malaysia Research Assessment Instrument (MyRA). This represents a comprehensive system developed to assess the research capacity and performance of all Higher Education Institutions (HEIs) in Malaysia. Thus, MyRA are used to accredit and monitor the research performance of public universities. The criteria are also used to assess the performance of universities to maintain their performance and standards as public RU.

Universities holding the status of RU received operational costs of 50 to 90.8 million RM (US$12 to 21 million) per annum in the first five years (from 2007 until 2012) from the Ministry of Finance. This covered research, fellowships, training, equipment costs and infrastructure improvement (Ministry of Higher Education, 2014). Moreover, in order to boost their industry involvement, RU were further awarded special monetary incentives, particularly the Research University-Research Grant Scheme (RU-RGS), Research University-Infrastructure Grant Scheme (RU-IGS), and Research University-Research Training Scheme (RU-RTS). Apart from the monetary incentives, RU were also granted non-monetary incentives including freedom of decision-making via the autonomy of governance, easier commercialisation and spin-off formation, attractive career paths, and attractive IP and licensing policies (Ministry of Higher Education, 2004). Due to such investment, it is evident that the government believes RU could generate income from their research. To further explore how RU could generate income for the nation, the next section discusses the role of RU in supporting the national agenda.

### 4.3.1 The role of research universities in supporting the biotechnology agenda

Aligned with the launch of the NBP in 2006, RU were seen as ideal mechanisms in promoting biotechnology and transforming the nation into a high-income country. To increase the country's income, Malaysia has targeted biotechnology as a national priority and in addition to generating wealth, it is expected to enhance productivity and sustainability as well as to generate wealth. In 2005, the National Biotechnology Division (BIOTEK) and Bioeconomy Corporation (formerly known as Biotechnology Corporation) were established under the supervision of the MOSTI to lead biotechnology development in Malaysia including Research and Development (R&D), human capital, marketing, and public understanding (Yusof, 2013). During that period (2005-2010), the government gave priority to seven R&D clusters and one of them was biotechnology. Along with this, the Bioeconomy Transformation Program (BTP) is launched to further develop the bio-based industry in Malaysia. The BTP outlined 10 Entry Point Projects (EPPs) to develop the national bio-based industry (Malaysian Biotechnology Corporation, 2015). The University-Industry Partnership department is also established to encourage and continuously monitors the performance of universities in biotechnology activities.

To further accelerate the biotechnology development, the following funds were introduced to universities by MOSTI to help academics pursue R&D activities until the commercialisation stage. These funds are: ScienceFund, TechnoFund, InnoFund MOSTI, Commercialisation of R&D funding (CRDF), Technology Acquisition Fund (TAF) (Malaysia Technology Development Corporation, 2017) and Biotechnology Commercialisation Fund (Bioeconomy Corporation, 2012).

The R&D activities undertaken by researchers at the local universities played a vital role in transforming Malaysia from a resource-based to a knowledge-based economy. Such conditions portrayed the evidence that the country had engaged with the national innovation agenda as one of its means to achieve success in the biotechnology industry. The impact of R&D in terms of new knowledge discovery, wealth generation and its contribution towards growth is capable of driving Malaysia towards a high-income country (Ministry of Education, 2012). On further inspection, it is now believed that the innovation is seen as a key component in moving Malaysia towards a high-income economy. By looking at the NIS and SIS of others developed countries, Malaysia could adapt the same model in achieving it. However, it will not work by transplanting a ‘high performance element’ from one system to another and then expecting the impact to be similar to what it was in the system of origin (Lundvall, 2007). This is true as different countries have different strong points which in turn determine their successfulness.

To transform into a biotechnology hub, the biotechnology ecosystem has to be attractive to investors. One of the successful factors in the biotechnology industry is their pool of skilled workers. Therefore, it is important that universities are recognized as places where these skilled workers are sufficiently trained. Furthermore, universities should ensure these graduates are capable of applying this knowledge in the workplace (Saruan *et al.*, 2015). Universities make major contributions to economic development by supplying college graduates. They have been one of the most valuable assets for communities in advancing education, health and social service needs of residents. They have an important part in supporting businesses to drive product, process and service innovation (Egorov, Leshukov and Gromov, 2018).

In addition to teaching and research, the role of the university has evolved as a ‘third mission’ (Etzkowitz, 2016). The university is moving towards more emphasis on entrepreneurship as a strategy to stimulate research and commercialise technology and inventions (Boni, Emerson and Model, 2015). Such a transformation in universities is captured by the triple helix model which emphasises the interconnections between university-industry-government (Etzkowitz, 2007). A university can also act as a business incubator by providing mentoring services, office space, equipment as well as other administrative support to assist in the formulation of new ventures (Wonglimpiyarat, 2016), thus encouraging researchers and students to act as social entrepreneurs. These developments, especially in Asia appears to have helped address widening social imbalances (Baskaran, Chandran and Ng, 2019).

### 4.3.2 Summary

Through this section, the structure and the importance of universities are explained. The structure of education in Malaysia is strictly governed by Ministry of Higher Education and being scrutinized through MyRA. The yearly evaluation is made to ensure the performance of the universities are at their best state. The MyRA evaluation has different sets of criteria aimed to assess different categories of Malaysian public universities. This to ensure the quality of the education is aligned with the market and global needs. As mentioned in various innovation models such as the National Innovation System and Sectoral Innovation System, one of the crucial components in the system is the learning society, which produces knowledge. Knowledge is considered as the most significant resource of an innovation system and learning as its central mechanism to achieve it (Schrempf, Kaplan and Schroeder, 2013). The NBP has garnered support from various industry stakeholders, public entities, universities, research institutes, and government agencies. These entities collaborate to enhance productivity and promote sustainable development. Additionally, these biotechnology players aim to capitalize on commercial prospects in the field of bio-based technology (Bioeconomy corporation, 2015). However, in order to achieve the high-income knowledge economy through biotechnology, the roles of SMEs also play an important part. Therefore, the next section will discuss the background and roles of SMEs in developing biotechnology industry.

## 4.4 Background of micro, small and medium enterprises in Malaysia

Over the last decade, SME and entrepreneurship development has emerged as a national agenda following the setting up of the National SME Development Council (NSDC). Initiatives over the years, including the institutional building and structured policy framework put in place, further reinforced by the implementation of the SME Masterplan has laid the foundation towards building a comprehensive ecosystem for the SMEs (SME Annual Report, 2016). In

Malaysia, the SMEs were largely dominated by the microenterprises and the number of enterprises were increasing in 2015 compared to 2010. The table below illustrated the number of SMEs in Malaysia.

**Table 4. 3: Number of establishment and percentage share of SMEs by firm size**

| | EC 2011 (Reference Year 2010) | | | | EC 2016 (Reference Year 2015) | | | |
|---|---|---|---|---|---|---|---|---|
| | **Micro** | **Small** | **Medium** | **Total** | **Micro** | **Small** | **Medium** | **Total** |
| No. of establishment | 492,814 | 129,960 | 16,960 | 638,790 | 693,670 | 192,783 | 20,612 | 907,0665 |
| % share to total SMEs | 77.1 | 20.2 | 2.7 | 100.0 | 76.5 | 21.2 | 2.3 | 100.0 |
| % share to total establishment | 76.0 | 19.9 | 2.6 | 98.5 | 75.3 | 20.9 | 2.2 | 98.5 |

Source: SMECorp, (2022)

In terms of size, most SMEs were microenterprises, which made up 76.5% of all SMEs. Small and medium-sized enterprises (SMEs) made up 21.2% of the total number of SMEs, while the other 2.3% were medium-sized SMEs. Comparing the structure of these SMEs from 2010 to 2015, the number of microenterprises grew by 40.8%, the number of small firms by 49.4%, and the number of middle firms by 21.5%. The services sector was mostly made up of microenterprises, which are small businesses with less than five full-time workers. In the manufacturing, building, and agriculture sectors, on the other hand, a large number of SMEs were well-balanced between microenterprises and small-sized firms, while only a small number were medium-sized firms (SMECorp, 2022).

Realising the importance of entrepreneurship towards individuals and communities as well as its contribution to the nation, the government has placed an emphasis on entrepreneurship beginning with the New Economic Policy (1971-1990), National Development Policy (1990-

2000), National Vision Policy (2001-2010) and the New Economic Model (2011-2020). Entrepreneurship also becoming an important element in various national programmes across ministries and agencies.  At this point, these activities demonstrated the government's commitment to the sector and its players. Up until 2019, RM13.7 billion (USD 3.28 billion) was spent by various ministries and agencies to conduct 153 entrepreneurship development programmes involving 637,808 participants (SMECorp, 2018).

### 4.4.1 The role of micro, small and medium enterprise in Malaysia

Malaysia has recognised the importance of small and medium enterprises development since early in the 1960s. The need to strengthen SMEs development is crucial because SMEs are expected to be an essential element of economic growth, employment creation and transformation towards a developed country (Gunto and Haji Alias, 2013). As time goes by, the government has broadened its attention from SMEs to also include microenterprises (refer to table 4.3.) as this category dominated the SMEs sector in Malaysia.  Many developments have taken place in the economy since 2005 for example, structural changes, changes in business trends and price inflation. As a result, a review of the definition was undertaken in 2013 and a new SME definition was endorsed which includes micro enterprises.

As an open economy, Malaysia's development is influenced by the external economic environment. This is demonstrated by the micro MSME which continues to play an important role in Malaysia's economic development plans. As of December 2020, a total of 1,151,239 establishments were classified as MSMEs, constituting 97.2% of total registered companies. In comparison, MSMEs contributed 38.2% or RM512.8 billion to GDP in 2020, and only 37% or RM435.1 billion in 2015. Additionally, employment in MSMEs has risen to 7.2 million in 2020, compared to 6.5 million in 2015 (RMK 12).

To support the development of MSME, the government launched various initiatives such as the National Entrepreneurship Policy intended as a long-term strategy for Malaysia to become an outstanding entrepreneurial nation by 2030 (Prime Minister Office, 2019). In addition, the East Coast Economic Region (ECER) was created to ensuring that vulnerable groups are included in the development of MSME. The ECER developed a range of entrepreneurship development programmes aimed at widening the abilities of target groups such as youth, women and the unemployed to participate in the economy.

The government has also focused on enhancing Bumiputera entrepreneurship. This group is given special attention due to their low economic income status if compared to ethnic Chinese and Indian in Malaysia (Department of Statistic, 2019). Back in 1969, a racial riot happened due to wide income disparities among the races in Malaysia.  Due to that, the New Economic Policy was put in action in the Second Malaysian Plan (Mat Daud, 2002) The plan was to eliminate wide income disparity among racial groups with the focus of expanding both the Malay and non-Malay share of the economy in absolute terms, while increasing the Malay share in relative terms (Handerson, Hulme, Phillips and M. Nur, 2011).

The development of the Bumiputera Economic Community (BEC) involved specific initiatives for Bumiputera companies based on their business needs. The entrepreneurs were assisted in terms of financing, support services, and capacity building. One of the government agencies responsible for coordinating the implementation programs for MSME in Malaysia is the SME Corporation (SMECorporation, 2021). Micro-enterprises will be linked to banking and financial institutions for ease of access to funding.  Initiatives will comprise establishing smart partnerships with R&D institutions to assist MSMEs improve product quality, increase market access, and enhance compliance to standards. In this regard, SME Corp will introduce integrated entrepreneurship development packages from start-up to market product placement activities (Economic Planning Unit, 2015). As the central coordinating agency for the overall SME development in Malaysia, SME Corporation Malaysia coordinates, streamlines, monitors, and evaluates the progress and effectiveness of SME development programmes implemented by 17 Ministries and more than 60 agencies (SMECorporation, 2021). At this point, it is clearly demonstrated that the government is continuously paying attention to the development of MSME across all sectors in Malaysia regardless of their size.

In relation to biotechnology, the establishment of BTP enables the SMEs to expand market access via Bioeconomy Corporation collaboration with the economic corridors and state development agencies to initiate collaborative bioeconomy cluster. Furthermore, the private sector can access the BTP Fund to part-finance the commercialisation expansion of their business and be connected to alternative financing options from various agencies. The BTP program also offers the opportunity for the industry to participate in Bioeconomy Malaysia Accelerator Programmes including the Bioeconomy Community Development programme, Technology Development & Innovation, BioNexus Go Global and Bio-entrepreneurship to enhance and accelerate the growth of bio-based businesses. In addition, the government continuously gives support through direct assistance and endorsement represented by relevant ministries with facilitation and advisory support through Bioeconomy Corporation which acts as the BTP Secretariat and implementing agency. These initiatives are in line with the 11$^{th}$ Malaysia Plan which focuses on creating a high income and inclusive nation (Economic Planning Unit, 2015).

**4.4.2 Section Summary**

This section describes the structure of MSME and its importance in Malaysia. The poverty reduction and equal economic distribution have become the central focus of the government since its independence. In general, the poverty rates in the country have declined significantly over the past three decades (Prime Office Minister, 2021) but are not enough to place Malaysia as a high-income league country. Therefore, the execution of the High Impact Programmes under the SME Masterplan gathered momentum to lend further support to SMEs during the year. Greater focus was given for start-ups and existing companies to support innovation. These are not only limited to sophisticated products or services but also those affordable for the excluded group such as the bottom 40% of the population pyramid and rural communities. In line with the NBP, a focus has been given to the biotechnology sector by introducing public-private partnership in the Government Transformational Program to accelerate growth in this sector. Industry players, government agencies and universities are expected to work together translate innovation into wealth. In sum, it can be said that the aim to achieve a high-income nation is continuously supported by various Malaysian Plans, across ministries and involving numerous of initiatives.

### 4.5 The importance of universities and MSME in supporting economic development

The previous section showed the roles of research universities and MSMEs in Malaysia. Both of these sectors have their own specific roles in developing the economy. The importance of this collaboration can be seen from the perspective of universities, industry and the economy.

In today's economic environment it is vital for public sectors organization and businesses to continuously innovate products, processes and services. By collaborating with a university partner, businesses gain access to cutting-edge expertise and techniques that they don't have in-house, enabling the development of new products and services (Mgonja, 2017). The government has spent millions of Ringgit in establishing biotechnology infrastructures during the first phase of NBP implementation (Bioeconomy Corporation, 2009). Through the university and industry partnership programs, the university can play a significant role in enhancing the capabilities of local businesses. In addition, the knowledge gained from the collaboration with the university can be used to improve the management and operation of the business (Mgonja, 2017).

In a modern knowledge-based economy, it is essential to convert scientific research into a competitive advantage. Similarly, collaboration between academia and industry is beneficial because both sides gain insight into how research may be applied to real-world issues. The collaboration with industry is enables academia to create scientific knowledge by using the data obtained from the industrial database. In turn, collaboration with universities is crucial for organizations in joint, scientific-based research projects in order to develop solutions for production-sourced problem (Mgonja, 2017). Collaboration with universities is crucial for organizations engaged in cooperative scientific research endeavors, as it facilitates the development of solutions for production-related challenges. Collaboration among academics facilitates the acquisition of novel ideas for their individual research endeavors, as well as the examination of the pragmatic implementation of theoretical frameworks (Mgonja, 2017).

At the economic level, emphasising entrepreneurship helps create employment for the country due to the initiatives taken by the government such as the establishment of NSDC, SME Masterplan and various financial support. Furthermore, the collaboration between the industry and university is successfully contributed to fostering academic entrepreneurship and bridging the gap between research and commercialisation. The university-industry collaboration should promote a mutual knowledge exchange which forms the basis for new innovations that ultimately lead to regional and national economic development (Kumar, Kumari and Saad, 2014).

## 4.6 Summary

This chapter aimed to provide information regarding the roles of universities and the MSME in supporting the Malaysian economy. In this context, the background of the Rus and their role in supporting the development of Malaysia was explained in detail. The second section focused on the background of MSME and their roles in the biotechnology industry. To conclude, the importance of research universities and MSME was highlighted along with an explanation of the way that the biotechnology industry could contribute to the economic development of Malaysia. From this chapter, it can be concluded that the government is the main player in developing this sector. In order for biotechnology and the bioeconomy to be sustainable in Malaysia, other participants from the universities as the knowledge generators and industry as the driver of economic growth will need to become more proactive. If universities and industry work together, they can be a powerful engine for innovation and the socio-economic development of the nation.

# Chapter 5

# The development of biotechnology in malaysia and the role of government at the national level in accelerating biotechnology related activity

## 5.1 Introduction

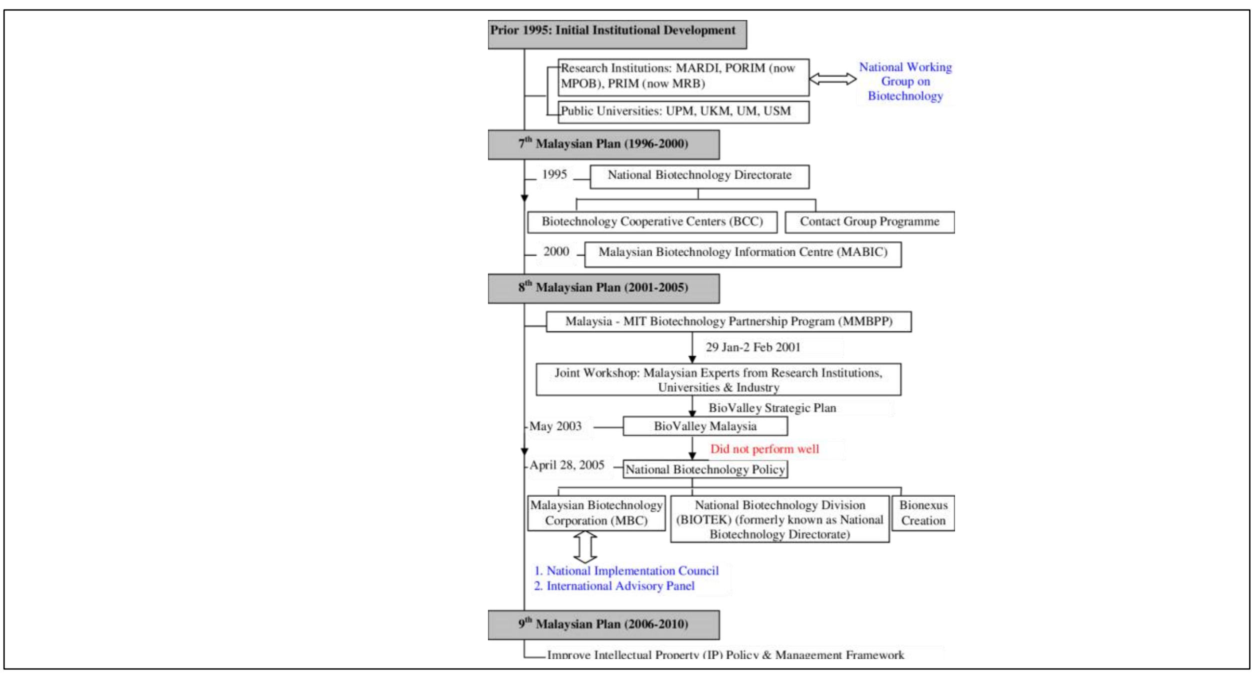
The objective of this chapter is to demonstrate the background of biotechnology in Malaysia and the roles of government agencies at the national level to support biotechnology related activity in the country. It covers the strategy and various initiatives taken, including the National Biotechnology Policy to boost the development of this sector. This initial knowledge represents the first stage of understanding the main research question. This knowledge is demonstrated through the narrative of biotechnology development in Malaysia using a review of documents collected from various academic journals, policy documents, reports and the government's official websites. It also draws on interviews with a range of policymakers. The aim of this chapter is to addressed the role biotechnology actors at the national level in enabling knowledge exchange and commercialisation of biotechnology in Malaysia. Specifically, it will address the first research question: What are the roles of the National Biotechnology Policy in encouraging biotechnology development and commercialisation activity in Malaysia.

In this study, the understanding of biotechnology policy and various initiatives implemented in the country serves as the basis for the next stage of understanding which is presented in Chapter Five, Chapter Six and Chapter Seven. This chapter is divided into two sections. In the first section, the discussion focuses on the background of Malaysia which includes the National Biotechnology Policy and the stakeholders supporting biotechnology development. The next section presents the finding and discussion resulted from the interviews regarding the roles of NBP in encouraging knowledge transfer activities and biotechnology commercialisation in Research Universities.

### 5.2 The Development of Biotechnology in Malaysia

Biotechnology is known as one of the high technologies that have the potential to bring about desired changes in many aspect of life such as agriculture, healthcare and also industry (BiotechCorp, 2009a). According to Arujanan and Quah, (2005) the past decade has witnessed the use of biotechnology to create cloned materials of oil palm, ornamentals, bananas, fruits and also for the perfume industry. With the focus of agricultural development, biotechnology is envisioned to transform and modernize the agricultural industry by enhancing productivity through better utilization of genetic resources within living organisms (MOSTI, 2013). The below diagram illustrated the development of biotechnology development in Malaysia.

**Diagram 5.1: Institutional Environment for Biotechnology Development in Malaysia**




Source: (Mokhtar and Mahalingam, 2017)

The biotechnology development in Malaysia can be categorized into four main periods. The first period referred to year before 1995, second period was from 1995-2000, the third period between 2001 until 2005 and the fourth period was in year 2006 and beyond. The first part witnessed the establishment of basic infrastructures such as the equipment and basic expertise to undertake R&D activities. This included the establishment of public research institutes and selected universities to carry out the R&D activities. At the same time, Ministry of Science, Technology and Environment (MOSTE) set up a National Working Group on Biotechnology to oversee and coordinate biotechnology activities (Mat Daud, 2002) .

The second part focusses on the establishment of several agencies under MOSTE to spearhead the development of biotechnology. This includes the establishment of National Biotechnology Directorate, Biotechnology Cooperative Centers (BCC), Contact Group Programme and Malaysia Biotechnology Information Center (MABIC). The third part attempted to create biotechnology cluster by establishing BioValley Malaysia. The cluster was expected to accelerate the research and commercialisation of technologies which are crucial in this industry.

The BioValley was launched by fourth Prime Minister, Mahathir Mohammad in 2003 but there was not much development or progress as expected and it was shrouded by problems (Cyranoski, 2005). Due to this, the new strategies were formulated. This embarks the fourth phase of the biotechnology development in Malaysia. In 2005, the fifth Prime Minister, Abdullah Ahmad Badawi launched the National Biotechnology Policy to stimulate the biotechnology sector into a new economic engine to enhance prosperity and wellness of the nation by 2020. To achieve this, more agencies were created and the Malaysia Biotechnology Corporation (MBC) was regarded as one stop agency to spearhead the development of the sector (Mokhtar and Mahalingam, 2017). As for the purpose of this study, this thesis focuses on the NBP and its role in shaping the knowledge exchange and commerciasation of the sector. The establishment of the NBP is the climax of the biotechnology policy development in Malaysia.

### 5.2.1 The National Biotechnology Policy Master Plan

Interest in biotechnology started in 1986 but was only visible during the 8th Malaysian Plan (2001-2005) and for its purpose, the National Biotechnology Policy (NBP) was established. Biotechnology starts to emerge in Malaysia in 2006 with the implementation of the National Biotech Policy and came under three phases. The policy came along with its masterplan to draw what it aimed to achieve and how. Table 5.1 below showed the three phases of NBP with its five years planning.

**Table 5.1: Phases in the National Biotechnology Policy**

| **Phase I (2005-2010) Building Capacity** | **Phase II (2011-2015) Science to Business** | **Phase III (2016-2020) Global Presence** |
|---|---|---|
| • Establishment of advisory and implementation Councils | • Develop expertise in drug discovery and development based on natural resources | • Consolidate strength and capabilities in technology development |
| • Establishment of Malaysian Biotechnology Corporation | • New products development | • Further develop expertise and strength in drug discovery and development |
| • Education and training of knowledge workers | • Technology acquisition | • Strengthen innovation and technology licensing |
| • Development of legal and IP framework | • Intensify investment promotion | • Promote global Malaysian companies |
| •Business development through Accelerator Programmes | • Intensify spinning-off of companies | |
| • Build Malaysian branding | • Strengthen branding | |
| • Initial job and industry creation in agricultural biotech, healthcare biotech, industrial biotech and bioinformatics | • Develop capability in technology licensing | |
| • Establishment of advisory and implementation councils | • Knowledge-intensive job creation | |

(Source: MOSTI, 2009)

The table includes the establishment of advisory and implementation councils as well as the commercialisation arms for biotechnology products. In the first phase, the focus has been given to the establishment of the infrastructures and the right ecosystem for biotechnology to grow. It also embarked on the phase of nurturing industry growth (Dir, 2007).

The second phase of the NBP involved exploiting knowledge into commercialisation activities and Phase III aimed to bring the brand into global markets. In this phase, selected potential biotechnology companies were given facilitation and support to expand their business in international markets. To further achieve the target, the NBP was also supported by the nine focus areas which provide guidelines for the strategic direction to achieve the target stipulated in the National Biotech Policy. Table 5.2 below shows the focus areas and the strategies used in each area.

**Table 5.2: The strategic Thrusts in National Biotechnology Policy**

| Thrust | Details |
|---|---|
| **Thrust 1**<br>**Agriculture Biotechnology Development** | Transform and enhance the value creation of the agricultural sector through biotechnology |
| **Thrust 2**<br>**Healthcare Biotechnology Development** | Capitalize on the strengths of biodiversity to commercialize discoveries in natural products as well as position Malaysia in the bio-generics market |
| **Thrust 3**<br>**Industrial Biotechnology Development** | Ensure growth opportunities in the application of advanced bio-processing and bio-manufacturing technologies |
| **Thrust 4**<br>**R&D and Technology Acquisition** | Establish Centre of Excellence, in existing or new institutions to bring together multidisciplinary research teams in coordinated research and commercialisation initiatives. Accelerate technology development via strategic acquisitions |
| **Thrust 5**<br>**Human Capital Development** | Build the nation’s biotech human resource capability in line with market needs through special schemes, programmes and training |
| **Thrust 6**<br>**Financial Infrastructure Development** | Apply competitive ‘lab to market’ funding and incentives to promote committed participation by academia, the private sector as well as government-linked companies, implement sufficient exit mechanisms for investment in biotech |
| **Thrust 7**<br>**Legislative and Regulatory Framework Development** | Create an enabling environment through continuous reviews of the country’s regulatory framework and procedures in line with R&D and commercialisation efforts |
| **Thrust 8**<br>**Strategic Positioning** | Establish a global marketing strategy to build brand recognition for Malaysian biotech and benchmark progress. Establish Malaysia as a centrer for Contract Research Organizations and Contract Manufacturing Organizations |

| | |
|---|---|
| **Thrust 9** **Government Commitment** | Establish a dedicated and professional implementation agency overseeing the development of Malaysia's biotech industry, under the aegis of the Prime Minister and relevant government ministries |

Source: (BiotechCorp, (2010)

The table above represents the focus area that the government identified in order accelerate the bioeconomy development in Malaysia. These 9 thrusts within the biotechnology policy highlight the framework being developed to support the growth of the Malaysian biotechnology sector (BiotechCorp, 2009). It emphasised Malaysia's intended direction and the Government's proposed measurers towards developing biotechnology for wealth creation and national well-being (BiotechCorp, 2011). By using the above mentioned strategies, it aimed that the biotechnology sector will become one of the core technologies to accelerate the transformation of Malaysia into high income country (Economic Planning Unit, 2016).

This section has provided the broad description of the overarching biotechnology policy development in the country. It includes the phases and strategies used in accelerating the bioeconomy within these 15 years of planning. To further succeed the planning, various number of government agencies are appointed and established. Therefore, the next section will describe the role of government agencies at the national level in supporting the NBP.

### 5.2.2 Agencies supporting the commercialisation activities

Along with the implementation of the NBP, agencies to facilitate the biotechnology companies were established such as BiotechCorp, Agri-Biotechnology Institute, I-Pharm Institute, Malaysian Genome Institute, and Inno Biologic Sdn. Bhd. These agencies are responsible to facilitate the companies in commercialisation activities and act as a commercialisation arm to the biotechnology industry. However, for the purpose of this study, only agencies related to agribiotechnology will be discussed. The table below also gives detail on the other key players in biotechnology development in Malaysia which includes the Ministry of Science, Technology and Innovation (MOSTI), Malaysia Technology Development Corporation (MTDC), and Institute of Higher Education.

**Table 5.3: Agencies Supporting the Development of Biotechnology**

| Agency | Roles |
|---|---|
| **National Biotechnology Division (BIOTEK)** | The National Biotechnology Division is a special division within the Ministry of Science, Technology and Innovation (MOSTI). It is responsible for steering the national biotechnology agenda through (i) Research and development; (ii) Technology development and (iii) Promotion of biotechnology. |
| **Malaysian Biotechnology Corporation (Biotech Corp)** | Biotech Corp acts as one stop center to lead the development of the biotechnology industry. It also responsible to oversee the overall execution and implementation of the strategies outlined through the National Biotechnology Policy Master Plan. In order to support the R&D&C activities |
| **National Institute of Biotechnology Malaysia (NIBM)** | NIBM responsible for leading, coordinating and implementing the national biotechnology agenda through the activities of research, development, innovation and commercialisation (RDIC) of the other three biotechnology institutes, namely the Malaysia Agro-Biotechnology Institute (ABI), Malaysia Institute of Pharmaceuticals and Nurtraceuticals (IPHARMS) and the Malaysia Genome Institute (MGI). NIBM's key role is to support and spearhead the commercialisation of the R&D activities at the institutes based on industry requirements |
| **Agri-Biotechnology Institute (ABI)** | ABI responsible for undertaking research, development and commercialisation projects related to agro-biotechnology in cooperation with various industry stakeholders, research institutions and universities. |
| **Malaysia Technology Development Corporation (MTDC)** | The MTDC is responsible for leading the development of technology business in Malaysia. The main responsibility of this agency is to promote and commercialize local research to the global market. The MTDC also offers fund support for the scientists in the universities, research institutes and industries who wish to expand their R&D activities to commercialisation stage. |
| **Higher Education** | Responsible to supply human resources for the expanding and changing economy with the aim that Malaysia will become a high-income country. It also creates, disseminate and apply knowledge as well as to innovate and invent new information and technology. |

Each of the agencies has their own responsibilities in order to harness the potential of biotechnology in Malaysia. This includes the types of grants offered by Biotech Corp. and MTDC). At this point it can be seen that various other government agencies are involved in supporting the development of the biotechnology industry.

### 5.2.3 Subsection summary

Overall, there is a very complex sets of institutional arrangements that are fragmented and based around particular Ministries and other state agencies compared to a country like the UK where only one or two government departments are in charge of biotech policy. In Malaysia, there are more than one government departments responsible for spreading awareness, expanding the research base and exploiting knowledge for wealth generation. From the above discussion, it is clear that there is a very strong focus on the exploitation and commercialisation of knowledge. However, the success of these biotechnology activities has been dismally slow and hindered by number of setbacks. These include the lack of collaboration between the agencies due to high-bureaucracy culture. It also reflects a rather linear model of innovation where the agencies often work in silos. The responsibilities of the different Ministries overlap and seem very bureaucratic and functional, revealing the highly centralised tradition of public administration in Malaysia. Furthermore, the changes in leadership from the former fifth Prime Minister to the sixth Prime Minister saw a significant shift of interest from supporting agricultural activities through an emphasis on the biotechnology industry to a role for government transformation as a regulator and catalyst of high-income nation. This new role of government has witnessed the changes from Biotechnology activities to 'BioEconomy strategies' (Bioeconomy Corporation, 2015). The bioeconomy has been promoted as the game changer for Malaysia to become a high-income developed nation and would be a key contributor to economic growth for a productive, competitive and innovative economy (Malaysian Biotechnology Corporation, 2015). Due to this complex system, the implementation of the NBP turned out to be quite challenging. The section below will explore the issues and challenges faced by the biotechnology players.

### 5.3 Challenges in enabling the knowledge exchange and commercialisation of biotechnology in Malaysia

This study adopted a naturalistic enquiry method to collect qualitative data. A series of semi-structured interviews were conducted involving eight officers who are working in the biotechnology sector at the national level. These interviews aimed to obtain further insight into specific issues from their experiences. This section seeks to identify what are the barriers in preventing knowledge exchange and commercialisation activities in the country.

According to the previous literature on biotechnology, Malaysia has lagged in this sector because of several factors, including the failure to employ advanced modern biotechnology (Arujanan, 2016; Ismail & Mohammed Yusuf, n.d.), lack of skilled human capital, a weak industrial base, lack of commercialisation effort (Mokhtar & Mahalingam, 2010), restricted media coverage (Smeltzer, 2008; Samani *et al.*, 2011), and poor cooperation within biotechnology innovation networks (Farid *et al.*, 2011). However, in contrast with the above research, this study found that the main challenges in successfully implementing national biotechnology policy (NBP) were due to three factors as follows.

i) Centralised control model and lack of Policy Planning
ii) Lack of Coordination of Biotechnology Agencies
iii) Lack of Engagement among the Biotechnology Players

### 5.3.1 Centralised control and lack of policy planning

In discussing this topic, the first step involved in policy implementation is the policy formulation. Policy implementation is so important that it has drawn much attention from scholars to conduct research on this topic. The previous literature reviews on the role of policy found that it does have a significant impact in influencing biotechnology development (Senker *et al.*, 2007; Mastroeni and Rosiello, 2013). The quote below represents the steps taken before the NBP is formulated. Before discussing the weaknesses in policy, it is first worth characterizing the development model and features of biotech policy in Malaysia.

> **R1: Chief Assistant Secretary**
> Actually, we have our own model of biotechnology industry. We did not simply follow other country's' biotechnology model. However, I must admit that before we decided to implement this model, we have visited several countries such as United States and Korea to understand their model.

The biotechnology model adapted in Malaysia was formulated based on the experience of other countries. This was evident by various visits including the United States and South Korea as reported in the Biotechnology Report of Malaysia (Malaysian Biotechnology Corporation, 2010). From these visits, comparisons were made in order to choose the best model to be applied in Malaysia, considering the available resources. Although Malaysia is developing its own approach but this policy has not worked so far.

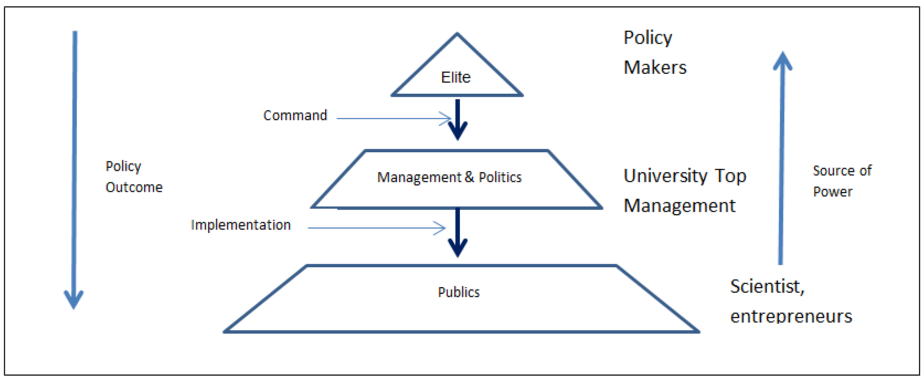
Malaysia may be able to learn from successful countries, but it depends on the degree to which existing institutions and social practices are similar (Schrempf, Kaplan and Schroeder, 2013). This situation relates to the National System of Innovation (NSI). From the perspective of NSI, the same sector in a different country may still perform differently since the national context is also important. One of the reasons that could explain the situation in Malaysia may be due to centralised control practiced by the government. This culture is demonstrated by the following extract:

> **R1: Chief Assistant Secretary**
> I mean when we formulate the policy and carry out the implementation of the policy, the acceptance of it is easy to get. For example, all Ministries and Government agencies are alert whenever there is a new policy being implemented, and it also includes the universities. It is not much to ask them to adapt with the policy, but it is their responsibility to accept the policy. They have to follow it.

This informant had been Involved in the policymaking activity and according to R1, it is not difficult to obtain involvement from all parties in the implementation of policy. According to his experience, biotechnology players such as the industries, universities, government and semi-government agencies accepted the newly introduced policy without much hesitation. During the policy launch, these players were invited so that they understood the advantages of the policy.

Malaysia practices the command-and-control style of administration as describe by R1. This style requires all stakeholders to accept all the policies put up by the central government. Since the implementation of the National Biotechnology Policy in 2006, the biotechnology industries and universities in Malaysia have been required to adapt the policy into their daily practice reflecting the top-down practiced culture in Malaysia (Malaysian Innovation Agency, 2011). By using this strategy, it is believed that the industry and the university would align their organization’s direction to meet the agenda set by the government. As for the public servant, they are required to sign a ‘Letter of Undertaking’ when they join the organization. The letter required the public servant to obey and support all the government agendas as mentioned in Regulation 2012 [P.U. (A)1/2012) (Public Service Department Malaysia, 2020). According to Malike (2008), in Malaysia, the policy is adapted by the institution in several ways. One of the influential models in policy approach in implementing a policy is the Elite Model. The concept of Elite is based on the notion that every society holds a ruling minority, a group that controls the most important power sources (Lopez, 2013). In this model, the society is controlled by the influential group which is the 'Elite' who consist of Prime Minister, Ministers, the laws, courts, bureaucrats, the legislative (Malike, 2008) and the king (Hussain, 2008).

**Diagram 5.2: Elite Theory**




(Source: Malike, 2008)

The diagram above showed how Elite Theory works in delivering the National Biotechnology Policy in Malaysia. The flows from top to bottom. In this context, the government will command the bureaucrats who are in management positions to implement policy at different levels. This includes the biotechnology community, industry and the general public.

There are pros and cons of practicing this type of tool in developing and implementing policy. The advantage of this style is that the reform is specified in advance and there is a clear plan of how to obtain the desired outcome. However, the problem is that legislators may not foresee all the circumstances of the policy. Therefore, they might not be able to adapt a law and legal framework to a particular locality or changing circumstances. The attractiveness of this top-down approach may lead to its downfall where it can create resistance from key actors (e.g. industry, farmers, the general public), especially when they feel that they have not participated in the decision making process (John, 2011). There is evidence in later data chapters of the limits of centralised control and elite policy making.

As a late entrance to biotechnology, the industry is still immature and may require the government to spearhead the development of the sector. Although top-down command can be used at this stage, there should be a balance in using this power. However, this practice is not appropriate to be used during the process of policy formulation as it is valuable to ensure that the opinion from all stakeholders should be taken into consideration. This includes the users of the agrobiotechnology research and should not be limited to the biotechnology stakeholders e.g. the formulation process should work closely with the Ministry of Agriculture since the agrobiotechnology is the hybrid discipline of biotechnology and agriculture. However, what happened was, the biotechnology agenda was set under the Ministry of Science, Technology and Innovation.

In line with the discussion above, R1 revealed that the implementation of the NBP did not fully reach all the stakeholder. This might be due to the missing representation of some group during the policy formulation process. Therefore, it resulted in incomplete data of all biotechnology companies.

> **R1: Chief Assistant Secretary**
> (………………...So far, they (companies) did not receive any tax exemption yet). That is what I meant in our early conversation – the biotech industry is not complete. There is something missing. The implementation of the policy did not totally reach all the biotechnology companies.

According to R1, he agreed that the formulation and implementation of the NBP does not cover all aspects needed in developing the biotechnology industry in Malaysia. This scenario exemplifies two issues. The first is regarding the incompleteness of data related to the number of companies involved in biotechnology. Secondly, the impractical mechanism for tax exemptions. Malaysia, who is just starting to be involved in the biotechnology sectors was unable to collect data on all the biotechnology-related companies during its first phase of NBP. This is due to the difficulties in identifying whether a company falls under the biotechnology or agriculture group since biotechnology is a cut-across discipline. In term of the tax exemption, the mechanism is unable to reach all the companies that entitled to receive it due to incomplete procedures set up by the BiotechCorp and the Inland Revenue Board of Malaysia due to the overly quick implementation of this policy. This indicates that there is a lack of policy planning where a gap existed between the government, implementers and the practitioners.

As a policymaker involved in the implementation of the NBP, R1 mentioned that the process of formulating the policy came from various parties such as the industries, learning institutions and NGOs. Research conducted by Mahalingam (2010), found the policy makers in a developing country such as Malaysia frequently assume central roles in initiating, shaping and pursuing public policies (Mahalingam, 2012). The research had identified six phases involve during the NBP formulation. Mahalingam (2010) also noted that the process of drafting the NBP took less than six months and was quicker than any other countries such as the India to established a policy and a regulation system during 1980s (Samal and Bhattacharya, 2017).

Therefore, it seems that the strategies used in the NBP is only focused at companies that had obtained the BioNexus status and are well established. SME’s such as the start-ups companies are unable to apply for the BioNexus status are not entitled to get the benefits offered by the government such as the tax reduction and need to survive on their own. In addition, BiotechCorp only focuses on companies that are able to compete in the international market. Hence, it seems that BiotechCorp is exclusively made for those companies that are well established.

The missing inputs from these group would cause inaccurate information on the current state of the sector and might fail to address their needs. At this point, it can be seen that a well mobilized policy consultation and policy network may make a critical difference in ensuring a successful adoption and implementation of policy. It further supports the importance of having all the biotechnology players involved in formulating the NBP.

As discussed above, R1 knew that the implementation of this policy failed to reach all the biotechnology players in Malaysia. He could sense that there is a gap between the formulation and implementation of the policy. This is further agreed by R3 who is working as a business development manager in a national technology transfer office. According to R3, the unclear definition of 'biotechnology' resulted in confusion in identifying biotechnology companies. Therefore, causing inaccurate data.

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> **R3: Business Development Manager**
> If I can further clarify, the definition of biotechnology itself means enabling the technology. So, it cuts into other sectors as well. DOS (Department of Statistics), they did on traditional and matured sectors but biotechnology is embedded inside this. They need to consider the aspect of probably the redundancy in calculating the statistics and everything. Right now, we are dealing with DOS how to clarify all these things and start to get the data on the ground of biotechnology.

R3 further added that there was a redundancy in identifying the biotechnology companies in the country. According to him, the confusion was due to a vague definition of biotechnology itself. As a result, it was very difficult to classify whether the companies that are being identified belong to traditional agriculture or agri-biotechnology. The statistics gathered by the DOS comprises of companies on the traditional and mature sector, with biotechnology companies in the subsections of these groups. However, less attention was given to differentiate these biotechnology companies. This explains why there is no comprehensive database related to biotechnology except for the companies supported by BiotechCorp.

In Malaysia, there is no specific agency that is responsible for gathering the number of the biotechnology companies except the companies that applying the BioNexus Status from the BioEconomy Corporation. The report prepared by Ernst and Young as consultants for the NBP did not specifically mention the total number of agro-biotechnology companies in Malaysia. The absence of a complete database had several negative effects on biotechnology development. For example, the incomplete data would affect the accuracy in budget allocation (O'Hare, 2019). The only complete information about biotechnology companies was provided for the BioNexus status company. These group had access to tax benefits, international exhibition opportunities and specialized training in business development prepared by the BiotechCorp. The report produced on Malaysian Biotechnology Statistical Indicators and the other reports by BiotechCorp only discusses the achievement of the BioNexus companies (MOSTI, 2013).

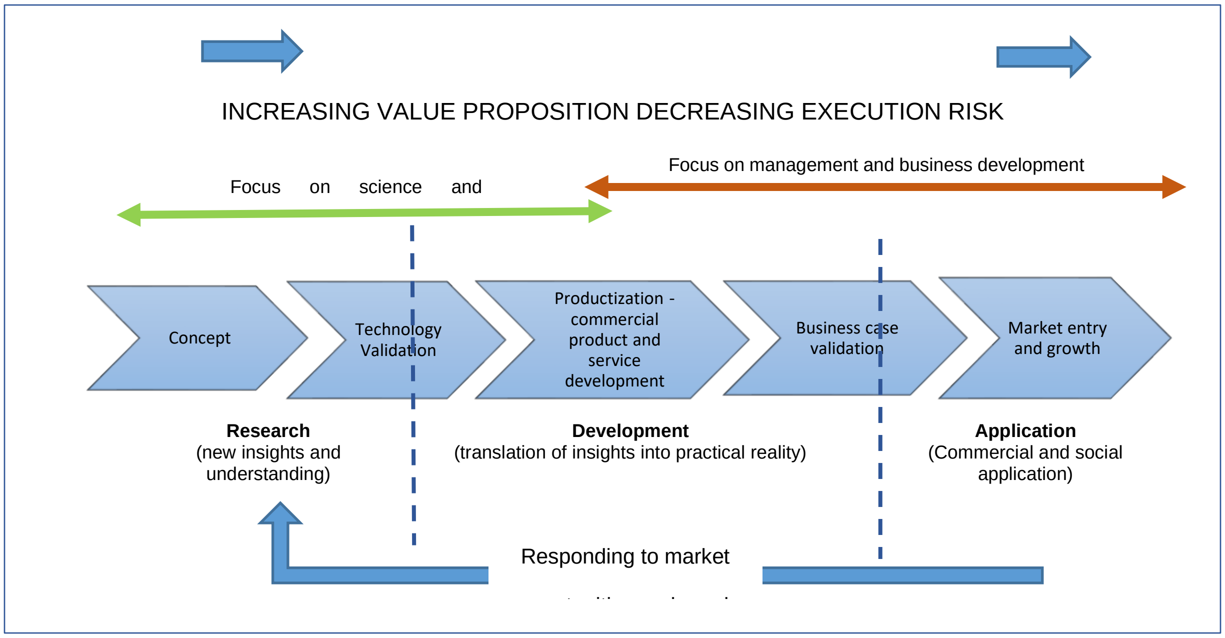
It can be concluded that the lack of information regarding biotechnology companies impacted the decisions made by policymakers. As discussed in the Literature Review, the policy process involves various biotechnology players to ensure the policy is able to meet its goal. Due to incomplete information, the government is unable to plan effective programs or initiatives to enhance the development of biotechnology such as the programme for new start-up companies or SMEs. Another key issue that characterizes policy development in Malaysia is the time required for the industry to mature. This was mentioned by R2 as below.

> **R2: Manager, Corporate Planning, Corporate Services Division**
> Normally people will say, the gestation period of R&D, biotechnology product is long and tedious. Okay, if you start from the fundamental, of course it will take long period. 20 years maybe and sometime the product does not take-off yet because by the time the research reach start up stage, the research is maybe obsolete (outdated).

According to R2, biotechnology involves many phases and 15 years is not enough to build a successful biotechnology sector. In some cases, the product may become outdated before it could be put into the market due to industry dynamism.

According to R2, the research sometime failed to reach the commercialisation stage within the time frame. This is due to the R&D process that requires experiments and procedures such as proof of concept. The lengthy process requires more time to fully develop and the projected time frame often used by government is not enough to see the successful result. The situation called the industry dynamism where it forces current products and technologies to be outdated quickly, leading to more demand for advanced technologies (Jansen, Van Den Bosch & Volberda, 2006). Below is a diagram demonstrating the process involved in commercialisation activities in the biotechnology sector.

**Diagram 5.3: Value creation pipeline from concept to market entry and growth**




(Source: Shahi, 2003)

Understanding how the research, development and application (RDA) process works and brings value is critical in order to maximize returns on investment in innovation. According to Shahi (2003), the process involves five stages. The first stage involves the concept where creative ideas begin to spark. Next, the idea must undergo technology validation to prove that the concept is technically feasible and workable. This stage is also known as ‘proof of concept’. The technology validation process serves as the interface between research and development. The third process is ‘productization’ where the validated concept or the technologies is converting into commercially ready products, services or technology platforms. The next process involves ‘business case validation where there is confirmation that there is a market for the product, service or technology. Lastly, is the process of ‘Market entry and growth’ where it involves the process to bring the product, service or technology to market.

According to Shahi (2003), the length to progress from one phase of the innovation development pipeline to the next varies according to the sector and the product, technology or service being developed. Hence, the productization phase might require as little as three to six months for developing a new software solution but may take eight years or longer with new drug development considering the productization phase in healthcare biotechnology, for example, must go for the pre-clinical and clinical trial development process before it can be approved and made available.

Diagram 5.2 shows that driving the innovation process from concept to market requires an extensive range of expertise and capabilities. A careful examination of the five discrete phases in the pipeline demonstrates that the first half of the process (from concept to technology validation to productization) is heavily dependent on strong strategic science and technology development capabilities. The second half of the process, which involved business case validation to market entry and growth requires strong management and market/business development skills. Hence, a successful product, service or technology platform development effort depends on a combination of very different skill sets, capabilities and resources. Clear milestones can be defined for each phase, generally increasing the value proposition and reducing the execution risk involved in bringing the initiative to fruition.

Successful biotechnology countries such as Spain, France, the United States and Korea had started their biotechnology industry several decades ago and have many established biotechnology firms that support product development. A critical factor in the successful development in the country was a high commitment from the government and mature industry. Therefore, aiming 15 years for this sector to mature is seems difficult to achieve. This issue is being raised by the next respondent.

> **R3: Manager, Corporate Planning, Corporate Services Division**
> I guess another issue that can be highlighted is that, all other nation which made commitment to biotechnology will be in a long term commitment. But Malaysia doesn't have that one. It comes under just a policy and the policy does not translate into any long-term action plan.

R3 is a senior officer who is working in the Bioeconomy Corporation (formerly known as BiotechCorp). R3 doubted that Malaysia could become a developed nation through biotechnology. According to him, the biotechnology industry is complex and demands a long gestation period. According to R3, the 15 years' projection to develop biotechnology is impossible to achieve given the available resources in Malaysia. When asked about the aim of the policy and the current status of biotechnology achievement in Malaysia, R3 admitted that the commitment towards making biotechnology the third growth engine for the economy is unrealistic.

This can be tracked back to the previous government project namely BioValley. The BioValley project demonstrated the unstable effort towards biotechnology activities. Before the implementation of the NBP, Malaysia had created a science park called the 'BioValley'. This is an example of how low commitment towards biotechnology could lead to the failure of the project. (Mokhtar & Mahalingam, 2010). BioValley was a cluster proposed by the government to attract the biotechnological industry to Malaysia. The establishment of BioValley was considered an important component for the Vision 2020 plan and Malaysia's future as a knowledge economy focusing on biotechnology-based activities (Ahamat, 2013). This cluster was created to gather a group of specialized companies to support each other to create a center of excellence. The BioValley Strategic Plan was developed through collaboration between the National Biotechnology Directorate and Massachusetts Institute of Technology

(MIT) through the Malaysia-MIT Biotechnology Partnership Program (MMBPP). There was not as much development or progress in the BioValley as expected and the project was shrouded by problems and the plan had to be overhauled and a new strategy unveiled. Due to this failure, the fifth Prime Minister, Tun Abdullah Ahmad Badawi decided to adopt a different approach for investing in biotechnology by launching the NBP and not continuing the BioValley project (Cyranoski 2005). Furthermore, the changes in national leadership also witnesses unsteady support towards biotechnology development.

**Subsection summary**

From the information and evidence gathered above, it can be concluded that the implementation of the NBP has faced a number of challenges. This can be seen from the unmet goals set earlier in the NBP. There are a number of reasons for this. Firstly, there were flaws in the earlier formulation of the NBP. The analysis revealed that the policy failed to address the insufficient resources needed to develop this sector. Secondly, policy maker also failed to include the representation of the stakeholders directly affected by the NBP due to the command-and-control style of policy formulation and implementation. The policy seems to underestimate the importance of the practitioner's roles such as farmers in supporting the policy. Although there are many inventions or products of agri-biotechnology available in the market, they cannot generate revenue when there are no users. Given that the private sector will continue to be the dominant force in biotechnology development implies that the majority of the poor farmers will be left out from the mainstream of the biotechnology revolution. This could be due to insufficient knowledge among the farmers about biotechnology that could help them to increase their yields. Furthermore, they are unsure of the other factors such as the effectiveness, risks, time and effort necessary to use the biotechnology technique (Sattler and Nagel, 2010). At this point, it can be seen that Malaysia from the perspective of innovation system is still weak.

In summary, the analysis suggest that this was due to the very complex institutional structure, overly centralised command and control culture in all government agencies, insufficient infrastructure in terms of data, lack of shared understanding of biotechnology, the unrealistic timeframe towards its implementation and the lack of long-term commitment in pursuing the effort in generating income from this sector. At this point, it can be seen that all actors have a significant role in accelerating the NBP. As each of these actors are interdependent on each other, all actors should understand their roles and others roles in ensuring the policy could operate smoothly. Another important factor that contributed to the slow progress in biotechnology development in Malaysia was lack of coordination among the biotechnology players and this is discussed in the next section.

### 5.3.2 The lack of coordination among biotechnology-related agencies in Malaysia

The second issue faced by the biotechnology players at the national level is related to the direction of the biotechnology agencies in executing the National Biotechnology Policy. One of the factors leading to the lack of coordination in the Malaysian biotechnology sector is due to a weak understanding of biotechnology adaptation. According to Subramonian and Rasiah, (2016), failure to engage this sector in the bigger picture might reduce participation and collaboration, and it could affect the implementation of the NBP. Below is an example of a dispersed understanding of biotechnology direction among the implementers.

> **R2: Manager, Corporate Planning, Corporate Services Division**
> Like yesterday, I went for a meeting in the Implementation Coordination Unit. We had to do a presentation regarding the projects that we have brought in because one of our roles is as 'pemudahcara'(intermediary). During the presentation, the officer in the meeting was still asking us what is actually 'Biotechnology'? Even though BiotechCorp is 8 or 9 years in its operation, we still have those questions from the people who created us.

R2 observed that not all government officers are aware of the National Biotechnology Policy, especially in its detailed subject matters. Another possible reason is that the implementer could not see the visible roles of the agency in supporting commercialisation activities thus, raising the question of the economic importance of this sector.

Amin (2013) examined biotechnology awareness among Malaysians and discovered that policymakers are among the group that has the highest level of awareness regarding the policy implemented in the country. Therefore, it is not convincing to say that the government officials do not understand the policy. The second reason is more plausible as the officer could not see the exact role played by BiotechCorp in improving the national financial state. Furthermore, there was confusion regarding BiotechCorp and its functions concerning other government agencies related to agriculture and biotechnology such as MARDI and ABI.

In Malaysia, there is no clear definition regarding biotechnology. The exact boundary between modern and conventional biotechnology has not been established (Amin et al., 2011). Amin et al., (2007) further added that as long as the study involved any biotechnology techniques or tools, they are grouped under biotechnology. Among research organisations in Malaysia which engaged with the R&D stage and commercialisation are MARDI, ABI, NIBM, and BiotechCorp. However, BiotechCorp only focuses on commercialisation activities. This involves bringing in investors into Malaysia and finding the right partner for the BioNexus status companies. The similarities and overlap between these three agencies may have led to the confusion of their functions.

From the researcher's point of view, having a clear understanding of the NBP's goals is vital in embrace biotechnology. The relationship built among the agencies should complement each other and not be competitive. Revisiting the concept of NIS, one of the crucial factors within the system is its institutions. The institutions and how the actor shape the interaction between them are important to ensure the system is workable. In a country without strong governance structures, someone with the same talent who works just as enthusiastically might still end up extremely poor. The importance of institutions must not to be underestimated. Therefore, the ministry and the top-level management should ensure that their officers know and understand their roles and responsibilities. By understanding their roles and responsibilities, it is hoped that the staff can increase their performance and as a result, be able to achieve the agency's KPI. However, the reality is not as simple as that. According to R5, he admitted that the agency is unable to meet the yearly KPI.

> **R5: Chief Operation Manager**
> So part of our KPI is how many patents we have, publication we produce, and how many products we commercialise. These are among the KPIs given by the government to us. So, if you ask me about the commercialisation, I would say that our commercialisation rate is still low. Research, we do have, but on the part of commercialisation, we are still not achieving it yet. Maybe because we are still new, the public still does not know about us or maybe because we do not actively promote ourselves. So these are the possibilities for this.

As highlighted by R5, he is aware that the biotechnology community and the public in general is unaware of the existence of the agency. Although the agency is part of the biotechnology cluster in the Ministry of Science, Technology and Innovation, he admitted that the agency is less visible in the biotechnology community. This is due to delay in the operation of the agency. Furthermore, the policy expectation is ahead of its implementation thus causing this agency to lag behind what is expected of it.

According to R5, one of his given KPIs is to commercialise the products invented in the agency. However, there is a problem in getting the people to use the facilities offered by the agency. As one of the Malaysia Biotechnology Cooperative Centers (BCC), it is the responsibility of the agency to produce commercialised products. One of the reasons that explains the unmet commercialisation KPI is the invisibility of this function of the agency.

Many reasons could lead to the invisibility of this agency. In this case, the first could be due to the late operations of the agency. In the same line with R6, the agency's operation is also affected by the staff's resistance to accept the corporatisation of NIBM (refer R6). Due to this delay, the agency is slow to offer its' services to support the commercialising of the biotechnology products that were being developed in the facilities in the agency. Secondly, R5 also mentioned that the agency was understaffed to run the promotional activities. Furthermore, the searching through the internet and Facebook showed there were only a limited number of activities organized by this agency since its establishment.

According to R5, he did not have much staff to help him to prepare and conduct the event to promote their services to the biotechnology community. Consequently, the biotechnology community is unaware of the existence of the BCC. It is also evidenced that the TTO failed to hire well-qualified staff due to a lack of resources.

In relation to the innovation system, one of the crucial factors in developing a successful biotechnology industry is sufficient human capital. As discussed by Iqbal, Khan and Senin, (2015), human capital with insufficient education and training will negatively affect the innovation system as they might produce a low quality of research. Revisiting the concept of Sectoral System of Innovation, high skilled workers are very important as this model concentrates on specific technologies. Due to that, sufficient human capital in specific technologies will influence the development in that particular sector. For example, Singapore began to recruit expatriates to run the industry and offered many schemes to support development in this sector (Mokhtar and Mahalingam, 2017).

The lack of staff significantly affects the proper management of the research organisation's inventions and dissemination of information to the industry. The absence of adequate technology management practices and lack of experience serve as major obstacles to establishing good linkages between academia and industry (Chandran, Sundram and Santhidran, 2014).

Hence, it can be said that the agency is unable to meet its KPI due to internal problems, including staff resistance to corporatisation, the understaffing problem, and the funding allocated to this agency. Due to the insufficient resources, the agency had difficulties in promoting themselves to the biotechnology community and was unable to attract scientists and companies to use the services and facilities provided. Apart from having visibility difficulties, the biotechnology agencies also experiencing internal problems in implementing policy. Interestingly, the results from the interviews identified that the implementers do not have a clear understanding of the roles of the different agencies involved. The next extract depicts the effects of having an unclear understanding of the agencies in supporting the NBP. The absence of any function in the system would affect the overall performance of biotechnology policy implementation. R6 revealed the internal problem occurred in one of the BCCs.

> **R6: Chief Operation Manager**
> So, by becoming GLC, which is 100% owned by MOSTI, we abide by the company act. So, our target is on 2012 (to do commercialisation) but is not yet successful because there was so much resistance from the staff. They feel more secure if they are under the Government. Furthermore, they do not understand the direction of the institute.

According to R6, the staff in the agency refused to accept the corporatisation of this agency. The government decided to corporatise this agency to reduce the bureaucracy and hasten the decision-making process in the organisation. R6 believed that the reason behind this was because the staff feel insecure due to organisational changes. Being a corporatised company, the staff are unable to enjoy the privileges as a public servant. He further added:

> **R6: Operation Manager**
> Actually, that was the time when I first joined. So because of that, there is a delay, and it continued in 2013. So because of that there is a slight delay in term of commercialisation. We are focusing more on the internal problem. So, in the first month of this year, we are now fully operational. In my opinion, we have wasted more than about two years trying to solve the internal problem.

Due to the resistance to corporatisation, the agency was unable to deliver its functions effectively to become one of the nation's commercialisation arms. As discussed above, the delay of the agency's operations affected the milestone projected in the NBP. Referring to the NBP master plan, the infrastructures phase covers the first five years of the policy implementation. This included the establishment of NIBM, ABI, MGI, and IPharm. The similarity among these four agencies is that they were established in 2006 except NIBM and were aligned with the first phase of the NBP (Phase 1: Capacity Building). The NIBM was established years earlier in 2002. The aim in this phase is to provide an integrated platform for participation by the scientific, business and funding groups to develop an eco-system that is capable of sustaining Malaysia's growth and progress in biotechnology (Corporation, 2007).

In 2011, the Cabinet agreed that the ABI, IPHARM, and MGI should be corporatised into a new autonomous not-for-profit entity to enable the three institutes to be operated more effectively, efficiently, and centrally. These three institutes are known as the Biotechnology

Cooperative Center and are monitored by NIBM. The main objective of NIBM is to enable the three agencies to minimise or eliminate the government procedural requirements and replace them with a dynamic, fast, efficient decision-making process (NIBM, 2018). However, due to staff resistance to this privatisation, the NIBM only operated with its full functions in 2014, which is towards the end of the second phase of the NBP (Second Phase: Science to Business).

However, there is another reason that has led to the reluctance to accept the new changes among the public servants in Biotechnology Cooperative Centers (BCC). The frequent changes at the ministry level have caused chaos in terms of the focus and responsibilities the ministry has to carry out. The changes at the ministry level have indirectly affected the roles of these agencies. Surprisingly, the Ministry of Science, Technology and Innovation has frequently rebranded its names in order to serve its roles aligned with the demand from the government. Thus, it has affected the directions and responsibilities of the BCC because it is housed under this ministry. Below is the chronology of MOSTI since 1973.

**Table 5.4: The chronology of MOSTI background**

| Year | Description |
|---|---|
| 1973 | The Ministry of Technology, Research and Local Government |
| 1976 | Change to the Ministry of Science, Technology and Innovation (MOSTE) in line with its new functions and responsibilities related to environmental issues |
| 2004 | The restructuring of MOSTE and the name was change again to Ministry of Science, Technology and Innovation (MOSTI) to spearhead the development of Multimedia, National ICT and Innovation |
| 2007 | The functions of Science and technology were broken up according to the clusters of Biotechnology, Sea to Space, Industrial and Core Cluster of Science & Technology |
| 2016 | MOSTI was restructured to give more focus on promoting R&D and commercialisation programs |

Source: MASTIC, 2019

The table above shows several changes have taken place in the Ministry since 1973 before it was rebranded to MOSTI in 2016. The constant pattern of change makes it much harder to have continuity efforts in the policy and its effective implementation. From the policy perspective, the organizational reform is not an unusual practice. The reform is made to enhance the previous efforts or roles to fit the new function. The reform has brought greater responsibilities and closer interaction with other parties which were in different ministries previously. The interaction has further strengthened the biotechnology cluster. However, in other cases, R2 explains the frustration in how her department played its role in accelerating biotechnology in Malaysia.

> **R2: Manager, Corporate Planning, Corporate Services Division**
> They do not understand what biotechnology is. The government says I am giving you my commitment to developing the biotech industry, but people are still not aware of it. For example, I still got a question like 'what is biotechnology' from the government officer who are together in the meeting presentation. I am supposed to develop this agency (to become one-stop-center for biotechnology in Malaysia) but still, people do not understand biotechnology. So, I think people tend to be self-resistance because they don't understand this matter very well.

As one of the important officers in Biotech Corporation Sdn. Bhd., the Malaysia one-stop center for biotechnology, R2 believed that the awareness about biotechnology among policy makers is still low. The lack of information and awareness of the benefits gained from adopting biotechnology still causes the officers to have a vague understanding of this area.

According to Arujanan (2007), the lack of understanding of biotechnology was caused by limited public awareness programmes. This includes the absence of concerted efforts among the stakeholders and many activities carried out on an ad-hoc basis to serve the interest of specific groups. In a different study, Amin examined the public awareness among Malaysians and discovered that there are only certain groups of the general public that have awareness of biotechnology. The highest score is led by the biotechnologist and policymakers, followed by biology students and biologist. The lowest level of awareness was observed among religious experts and the general public (Amin, 2013).

In examining the second phase of NBP, this focused on ‘bringing the science to business’. Through this phase there were numerous corporate communication and media events to improve the awareness of biotechnology-related facts and opportunities. Among them were BioCareers 2009, BioIndustry Dialogue and Exhibition 2009, ‘Jom Heboh’, and BioUsahawan Press Conference 2009 (Malaysian BiotechCorp, 2010). These outreach events specifically focused on enhancing the awareness of biotechnology and encouraging the use of biotechnology application in the daily life of the general public. The events were also intended to attract kids and teenagers through participation in biotechnology games, quizzes and other interactive sessions (Malaysian Biotechnology Corporation, 2010). Another initiative by Biotech Corporation during the first phase of NBP was the ‘biotechnology segment’ at the end of the prime news time, roadshow, and exhibitions. During this period, the Malaysian Biotechnology Corporation and Malaysian Biotechnology Information Center (MABIC) was established to spread the awareness to the general public.

**Subsection summary**

As discussed above, it can be seen that there is poor and fragmented coordination among the biotechnology agencies at the national level. This is demonstrated by the low understanding of the role of different agenda by the implementers in these organizations. In order to spread the awareness, the government have drafted various programmes and initiatives to further accelerate biotechnology. However, the data presented above suggests that the implementers have been unable to engage this agenda as part of their responsibilities.

In summary, the analysis suggests that the lack of coordination among biotechnology-related agencies was due to the failure of the agencies in supporting commercialisation activities, the delay in the operation of the agencies that is ahead of its implementation, insecure feeling among the staff due to frequent changes at the ministry level and low awareness of the biotechnology agenda among the policy makers and potential biotechnology users. At this point, it can be seen that the institutional roles in biotechnology are weak and fragmented. This could be seen from the flawed policy design and its implementation. This is demonstrated where the policy seems unable to engage all the actors related to biotechnology in furthering the commercialisation activities in this sector.

### 5.3.3 Lack of engagement among the biotechnology agencies at national level

The establishment of the NBP has created a number of agencies to support the development in biotechnology. This section focuses on the engagement of biotechnology agencies with other government agencies. The government agencies involved are those under the MOSTI purview and other ministries such as the Ministry of Agriculture and Ministry of Higher Education.

> **R5: Director**
> The policies are all there. The value chains are in the policy. So it is based on the implementation, but sometime, of course, there are hiccups here and there because sometimes it needs coordination between agencies. Interaction between agencies is not so bad, but when it is across ministries, it gets worst. So, that is the most visible problem that I can see.

The statement by R5 as the director in one of the biotechnology cooperative centers (BCC) evidenced that there is a significant problem in terms of coordination among the various state agencies. The director sensed that the players at the national level are having difficulties in working together, especially in achieving the specific goals highlighted by the government. This situation suggests that there is a barrier that restricts them building close engagement with each other. The situation suggested that there are barriers in working together due to work practice. This is also supported by R3. According to him, it is true that the collaboration among the agencies under the same ministries are easier compared to the interaction across the ministries This is further elaborated by R3.

> **R3: Business Development Manager**
> So again, the issue of understanding, from MOSTI point of view, they claimed that MARDI is not in their ministry. So the cluster only limits to agencies under MOSTI. So that is why they create a biotechnology cluster. There is no engagement with people outside the cluster.

R3 is disappointed with the system practiced by MOSTI. The engagement between the agencies in the biotechnology sector is limited inside the cluster and not across the ministries. According to R3, the segregation made between the agencies has widened the gap among the biotechnology agencies and within the biotechnology community. The situation shows signs of institutional barriers and political competition between the ministries. In relation to this, R2 shares her experience as the result of Malaysia's political competition practice which involves working in silos and having their own interest to serve.

> **R2: Manager, Corporate Planning, Corporate Services Division**
> Because the NBP is supposed to be a document – MOSTI'S document. So, the agency, BiotechCorp is one of the agencies that is supposed to carry the responsibility for the NBP, but there

> are agencies out there that were supposed to share the responsibility, maybe not everything but a portion.

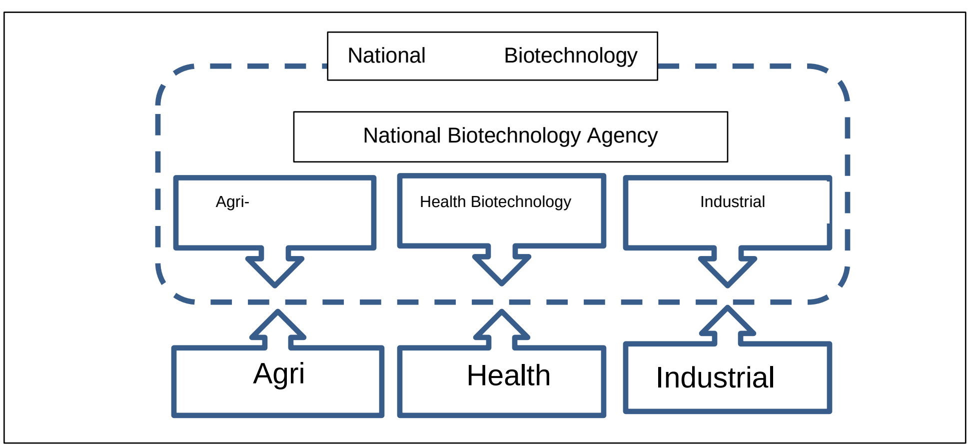
According to R2, due to the institutional barriers, there is limited sharing of responsibility among the cluster's members. Although BiotechCorp is known for its one-stop center for biotechnology activities and the lead agency for the biotechnology sector, the other biotechnology agency must support and also portray themselves as part of the biotechnology cluster. This is because these agencies shared the same goal which is to encourage commercialisation to develop this sector. Most of the time, the discoveries made in department are kept to themselves and every agency tries to become the champion in their field.

One of the reasons that leads to this is that each agency abides by the ‘red tape’ culture. The red tape culture has restricted or prevents decision-making before the issue are discussed with other members of the top management level. Furthermore, when the interaction involves other ministries, it become worse. This is because the agency must cross different ministers to get approval or collaborate in any particular decision or issue.

Malaysia has 38 public research institutes and they belong to different ministries (Ali Hassan, 2012). Referring to Science Outlook 2017 prepared by the Academy Science Malaysia, there are 28 agencies under the MOSTI (see appendix C). The box highlighted in green showed MOSTI and its agencies. For example, NIBM is one of the agencies under MOSTI, and the biotechnology cooperative centers (BCC) such as the ABI, IPHARM and MGI are under the NIBM. Another example that is closely related to biotechnology is the MARDI. However, this agency is directly under the Ministry of Agriculture. Although the biotechnology cooperative center (BCC) has quite similar roles with MARDI, they operate in silos. This is largely related to the bureaucratic practices embedded in the government culture in Malaysia. Collaboration cannot be easily initiated because there are procedures that need to be followed. As a result, they do not share the knowledge discovery in their facilities with the people outside their agency. The situation demonstrated that each of these agencies are operating at arm's length from each other. This was due to the political competition between ministries. According to (Islam, 2010), bureaucracy and bottlenecks must be removed to bring smoothness in public administration.

Referring to the MOSTI report of the Assessment of Phase I and Review of the National Biotechnology Policy, there are three types of policy design to adopt biotechnology strategy, namely i. Top-down governance, ii. Sector-based public-private-partnership, and iii. Interagency-collaboration. These three types of models reflect different degrees of centralisation or decentralisation of the government's involvement and initiatives (MOSTI, 2013). As discussed in Section 5.3.1, Malaysia practices top-down governance where all activities regarding biotechnology are monitored closely by the central government. Below is a diagram of the Top-Down Governance in the biotechnology sector.

**Diagram 5.4: Top-down governance of biotechnology sector in Malaysia**




Source:MOSTI(2013)

The top-down governance conceptual model is organised around a centralised National Biotechnology Strategy, under the sole purview of a dedicated biotechnology agency. This agency is responsible for the strategy roll-out in agriculture, health and industrial biotechnology. This model allows for a coordinated approach to biotechnology with a clear set of defined targets, FDI attractions, and clustering of resources through the dedicated agency and the other government bodies. Most of the adopters of this approach are new entrants such as Malaysia, Thailand, and the Philippines (MOSTI, 2013). However, the adoption of this model limits the overall cooperation within the economy such as the interaction between the biotechnology sector and other agencies and ministries.

The problem with centralization is that the decision power is only made at the top level and due to that the decisions may be misunderstood while being passed down. Although the government had taken a step to reform the governance structure by upgrading to fewer government agencies such as the NIBM, ABI, IPHARM and GMI, as the statutory agencies, the decision made in the agencies are still required to obtain approval from MOSTI. The second disadvantages caused by centralization is due to the delay of work information. This may happen due to the approval needed from the top level before any decision can be implemented at a lower level. This reflects that the agencies are still tied to the centralization of authority.

In a bigger perspective, the centralization of authority has limited the engagement between agencies from different ministries. The situation happens as the agencies need to cross the ministry level whereby both of the agencies need to get the approval from their ministry before any collaboration could be made. At this point, it can be seen that the ministries and their agencies are working in silos. This reflected that the biotechnology cluster needs to be understood as a community, not as a mechanical collection of resources and actors (Kim, 2011)

The TPM Biotech, for example, is one agency under the purview of MOSTI, and not many formal procedures are involved to organize the meeting within this biotechnology cluster. However, things are different if there is a meeting or event that requires participation from agencies across the ministries. It is understandable why the government uses this top-down approach and bureaucratic procedures to handle the industry, especially in developing countries and the late entrance of biotechnology. This approach allows the government to control the directions and interaction between players in the biotechnology sector. However, too much interference from the government may lead to the problems identified above and an overdependent culture on the central government.

**Subsection summary**

From the discussion above, it can be concluded that the biotechnology agencies in Malaysia lack engagement at the national level. This is due to the culture of red tape and working in silos. When these two factors are combined, the interaction is less likely to happen, and every agency will pursue their own interest without having to care about the roles of others. The interaction between them can be considered as competition rather than to complement each other. The objective to establish biotechnology agencies is to help more companies commercialise their products and penetrate the international market. However, when there is no collective action, the efforts are fragmented.

## 5.4 Chapter summary

This chapter aimed to answer the first research question in the thesis regarding the issues faced by the biotechnology players at the national level in enabling the commercialisation activities in Malaysia. The discussion was divided into two sections. The first section provided the reader with the biotechnology background in Malaysia and the later section focused on the issues faced by the biotechnology player in designing and implementing national policy.

In the first section, the roles of government agencies at the national level supporting biotechnology related activities are described. This includes the actors involved with the implementation of the National Biotechnology Policy. This has been translated into the nation's agenda by incorporating the policy into various ministries such as the MOSTI, MOA and Ministry of Higher Education. This commitment to accelerate the R&D&C activities are supported by a large number of agencies operating under ministries, such as the Bioeconomy Corporation, NIBM and ABI. The agencies are responsible for facilitating and providing the necessary support for policy such as the financial and skills required to turn the R&D activities into inventions that can be commercialised.

The description of these agencies shows a very complex structure that is highly fragmented and with significant overlap between different part of government. Agencies are organized on both a sectoral basis of biotechnology and agriculture. around particular resources such as finance and training for the biotechnology community and also in terms of different part of the innovation process which include the research funding, technology transfer, and support for the industry. The centralised command and control culture has further slowed down the commercialisation activities in this sector. This style of government and administration seems unable to facilitate innovation and commercialisation activity of this sector. This section provides background information to help understand the context of in which policy is created and implemented.

The second part of the chapter discussed the issues that exist at the national level in developing the biotechnology sector. From this analysis, the data has shown that the second phase of the NBP is unlikely to meet the target. The interviews demonstrated that there are several key issues that occurred at the national level, resulting in the slow progress of wealth generation through biotechnology commercialisation activity. Three issues are highlighted. They are (i) lack of policy planning, (ii) lack of coordination among the biotechnology-related agencies, and (iii) lack of engagement among the biotechnology players in Malaysia.

In term of policy planning, it is noticed that the institutional structure of the biotechnology agencies is very complex and operated in overly centralised command and control culture. In addition, the lack of data regarding the structure of the sector, the unrealistic timeframe towards its implementation and lack of long-term commitment in pursuing the effort in commercialisation activities has resulted in slow development. In the second factor, it is shown that there is a problem in terms of institutional process and failure of the policy thus causing a lack of coordination among biotechnology-related agencies. In terms of the institutional process, the organizations are unable to bring the element of togetherness among its staff member while pursuing the agency's goals. This is partly due to the poor policy design that failed to recognize the importance of the employees' roles while pursuing the policy. This is due to the top-down governance that has long embedded in Malaysia. For example, the government's decision to corporatize the national agency. The employees refuse to accept the new change because they feel insecure with the changes. In the last factor, it is discovered that the highly bureaucracy practice and the very complex organizational structure has leaded to the lack of engagement among the biotechnology agencies. The analysis suggests that the ties between the ministries and other biotechnology actors are weak. Furthermore, the adoption of this policy and development model had limited the cooperation and interaction between the biotechnology sector with the other agencies and ministries therefore resulting in working in silos culture.

The overall policy set by the Malaysian government along with the creation of high-quality infrastructure and the active role of intermediaries in facilitating and promoting commercialisation activity provide a promising future for the biotechnology industry. However, implementers in the system are unable to manifest the biotechnology policy blueprint into the real setting in Malaysia. The mechanisms used to accelerate the biotechnology sector seem unable to reach its target. This appears to be due to the ineffective policy, lack of effective mechanism used in accelerating innovation and engagement between the government, universities and industry. This highlights the need for a greater focus on ensuring the implementation of policy at a local level and engagement between the agencies. This is where the concept of Triple Helix is useful to understand the issue. The policy is lacking in its formulation, thus, making the implementation of the policy difficult all the way. The bloated bureaucracy and top-down approach practices have made the situation worse as everyone in the government agencies is tied to the institutions culture. Moreover, the agencies at the national level were working in silos and created the competition among them. The situation at the national level showed that the effort to make the biotechnology industry as the third growth engine is scattered. Players at the national level are working towards achieving their own goal and fail to engage the biotechnology sector holistically. In this section, the policy adaptation in the national level is discussed. The next chapter will discuss the roles of policy in supporting commercialisation activities at the university level.

# Chapter 6

# The challenges of translating the national biotechnology policy into local practice

## 6.1 Introduction

In the previous chapter, the roles of agencies in supporting the biotechnology agenda at national level were discussed. Their roles are important to help other stakeholders such as the universities and SMEs to be involved in biotechnology and exploit their knowledge into commercialisation activities. Therefore, this chapter attempt to discuss the roles of universities in supporting the biotechnology agenda specifically in commercialisation activities. The focus of this chapter is to understand and explore the challenges faced by universities in translating the National Biotechnology Policy (NBP) into local practices. One of the aims in the NBP is to commercialise R&D inventions from the university. In Malaysia, from the perspective of the Triple Helix model of innovation, the relationship between the university-industry-government can be categorized as the statist model where the government plays a dominant role in the industry. In order to grow this industry, the universities serve as the knowledge generators that will strengthen this industry. Focusing on the commercialisation activities, this chapter will explore the challenges facing by the academics in pursuing the activities from the lens of Sectoral Systems of Innovation (SSI).

## 6.2 Challenges of commercialisation activities at the university level

In discussing this topic, commercialisation at the universities level refers to academic entrepreneurship, licensing, joint venture, start-up and sale. The respondents range from top management to academic researchers. These include directors of institutes, heads of department, head of the laboratory, deans, professors and senior lecturers. Three major themes emerged from the interview sessions which included: (i) the lack of support mechanism; (ii) lack of motivation in pursuing commercialisation; and (iii) small market for biotechnology businesses.

### 6.2.1 The lack of a support mechanism

A university is composed of many departments to ensure its smooth operation while acting as a hub and knowledge provider in undertaking research activities. In engaging with its new commercialisation role, the university has established the research and commercialisation centre to cater for this activity. The research centre and the commercialisation centre both play crucial roles in supporting both the government's and the university's agenda in generating income. Both centres play different roles but are closely interrelated. However, based on the responses from interviewees, these two units are inadequate to support their development in commercialisation activities. The interviews highlighted a lack of university support and funding constraints as the main obstacles for academics to engage with commercialisation activities.

#### 6.2.1.1 Lack of university support

As part of their third mission to commercialise research and cultivate growth in local economies, universities have been accorded a huge responsibility to carry out this activity. This explained the establishment of the TTO at the university level and various initiatives taken by the government and universities to be involved in commercialisation. Despites these initiatives, the respondents believe that there is still room for improvement. To begin the discussion, R24 provides an example of the responsibilities of academics in tolerating the burden generated through commercialisation activities.

> **R24, Technology Transfer Officer**
> *Sometimes it looks like this commercialisation thing is a burden for the researcher. There is no support* [from the university]*.*

From R24's perspective, the commercialisation responsibilities imposed on academics causes difficulties for them in balancing their respective roles as a lecturer and as a business person. Constrained within the responsibilities of an academic, they are strongly encouraged to engage in commercialisation activities even though the university environment is not ideal for this.

As Malaysian Public Universities are undergoing the process of transformation, efforts from every component of the universities are demanded, especially from the academic staff. In recent years, universities have to compete locally and internationally to achieve high rankings and to fulfil their yearly performance evaluation for the purpose of promotion and appraisal. These ambitions have increased the workload of academic staff and extended their roles from teaching to a myriad of other responsibilities including research, consultation, administrative work and community service (Basarudin, 2016). Such responsibilities are thus causing difficulties for academics to balance their time in order to fulfil the requirements of their job. On top of that, as a RU, the academics are being evaluated on a different track, one that requires them to be involved in commercialisation activities. Although commercialisation is not part of the workload and the KPI's assessment, this component is important to academics for the purpose of promotion and appraisal (Basarudin et al., 2016). Therefore, R24 believes that the support system in terms of work burden is inadequate for academics to carry the dual roles. Another issue arises here, whether these criteria balance overall with the benefits received. In line with this, R19 further exemplified and voiced her feelings regarding commercialisation activities.

> ***R19, Senior Lecturer, Scientist***
> *………… we need to groom the person on how to become a good researcher. So, I think it is the same in this case. You need to identify who is the person that is the best in this area, and you need to continue to monitor them and provide help if the person is stuck in the middle or needs help. Then you monitor the progress. That is why I said we are left alone.*

The quote above regards the disappointment felt by one of the researchers regarding the support given by the university. Here, R19 feels that the university should play a more active role in identifying researchers, especially in the selected area(s) and refine help to develop the researcher's talent. Furthermore, R19 feels that there was no individual support system for academics concerning commercialisation activities. Such a condition suggests that the university is lacking in enhancing human capital development.

From the analysis undertaken through the official websites of the five public RUs, the universities offered many kinds of training for researchers which focus on entrepreneurship, business planning, and the financing of commercialisation activities. However, as complained by R19, universities lack in terms of having a team work support system. Social support system for example has the potential to encourage academic entrepreneurship (Gubbins, Harrington and Hines, 2020). The close ties formed from social support has major impact on how entrepreneurs conceptualise, think and act in the new venture (Learning, 2019). The missing work support system has demotivated academic researchers from engaging in commercialisation activities.

Since the nature of academic researchers is hectic given their traditional role as lecturers, there is no role-model available for them to seek opinion in solving their workload problems. The publicity of entrepreneurial role models is central to facilitating the commercialisation of research. The existence of role models will encourage others to become entrepreneurs

(Philpott *et al.*, 2011). During the interviews it was found that there was no such critical mass in the cases investigated. The universities seem to overlook or neglect the need for individual support which could also cause the academic researcher to feel over-burdened in continuing their commercialisation efforts. From the sectoral system of innovation point of view, one of the important components in the system is knowledge and technology. Clearly, the academics possessed these criteria, however, from the interview it seemed that the knowledge and technology alone is unable to drive the academics into commercialisation activity. At this juncture, it can be seen that there is a distinct gap concerning the researchers' capabilities given that the aim of the university is to generate income resulting from commercialisation activities. As perceived by R20, academics lack this capacity to perform dual roles as both academics and entrepreneurs.

Even though the government has encouraged academics to be involved in commercialisation, this has been difficult to achieve given the conflict in fulfilling their primary roles. As in 2014, there was still no official guidelines regarding academics who wish to become involved in commercialisation. Furthermore, the annual performance evaluation often values research more than commercialisation activities. Aside from the academics' roles to support commercialisation, non-academic staff, such as the technology transfer officer, also influence the university in progressing these activities.

> **R20, Professor, Head of Department, Scientist**
> *However, the main challenge regards the researchers themselves as they are untrained. Although, even if they were trained, they still have other commitments like teaching, research, and administrative duties like myself to contend with. So, in this respect, commercialisation activities are a new field for us.*

In this quote, R20 highlights the issue of time management faced by academics in representing themselves as academics and entrepreneurs. As discussed in the previous section, the process of commercialising products is complex, and with limited time to focus on this activity, it is difficult for academics to remain motivated. Thus, R20 reveals that the academic staff are still unfamiliar with commercialisation and what to expect from this activity.

Discussing the example given by R20 further, she admitted that many of the researchers struggled with commercialisation activities since they did not have a background in business, including knowledge and experience in the process of applying for intellectual property (IP), or in ‘pitching’ ideas and locating a good business partner. The lack of these skills could also demotivate researchers’ inspiration and willingness towards commercialisation given their limited experience and exposure in this field and time to commit to each process. This situation occurred due to lack of university communication with staff. Therefore, improved communication can be considered an important practice in order to give a positive feeling for the lecturers when they going through the change process (Hedman and Valo, 2015). Aside from that, the number of staff in the TTO also affected the overall operation of the office in helping academics to pursue commercialisation.

> **R11, Professor, Director, Start-up Company Owner**
> *So, we have that infrastructure; therefore, the industry has the confidence to come to sit with us. Secondly, you must have enough staff whether it is research officers, or supporting staff for multidisciplinary areas and also business-minded oriented people.*

As mentioned by R11, there are a range of resources offered by the university to attract industry collaboration. Besides the facilities available in the university, high-quality researchers and committed staff also ease the process of expanding commercialisation activities, especially when it comes to joint ventures or collaborating with a third party.

When dealing with industry, the university must consider the need for fast results, and as such, the university must keep pace with the demands of industry. Moreover, the TTO must hire a sufficient number of staff with a business mindset. R11 further added that the staff in the TTO must operate and work based on the deadlines given by industry. As such, this means that they need to work beyond normal office hours. That is why R11 believes that having a sufficiently skilled and experienced number of staff in the TTO is important to ensure the function of the office and that its operation runs smoothly.  The result is similar to that fund by Munari, Sobrero & Toschi (2016), implying that programme managers and technology transfer officers are very important to build connections and engage researchers with different actors in the local ecosystems, such as companies, investors, public authorities and other supporting institutions.  This point is reinforced by R13 who also believes that the number of staff in the TTO is important in helping her to manage commercialisation activities.

> **R12, Professor, Director**
> *I don't have permanent staff. The rest are on contract. The permanent* [post] *is only my office boy, my driver and myself. I hold billions of dollars (ringgit) in me because I am the patented technology office. I think I should have one accountant, a lawyer, one office manager at least, and a business development manager. And I should have permanent administrative staff too. A permanent staff member keeping my data, my IP and I should have my permanent legal officer and permanent accountant too.*

R13 mentions the importance of having permanent staff members to assist the function and operation of the TTO. A professor and director of the TTO, R13 needs assistance from legal and accounting aspects when dealing with commercialisation activities. An administrative assistant helps R13 in making sure that all procedures involved in this process are systematic, organised and easily retrievable at any stage. Therefore, R13 believes they need to have a legal officer, accountant and an administrative assistant. The absence of these three posts would invariably delay the overall process of commercialisation, especially involving IP applications and during the collaboration stage. The lack of staff affected the performance of commercialisation activities in the university.

Moreover, the above quote describes the various roles and types of employment in the TTO. As the director of the TTO, R13 believes that certain posts in the office should be employed as permanent staff. This is because the process of hiring and recruiting staff can be difficult, in addition to the cost of training staff to become competent experts in their respective fields, which is both time-consuming and expensive. For those staff hired on a contractual basis, it could pose problems when they decide to leave the office or when their contract is terminated for whatever reason. In this situation, the senior technology transfer officer would need to train and orientate new staff. Hence, this would incur additional costs along with more time and effort. In addition, the operation of the office would also become less efficient until the new staff could adapt. This is also supported by previous research where limited entrepreneurial skills could discourage academics from filing for patents (Ranga et al., 2016). However, regarding this situation, it is unfair to say that there is no support from the university. According to the respondent below, there is support for those academics who wish to be involved in commercialisation activities.

> **R16, Professor, Head of Department, Scientist**
> *I try to get them the research grant. The local grants and international grants, I got them to do collaboration work, and our recent activity towards commercialisation is that we are going to launch the UPM Steinbeis Networking Centre.*

At the faculty level, R16 as the head of the department, fully encourages academics to obtain the research grant to pursue their R&D activities, especially if it involves the pre-commercialisation stage and commercialisation. R16 would encourage them to apply for the right research grant and would try her best to assist them in obtaining funding. R16 is also quite flexible with academic researchers, by granting approval for them to collaborate with other parties in order to obtain grants. According to R16, the latest initiative undertaken by the university was the launching of the UPM Steinbeis Networking Centre.

The Steinbeis Malaysia Foundation is a non-profit organisation established through an initiative of the AIM. The Steinbeis Malaysia Foundation applies the German method of collaboration in engaging both academia and industry. The foundation aims to increase collaboration with respect to outsourcing the innovation to industry, thereby increasing the productivity of companies (Malaysian Innovation Agency, 2015). As of February 2016, four public RU have collaborated with the Steinbeis Malaysia Foundation. Aside from the Steinbeis initiative, R17 also mentioned that the university had collaborated internationally to refine academic researcher’s skills regarding the ‘pitching’ process.

> **R16, Professor, Dean, Scientist**
> *They also trained our lecturers to do the pitching. So, some of our lecturers had already received training on pitching for the product with, you know, under PSP we had a collaboration with Stanford Research Institute International* [SRI International]. *We want to look at that as well. They pitch you on NABC; Need, Affordability, Business and Commercialisation.*

The quote mentioned above regards the collaboration undertaken with international institutions in providing researchers with the knowledge they need to obtain about business and commercialisation. At this point, collaboration with international institutions demonstrates that the university provides suitable training for academics to become involved in commercialisation. Similarly, R20 also mentioned that Putra University Malaysia (UPM) has collaborated with international consultants.

***R20, Professor, Head of Department, Scientist***
*They gave us training, and they even engaged a group of consultants from the* [United] *States to the* University of Putra Malaysia*. So, they are people from Silicon Valley; they will come to us every once or twice a year. And now we also have consultants in UPM.*

As mentioned by R20, UPM also collaborates with international consultants to improve the skills of researchers who participate in commercialisation activities. Furthermore, the university has its own internal consultants in UPM to assist researchers. Compared to international consultants, having local level consultants enables researchers to seek solutions at any time. Besides the grants and the consultation offered by local and international organisations, the university also offers a platform for researchers to introduce their products to different stakeholders and potential users via university organised exhibitions. As one of the top administrations in UPM, R16 mentioned that the university organises an 'Invention, Research and Innovation Exhibition' or Pameran Rekacipta, Penyelidikan dan Inovasi (PRPI) to expose researchers to industry.

**R16, Professor, Head of Department, Scientist**
*Once they got it patented, they can get involved in a competition called the PRPI competition. It is a science competition where you show your invention. So, people will come and look at your invention. Once you get the patent, the PSP or UPM Holdings, they will try to commercialise abroad.*

The above quote concerns the commercialisation platform offered by the university for researchers to seek collaborators. The event was initiated in 2014 and is held once every two years. The initiative receives participation from 400 researchers, and the winner of the competition is able to achieve a place in national and international exhibitions (Innovation and Technology Managers Association, 2014). The event exposes researchers to a competitive environment where they gain experience before entering other exhibitions such as 'The International Conference and Exposition on Inventions' initiated by the Institute of Higher

Learning (PECIPTA) or the ‘Malaysia International Invention and Innovation & Technology Exhibition’ (ITEX), to name a few events at the national level. This is in addition to exhibitions held in Pittsburgh, Geneva, the United Kingdom (UK), Korea, and Germany at the international level (Utusan Malaysia, 2012).

For example, in UPM, once the university finds willing parties for a particular invention, the next step is to involve the Putra Science Park or UPM Holdings to elevate the invention or innovation to a higher level. Another example is from the University of Technology Malaysia. Here, the university organises an exhibition, the ‘Industrial Art & Technology Exhibition (INATEX), where the event aims to promote the research findings or products. Both exhibitions act as a platform for university researchers to build a network within industry and commercialise their research results (University of Technology Malaysia, 2016).

Aside from the platform offered to researchers, the university also provides researchers with advice and a programme that matches the researchers with graduates under the Simbiosis Program under MTDC to run the start-up company. Most of the time, the TTO at the university level is responsible for offering support to researchers. In some instances, heads of the department will also play a part by engaging their staff with industry. Through previous experience, R17 often received direct inquiries from potential industry collaborators regarding the solutions provided by the university. From there, R16 would help the inquirer to match the problem with the expertise in the faculty. This is similar to the experience of R14.

**R13, Professor, Head of Department, Scientist**
*Normally we will have a meeting with the industry people, the university and the researcher, and from there, we will see whether there will be a link or compatibility between them. We will try to help both the researcher in that we can capture the opportunity because the industry has already shown interest, so we will try to help the researcher as much as possible. Although it starts with a small project, eventually, when they start working, this is where the relationship starts.*

From R13's experience, the collaboration is often initiated with a meeting between the university and the industry seeking solutions. Through this meeting, the industry team explains the challenges they are facing, and the university will propose possible solutions. The relationship between these two parties will expand later once both (the researcher and the industry team) build trust with one another. Before the collaboration meeting occurs, the TTO will advise the researcher on the agreement between the researcher, university, and industry.

According to the quote above, it can be clearly seen that the university helps the academic(s) to form collaborations with industry. R13 further added that in the process of collaboration, the TTO plays an important role to ensure compatibility between both parties. This includes ensuring that the agreement is equitable and both parties benefit from the arrangement.

**Subsection Summary:**

In this section, the discussion surrounding the support given by the university is presented. According to R24, R19, R20, R11, R12, R16 and R13 they believed that the environment within the university needs to improve in order to attract academics to become involved in commercialisation activities. The limited support afforded by the university relates to the workload of academics, lack of entrepreneurial skills and human resource planning, especially in the TTO. However, in contrast, other respondents mentioned that the university had given its best endeavours to assist academic researchers in furthering their involvement in commercialisation activities. This included running a series of workshops to strengthen entrepreneurial skills amongst academics, opportunities in collaborations and exposure to the industry. At this point, it can be said that the universities have tried to accommodate the needs of the academics involved in commercialisation. Although the universities have provided various training on aspects of commercialisation they often failed to communicate the changes that will take place along with this new role. Therefore, this missing link would explain why not many academics have become interested to join commercialisation activities. Given the support available by the universities and the knowledge possessed by academics, the commercialisation activities require more facilitation as commercialisation activities involve tacit knowledge.

However, there are certain conditions under which the universities are unable to make decisions as they fell under government discretion. This included academics' work burdens, yearly performance evaluation and staff recruitment. This is due to the top-down culture practiced in Malaysia and the universities partial autonomy power. Therefore, such conditions revealed that the university has no full autonomy when it comes to the above-mentioned matters. This is because the scope of work, yearly performance evaluation and staff recruitment are under the purview of the Public Service Department, Malaysia (Public Service Department, 2020). Changing such a condition would require a major revamp at the national level. Aside from lack or limited support of the university, financial aspects also contributed to the slow progress of commercialisation activities. This is discussed in the following section.

#### 6.2.1.2 Lack of financial support

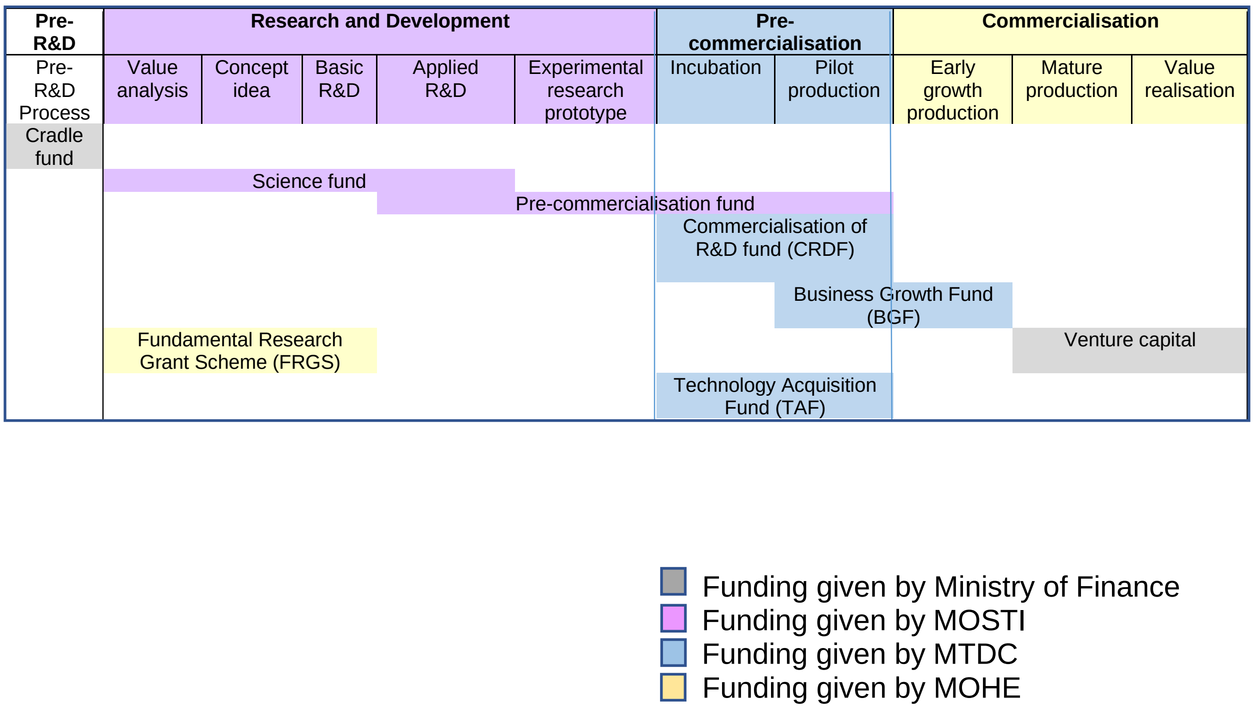
Apart from the support provided by the government and the university, financial support is important to ensure that commercialisation activities function smoothly across all levels of the university. With adequate financial funding, commercialisation activities would show significant improvement (Rahman Ahmad, Farley and Kim Soon, 2014). With enough funding, universities are able to support its day-to-day research operation which includes the cost for hiring professionals and skilled researcher; to obtain up-to-date materials and the cost of purchasing and maintaining the appropriate equipment to be used to conduct the research activities Aziz, Harris & Norhashim, (2011). However, the funding gap problem is prevalent in young, technology-oriented start-up enterprises. As a result of the funding gaps, companies with growth potential are not able to obtain the necessary capital for their operation; (Pasumarti and Pattnaik, 2020). Despite government funding, the start-ups companies often face difficulties in obtaining funding resources from financial institutions. To begin with, a quote from R13 is presented as an example. According to R13's experience, there is a lack of venture capital that is available to invest in agri-biotechnology related research in the university.

> **R12, Professor, Director, Scientist**
> *Sometimes I don't see the sustained funding, and I don't see the risk capital coming in. Even when they get the early funding – Precom, Technofund, or Cradle, to get the risk funding which is the follow-on funding from the bank, even from the venture capital, I did not see it. You can see the statistics. All the big capital for agriculture is not spent. They just keep it in the bank. Agrobank? SME Bank? They don't seem to dare to give up the money because they cannot guarantee the returns in the five years of their fund.*

The quote above reflects the allocation of funding to the agriculture sector. According to R12, financial support in biotechnology is unsustainable. Even though funding is allocated during the early stage of R&D, there is no continuity in the later stages of commercialisation.

Through document analysis, it is discovered that the government do provide various of fundings to support commercialisation in later stage of commercialisation, however the number of grants is limited with high competition. That explained why the financial support in R&D&C activities are difficult to obtain. Below diagram represent types of funding available in R&D&C stages.

**Diagram 6.1: Stages of R&D&C activities**




Source: Economic Planning Unit, 2013

The above diagram shows the stages of R&D&C and the involvement of the key stakeholders. Academia involves during the early stage of the whole process where they provide the knowledge to be exploited. During this early stage, funding is provided by the government and this in the pre-R&D, R&D and Pre-commercialisation. The next step requires venture capital however, none was found during the research. Due to this, the government once again had to step in through its subsidiary to invest during the later commercialisation stage. The whole process reflects a very linear model of innovation and in part explains, the huge number of different agencies established in Malaysia with each contributing to a specific stage or aspect of innovation.

As mentioned by Pasumarti and Pattnaik (2020), funding gaps evolve in the case of start-up companies as a result of their special characteristics. During the seed and early stages of their lives, these companies are in the phase of product development or they have just made their market entry. Start-up enterprises face problems in attaining bank loans due to a lack of collateral or guarantees. Start-ups enterprises also have to go through lot of paper work which is time consuming. In many cases, due to lack of financial support such as discontinuation of grants would often lead to failure or the discontinuation of the project (Bannò and Allura, 2020). As such, there were cases where academic entrepreneurs were resorting to injecting their own money into the company. One of the respondents who had experience of this was R21. According to R21, his partner needed to use his own capital to bring the product to the market.

> **R21, Associate Professor**
> *I don't think the university has the facilities. We are talking about manufacturing facilities, the Bottling plant. So, what we did was, we came out with the capital and built our own.*

The above quote depicts the difficulties of R21 while expanding the business. Trapped in upscaling activities, R21 discovered that the university lacked the facility that the company needed to manufacture its R&D product. As such, he believed that the company must not depend on the government or university in acquiring financial support to solve the problem. In R21's experience, he believed that the university is unable to cater for the needs of entrepreneurs.

The ability to raise enough financing appears to be one of the most common problem faced by owners of SMEs. As for the start-up companies, they experience difficulties in accessing financial support during the expansion stages such as incubation, pilot plant, early growth production, mature production and value realisation (NBP, 2005). Most often, researchers face difficulties in progressing to the commercialisation stage given limited venture capital, poor financing for start-ups and new ventures, difficulties in accessing funds at the expansion phase especially through equity arrangements, soft loans and expansion funds (Govindaraju, 2010).

This situation clearly represents the point highlighted by R13 previously, that there are only a few banks related to agriculture and specific banks for the development of SMEs. Here, these banks have a special division for SMEs to apply for loans. However, in most cases, the bank is reluctant to approve the loan application especially when it comes to financing research equipment. Furthermore, the incomplete accounting record might be difficult for the SMEs to obtain loans (Salikin, Wahab and Muhammad, 2014). Most often, the bank and VC are concerned about the high-risk profiles of the start-ups, and the costs and risks involved. This includes investment in the equipment where it depreciates quickly and even more when the equipment is shared with several other parties. Typically, fund providers prefer one-to-one deals that clearly stipulate who is responsible, who benefits from the facilities and who carries the risks. Moreover, the products invented in the university mostly do not exceeds the technological readiness level needed by the industry. Due to that, investors are reluctant to invest or joint partnership with the start-up company (Munari, Sobrero and Toschi, 2016). In term of grant application, the process often takes time and there is no guarantee of success. Additionally, the grant provider requires an extensive research plan as this is one of the criteria evaluated in the grant application (Hulsink and Scholten, 2017).

In order to obtain financial support from the government, for example through the pre-commercialisation grant provided by MOSTI, researchers need to demonstrate the sustainability, relevance and feasibility of the project proposal. The research conducted by the applicant must briefly demonstrate that the R&D project is unique, has commercial value, value for money, has great project management and, further, how the project will provide impact to the social, economic and environment in Malaysia (MESTECC, 2019). Failure in meeting the criteria would cause the application to be rejected. Furthermore, the company manager often believed that it is difficult to bring the shareholders together in between investment rounds to discuss the division of shares. It simply takes too much time, which means it is not a viable alternative, and the same applies to banks (Hulsink and Scholten, 2017). Such conditions would delay the operation of the company, thus leading the manager to invest in their own company rather than seeking support from the fund provider.

Despite the reliance on public grants such as those offered by MOSTI and the use of personal funding, academics could attempt to collaborate with industry as a way of funding their research. For example, through a joint venture arrangement or through a collaborative project. As suggested by R13, he believed that the academic researcher needs to gain the collaborator's trust in order to become actively involved in joint activities.

> **R13, Professor, Head of Department**
> *So, when they work together and build trust between them, they will ask the researcher to run this particular project. This is what we are doing actually. It is very important to build trust, if not, it will be difficult to get the money/funding. Once they know how you work, how they can get the results and only then they are willing to invest the money.*

The above statement reveals that trust is an important element in determining and progressing the collaborative activity between the university and industry. As such, to gain this level of trust, academics need to show the quality he/she has in managing the research project. By doing that, there will be a chance that the industry people will collaborate with the same academics again. At this point, R13 suggested that the academics should become more proactive and become the technology champion.

Trust between the industry player and the university was determined by the partner's reputation and leadership behaviour in emerging countries such as the South Korea (Hemmert, Bstieler and Okamuro, 2014). Accordingly, establishing the trust of the industry player or partner may reduce collaborative barriers (Bruneel, D'Este and Salter, 2010). In addition, keeping key stakeholders interested in the project is important so that the firm will continue to provide ongoing financial support, help in overcoming obstacles and persuading opponents to cease resistance. These champions facilitate the connection, communication, and coordination between internal managers and the scientist or researcher of both parties in establishing mutual trust (Hemmert, Bstieler and Okamuro, 2014). Therefore, it is important for the researchers to become the 'technology champion' in their field in order to attract the investor. At this point, it can be seen that due to the lack of qualities being displayed by the academics, the investor could not notice them and was thus reluctant to engage in collaboration with them. This apparent mistrust of investing in research spin-offs among large companies hinges on their preference for taking over more reputable firms. Most research start-ups, seem risky and unstable ventures, a perception that deters such groups from investing in them. From the business perspective, the potential investors also fear that the researchers and university personnel who launched the start-up will resist and reject their plans, due to expectation, time frames and insurmountable differences in culture (Yagüe-Perales and March-Chordà, 2012). This will later be explained in chapter 7. Due to lack of communication, it can be seen that both parties are unable to come at the agreed solution in funding the project.

**Subsection summary**

In this subsection, the issue regarding financial support was discussed. It was discovered that public financial support remained limited in Malaysia, especially in the pre-commercialisation stage and beyond. There are two reasons that could possibly explain such a condition. First of all, the investors were unaware of the technologies developed by the academics. This could be due to insufficient platforms to connect these two players, and maybe the academics were less skilled in promoting themselves. Second, many of the investors were concerned about the ownership of the investment since there was no strict guideline determining who should own the technology. Furthermore, the investors were concerned about the risks they would face in financing the new start-up company. Due to these factors, new start-ups have difficulties in gaining financial support for the development of their products.  At this point, it can be seen that financial support is very limited, involve rigid procedures and research conducted in the university is often unable to attract the investors due to inventions are still at embryonic stage.

#### 6.2.1.3 Conclusion

This discussion highlights the weaknesses of support mechanism for academics in pursuing commercialisation activities.  From the evidence presented above, it can be said that the mechanisms used in encouraging commercialisation activities in the universities were partly not effective. This included the limited support by the university regarding the academics' workloads, lack of entrepreneurial skills and insufficient skilled officers in the TTO and the insufficinet financial resources needed by the academics involved in commercialisation activities. In the university setting, it was demonstrated that the academic researchers not only needed support in terms of entrepreneurial skills but also to compensate for their heavy workload. Indeed, commercialisation activities were not the only criteria evaluated in the yearly performance of academic researchers, and as such, there should be a different evaluation track for those who are involved in commercialisation activities. Although there is encouragement in terms of training to enhance commercialisation skills, the universities failed to recognise the staffing issues of the researchers such as the new responsibilities for academic staff. The above conditions suggest that structural constraints existing in the RU. This is evident from the so-called partial autonomy given to the university, where funding and managing the universities lie with the respective State governments and the central government provides overall guidelines and policy direction. Therefore, although the universities acknowledge the flaws in its systems, nothing could be done without State and Central government approval.

In terms of financial supports, one of the most significant factors to emerge from this study is that, capital is the most critical financial component in running the R&D and commercialisation activities. External financing will keep the R&D activities growing and accommodate its expansion. it was discovered that most of fund providers were reluctant to invest in the start-up companies due to associated risks such as the slow return on investment, ownership, and risks related to its newness. The issue of bureaucracy also affected this, and as a consequence, a high level of collaboration between industry and universities seems a long way off. The difficulties in obtaining financial support would discourages academics in pursuing their start-ups.

### 6.2.2 Lack of motivation in pursuing commercialisation activities

The preceding section explored the mechanisms used to support the commercialisation activities in the five RUs. The results showed that support from the university and financial support are both important in enabling the product from the laboratory level to be translated to the business level. The human factors in this section refer to the academic researchers in the university and the technology transfer officers who deal with the commercialisation activities. In this subsection, a discussion regarding human factors is further explained. From the interviews, the respondents mentioned that motivation affected commercialisation activities which includes the lack of internal and external drive to engage in commercialisation activities. Entrepreneurial activities are driven by the internal capability of the academic scientist and external resources such as the university environment (Kroll, 2009). Therefore, the next section will discuss how internal drive influences academics to become entrepreneurs.

#### 6.2.2.1 Internal drive

Previous researchers such as Guo, Restubog, Cui, & Zhou (2019) found that motivation was one of the most significant drivers for researchers to become involved in commercialisation activities. Motivation is key since it connects both the scanning and decision-making process of the individual and conveys relevant meaning to the results of the scanning process. In their engagement with business, academics may become motivated, resulting from the personal benefits or the benefits of other stakeholders which range from pecuniary to a variety of non-pecuniary grants. Intrinsic motivation represents a self-determined behaviour prompted by an individual’s willingness and genuine desire which results in intangible outcomes (Antonioli et al., 2016).

> **R13, Professor, Head of Department, Scientist**
> *I don’t know how to comment on the entrepreneurial university. We are the researchers. Entrepreneurship is not in our blood. We are not businessmen.*

The above quote suggests that R13 was having difficulties in adapting to the entrepreneurial roles expected of the profession. According to R13, the university is encouraged to generate its own income and to engage with the concept of an entrepreneurial university, therefore they were required to involved in commercialisation activities. The quote suggests that the researcher lacked any interest in becoming an entrepreneur.

From the statement of R13, by engaging with RU status, academic researchers are highly encouraging to exploit their R&D. According to Lam (2011), academic scientists involve in R&D activities either to achieve ‘gold’ (financial rewards), ‘ribbon’ (career rewards) or to solve the ‘puzzle, (intrinsic satisfactory) (Lam, 2011). Most of the academic scientists prefer to choose ‘puzzle’ and it is the challenge for the university to encourage them to exploit the R&D for financial reward. As found by Galán-Muros *et al.*, (2017). confirming that academics need to see the personal benefit of their engagement to do so. Therefore, incentives offered to the academic should be attractive enough to attract them in commercialisation activity.

> **R13, Professor, Head of Department, Scientist**
> *To be a businessman, you must be an opportunist. Researchers are not opportunist as they will do the work until they are 100% sure and only then will they say okay it is time, but by that time, the researcher would probably be too old to start a business.*

R13 claims that most often, academics often wanted the research to be as complete as possible before being made into a product which means that the project takes too much time. The academics were not ‘business-minded’ –the main responsibilities of academics were to teach, supervise, and engage in research activities, which are the traditional roles of the university Mohd Yusof (2013). Furthermore, the permanent position they have with a fixed monthly salary created no pressure for them to become opportunists.

. Academic researchers must, often need to validate their findings to ensure that the research is of high quality and are required to perform several tests within the stage known as pre-commercialisation. In this stage, the proposed solution needs to be tested in the actual field to ensure its effectiveness. However, this process requires considerable time and funding to progress from the prototype to the pilot stage. According to Miller, Cunningham and Albats (2017), the academic researcher's ability to recognise commercial opportunities is due to their efforts in developing or acquiring market-related knowledge. An opportunistic academic researcher should be able to provide a quick solution for industry players before seeking a more detailed and permanent solution to the problem.

To become entrepreneurial, the researcher must have the ability to anticipate what the possible trends or problems are that could emerge over the next decade. By acquiring such anticipation or preparedness, the researcher could conduct research, and by the time the industry faces the problem, the researcher might then be in a position to offer a unique solution. Another internal skill that is lacking in academic researchers is profit-oriented thinking. Since the process of attaining the R&D product for commercialisation is difficult, expensive and prolonged, the academic researcher needs to impose a suitable price for the product that is worthy of the required investment at all stages. However, respondents were reluctant to impose a high price item as illustrated next.

> **R19, Senior Lecturer, Scientist**
> *Actually, there are so many people who have the problems as I have. If you meet the academic researchers, it is normally like that. For example, in selling the product, there is one professor who cannot sell the product. If someone says my product is expensive, then I will sell it at a lower price. But business people are different. They say, 'business is business'. Every little cent counts. You put lots of money in there, of course, you cannot sell cheap. Like me, I just cannot sell, I will mark down the price further.*

> **R19, Senior Lecturer, Scientist**
> *I am telling you; I am not business-minded and I am not a money-oriented person. If you talk about the money, the revenue, of*

> *course, all people want to become rich, but for me, I don't have that feeling.*

According to R19, entrepreneurship is a very challenging activity, and one that conflicts with the principle of being an academic. However, profit is not the main priority when R19 is conducting research.

Coincidently involved in a collaboration with traditional practitioners to seek the medicinal compound in a plant, R19 agreed to collaborate as this research could bring credentials to the academic and enhance their careers. To this scientist, knowledge application through involvement in commercial ventures exhibits a kind of puzzle-solving activity that satisfies their 'intellectual curiosity' (Lam, 2011). However, among all these respondents, R20 believed that she had the trait of a businessperson.

> **R20, Professor, Head of Department, Scientist**
> *Maybe I am sort of an entrepreneur. I like the challenge, but I didn't realise that it is so tough. It's so tough because you are still a lecturer. I'm a full-time researcher, and I have students, administrators and also the head of the department and on top of that, it's another key performance indicator.*

The above quote represents R20's desire to be involved in business while working in the academic field. Respondent R20 enjoyed her current career as she is able to manage her time efficiently to combine research and entrepreneurship. She has been successfully involved in business and at the same time is committed to her main job as an academic.

The above statement also indicates that not all academics lack entrepreneurial skills and are openly willing to be involved in business. Respondent R20 was also conscious that she needed to abide by all the rules and regulations set by the university. Moreover, R20 was advantaged by having an assistant to help her run the business as she believed it was almost impossible to manage the business while being committed to her responsibilities as an academic leader.

Additionally, all RUs have to establish a set of KPI's that all academics must adhere to. However, the criteria may be different from one university to another depending on the national environment, the type of institution and field. Thus, integration of the third mission of the university, including entrepreneurial activities or the commercialisation activities, might be shaped by different conditions and organisational contexts (Galán-Muros et al., 2017).

Interestingly, the decision to become an entrepreneurial academic could be related to personality theory where people have a strong need to achieve and to control their own destiny. Having such a personality drives them to seek business opportunities and to challenge themselves to take on risk in order to achieve their business goals. Their personal qualities include determination, ambition, responsibility, being proactive, flexible, able to tolerate ambiguity, and self-confidence (Bridge, O'Neill & Cromie, 2003). Academic researchers were most likely to join a commercialisation activity when they possessed entrepreneurial leadership (Pane & Dileep, 2015). However, there are also those academics involved in commercialisation due to the need to obtain funding. In their desperation to test their research idea, some academics decide to pursue commercial activities mainly to obtain the much needed funding for research in an increasingly resource constrained environment (Lam, 2011).

From the above explanation, R20 believes that she has the quality to become an entrepreneurial researcher. Regarding the quality of entrepreneurs mentioned by Pane and Kumar (2015), R20 had a high internal locus of control and strong internal motivation to bring the product to the market place. Also, R20 had a good support system surrounding her, which enabled the product to be commercialised. As the head of a department and professor, she had a secretary who assisted her in managing her workload, both as an academic and as an entrepreneur. In contrast, the other respondents did not hold an administrative position and consequently had difficulties in balancing their roles as an academic and entrepreneur.

**Subsection summary**

In this section, it was revealed that internal motivation could affect the researcher's decision to be involved in commercialisation activities. Academics often lacked internal drive when it came to commercialisation activities. This included a lack of entrepreneurship thinking, not being opportunistic nor profit-oriented and having difficulties in adapting to the dual role of being entrepreneurial academics. However, for those who were successfully involved in commercialisation, this was because they had good support systems considering the position they held at that moment.

At this point, it can be seen that the traditional roles of the university strongly limited these academic researchers to be involved in commercialisation. One reason that could possibly explain the lack of internal drive was due to the unseen personal benefits this activity will bring them. Commercialisation activities often demanded more effort and time from academics and the reward for such work was often inadequate. Therefore, the RU should provide favorable conditions that are able to attract academic scientists to conduct R&D until commercialisation stage. The most significant observation of this subsection is although academics are expert in R&D activities, this knowledge alone cannot promise the successful result of commercialisation activity. This is because, in pursuing the business activity, the academics need to have some sort of business thinking. What is important is to convince the academics that commercialisation is also part of R&D activity and that it should not be only about knowledge discovery but also the transfer of this to industry Apart from the internal drive, external resources also influenced academic researchers' involvement in commercialisation activities. These are discussed in more detail in the following subsection.

#### 6.2.2.2 External resources

The previous subsection explained about internal resources. This subsection will explain how external resources could influence the researcher's motivation to exploit their research. Most of the researchers admitted that they lacked the internal drive to explore commercialisation activities further. R20 believes that the university is pressured by the government to generate income to cover its expenditure. Hence, the university must be in a position to utilise external resources for R&D activities to progress to the commercialisation stage.

> **R19, Senior Lecturer, Scientist**
> *I think the university realises the problem so what the university did was it encouraged the researchers to come out with spin-off companies or a start-up company. But the problem is we are not business people. So, in many cases, it stopped there.*

Involved in commercialisation activities, R19 realises that there is a tension between being an academic and a businessperson. As they need to keep up their traditional roles of academics, the commercialisation activities just add additional responsibilities to be shouldered. As the universities are encouraging their staff to get involved in this activity, they overlook the competence of their staff.

Notwithstanding, based on this observation, even though there is a system to support the commercialisation activity in the university, the researchers rarely committed themselves to this as they need to achieve a high score for their KPI at the year-end. Furthermore, academics often do not disclose their invention as they are unwilling to risk delaying publication in the patent and licensing process (Thursby & Thursby, 2015). Compared to the commercialisation activity, the evaluation of the KPI is seen to be more critical in fulfilling their career. As mentioned in the preceding section, commercialisation activities consume a significant amount of time and effort, and in many ways, the process is unpredictable. At this point, the support system to cater for the dual roles seems to be missing. The performance evaluation for the academics is the same whether or not he or she is involved in commercialisation. Academics who pursue commercialisation should be evaluated through different a career path since the output of their research is different.

According to R19, academic scientists are unable to run the business on their own merits given their limited business expertise. He further adds that, instead of the lack of business exposure, the experience in setting up the start-up companies also affected this activity. Thus, the universities have adapted the Symbiosis-MTDC business model to compliment the inadequacies of the academic's skill set. This was further elaborated by R14 below.

> **R13, Professor, Head of Department, Scientist**
> *They* [the academics] *joined the company full time but not to run the business but to work on the technical part of the product. The operation of the company is run by someone else, somebody who knows how to run a business. Academics don't know how to run a business. We are very poor at that.*

Working as the head of department, R13 agrees that it is almost impossible for academics to run or operate a business while retaining their role as an academic. Such a condition will create conflicts between the roles. Business models such as the MTDC-Symbiosis program encourage the academic researcher to form a company with graduates under the program. The graduates under the MTDC-Symbiosis program have undergone various training programs to prepare them to become excellent company managers to run university start-ups (University of Technology Malaysia, 2020). The details of the MTDC-Symbiosis program can be found in the appendix. Upon agreeing with this, R10 believes that most academic entrepreneurs do not have experience in conducting business.

> **R9, Professor, Top Administrator, Scientist**
> *Well, most people who have a start-up company do not have much experience. They are normally the academics and do not have the exposure and so on. So, the journey is quite hard, and the success rate is not too good, but a few are successful.*

As mentioned by R9, most academics lack business experience. This could be their first time founding a company and, due to this, many of them are stranded in the 'valley of death' stage of the commercialisation activities. However, in some cases, the R&D activities turned out to form the basis for successful university start-ups companies.

As academics move from an academic to a business environment, the nature of their job scope increases, as well as their network. By committing themselves to commercialisation and involvement in start-ups, they act as a bridge to connect the private and academic sector, thus making their network more complex. In such complex arenas, the academics needs certain competencies for the start-up to grow (Rasmussen et al., 2011). Intangible knowledge such as having experience in start-up companies could become advantageous in the evaluation of entrepreneurial opportunities (Shane, 2000; Wright et al., 2007). However, as told by R10, academics typically lack this quality and many of them are therefore unable to sustain the survival of the company.

Previous research found that business managers with previous experience in setting up a company are likely to perform better compared to those who do not. Thus, this tacit knowledge could help firms to plan their growth and overcome the critical stages in the start-up process (Vohora et al., 2004). In realising this issue, universities have established a TTO to assist academics in excelling in their business role. The TTO also acts as a consultancy for academics who intend to exploit their products into something that can be commercialised. However, the findings from (Clarysse, Tartari and Salter, 2011) found that the TTO plays only a marginal and indirect role in driving the academics to further set up start-up companies.

As argued above, experience in business is tacit knowledge and can only be gained by actual experience. Therefore, the TTO plays less visible roles in this aspect. However, the TTO could help academics to find a credible company manager for the start-up company. This is further pointed out by R21.

> **R20, Professor, Head of Department, Scientist**
> *Initially, I don't have any idea. I'm still learning. We are not like the young generation of today who learn an entrepreneurial subject. We are not exposed to entrepreneurship, so through this program, I just learned how to do this*.

The above quote explains the difficulties of engaging in entrepreneurship activities. R20 further adds that, due to a lack of entrepreneurship experience, she found that commercialisation activity is really challenging. However, under the Symbiosis-MTDC program, R20 could learn about entrepreneurship from her company manager. Realising her lack of entrepreneurship experience, R20 revealed that during undergraduate and postgraduate studies previously, there was no exposure towards entrepreneurship. Such a condition suggests the business education is important in building an entrepreneurial culture.

As a result, the academics rarely exploited their research. They often overlooked the potential of their research to be commercialised. Previously, university curricula focused on the course itself rather than on entrepreneurship. Indeed, universities have poor business orientation and focus on preparing the students for jobs rather than for self-employment (Sharma, 2016). The design of formal education in the past has discouraged entrepreneurship as it is designed for conventional careers and thus has the effect of reducing rather than increasing creativity and entrepreneurialism. Therefore, it can be said that entrepreneurship education is arguably one of the most critical step for embedding an entrepreneurial culture in the university (Philpott *et al.*, 2011).

The Symbiosis programme has showed that teamwork between the academic and the company manager seems workable since the academic possesses strong research experience which could help them to translate the complex ideas into understandable forms that are easier to convince the heterogeneous audiences (Maurer, 2001; Shane & Stuart, 2002), which contributes to the development of more innovative firm offerings (Sullivan & Marvel, 2011). These company managers are either chosen from the 'Symbiosis-MTDC' program or suggested by the academic researcher. The company managers from the 'Symbiosis-MTDC' program are equipped with the necessary entrepreneurial skills as they will run the business with the academic researcher. The matching program has helped many academic researchers to set up their start-up companies.

This coincides with the importance of an innovating competency to recognise and exploit opportunities that start-ups need when they move from the academic arena into a commercial environment (Rasmussen et al., 2011). However, these skills cannot be learnt overnight. Realising that academics have difficulty in adapting to these new roles and the deficiency of their business skills, the universities decided to increase the level of external support for them in terms of training and facilitation.

**Subsection summary**

This section focused on the external factors that influenced academics to participate in commercialisation activities. The discussion revealed that external support was important to boost academics' motivation to engage in commercialisation activities. Engaged with the roles of research university and commercialisation, this change has forced the university to quickly adopt the new role as an entrepreneurial organisation. The approach used to encourage the academics, however, appeared insufficient to keep them motivated to get further involved in commercialisation activities. This included work burnout, insufficient business training and insufficient exposure of business opportunities. Further, the current mechanism to evaluate the yearly performance of academics' entrepreneurs seems inappropriate given the new task they have to perform. Another interesting point found in this subsection was the lack of a strong entrepreneurial culture in the university. Although the Symbiosis-MTDC program is looked as the bridge to connect the missing link in university commercialisation, the finding in this subsection suggested that university entrepreneurial culture is still fragile. It seems like the university governance unable to fulfil the needs of the academics in this new relationship showing the loosely coordinated interrelationship between them. Thus, more time is needed to prepare the university in providing effective external support to groom academics to become business players.

### 6.2.2.3 Conclusion

This subsection explained the drive towards commercialisation activities in universities. With the arrival of the knowledge-based economy, the role of the university as a knowledge provider has rapidly emerged. In achieving the aim of engaging in entrepreneurship, many factors need to be considered such as internal drivers and external resources. The failure to address the insufficient internal and external resources had led many academics to feel impotent to accept this new responsibility. They found it very difficult to fit themselves in the hybrid role of both an academic and entrepreneur (Würmseher, 2017). Highlighting the issue of structural problems and low entrepreneurial culture in the universities, the discussion above demonstrated that the universities are still bound by their traditional roles and stuck in structural constraints. Although granted with their own autonomy, the Higher Education Institutions in Malaysia rely heavily on bureaucratic practices and as a consequence, universities find it difficult to strive to become entrepreneurial organisations.

The discussion also revealed that full autonomy is important in delivering effective policy. This phenomenon can be simply interpreted, based on the theory of Sectoral System of Innovation and Triple Helix. A sectoral system undergoes processes of transformation and change through the coevolution of its various elements. This includes the individual and organizations at different levels of aggregation with specific learning process. They interact through process of communication, cooperation, exchange knowledge, competition and command. These acts and interactions among them are shaped by the institutions (Malerba, 2002; Tian,2009). Therefore, at this point it can be seen that the dynamism of commercialisation activities that occurred in university is influenced by the interaction process highlighted in the SSI. With limited external support and low internal drive of commercialisation, this has become the barriers for the academics to further explore the knowledge they produce. From the perspective of Triple Helix, this barrier has restricted the RU to closely collaborate with government and industry. The next subsection will discuss the readiness level of the country and products while pursuing commercialisation activities.

### 6.2.3 Small markets for biotechnology businesses

In this subsection, the readiness level of commercialisation activity is discussed. This refers to the readiness of the products and the country’s readiness to adapt and leverage agrobiotechnology commercialisation. The first part of this subsection focuses on the country's readiness, and the subsequent part will discuss the motivation to commercialise the product.

### 6.2.3.1 Readiness of the country

Developing all sectors of the bioeconomy in concert will provide global food security, improve nutrition and public health, make industrial processing cleaner and more efficient and make a significant contribution to the effort to mitigate climate change. For maximum benefit, the various sectors of the bioeconomy must be properly linked, since they are all interdependent. Concerted action will not only create strong individual sectors, but strong and effective links are needed to create a bioeconomy web. This inter-connectedness means that all sectors must be equally strong; one weak link could significantly reduce the overall effectiveness of the web and limit competitiveness (Lokko et al., 2018). However, as demonstrated by most of the respondents in this chapter, although the government tries to link all the biotechnology players, not all of the elements of biotechnology are at the greatest strength. Such a condition suggests that the country is still developing in this area. One of the main issues of is the employment that this area could offer.

> **R9, Professor, Top Administrator, Scientist**
> *First, I think the biotech industry is a little bit, it is still in its infancy. Not widespread yet and that is why people who graduate from biotechnology found it hard to get employed. I knew this because two or three years back I went to the United States, Rochester Institute of Technology, and in biotech alone, we had about 80 Malaysian degree students and most of them telling me that when they return to Malaysia, they don't get any employment. Many of them have to work in a different sector, and they seek my advice and what they should work in. So, it is still a growing industry.*

The quote above underscores the developing state of the biotechnology industry in Malaysia. According to R9, there are limited opportunities for Malaysians in this industry, especially for students in obtaining employment in the biotechnology sector. This can possibly be associated with Malaysia as a latecomer in the biotechnology field. As such, there are many aspects that Malaysia needs to invest in.

Any country that actively develops this high-growth sector in their jurisdiction will be sure to profit heavily in taxes and job creation. However, there are challenges unique to this sector as entry is complex and costly. As demonstrated by the successful commercialisation of biotechnology in Daedok Valley, apart from sufficient funds and strategic partnership, human capital is important to develop this sector. There are multiple skills and attributes that contribute to employment opportunities in the Malaysian biotechnology industry. The personal qualities needed for employment in this sector relate to risk taking, initiatives, purposeful analysis of information, environment scanning and a willingness to self-teach (Aziz and Rowland, 2018). In particular, scientists with know-how skills are essential for the start-ups as it needs access to good technology and associated patents in order to produce revenue (Malazgirt, 2011), and thus support economic development. The limited opportunities for employment in this sector could be partly due to immaturity and small size of the industry.

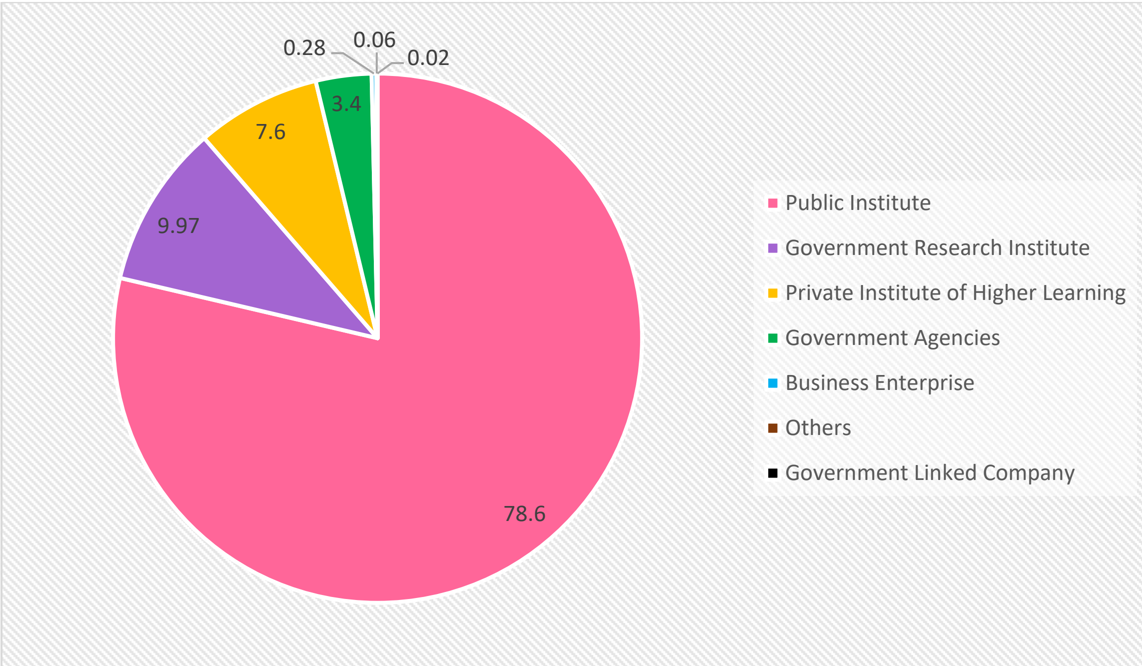
Universities as knowledge generation centers could provide useful, work-relevant entrepreneurship training in their biotechnology and science programs and explicitly train students in how to start their own businesses. However, universities prepare students for employment and due to this the students see themselves as entrepreneurs within the context of their employment. At this point, the importance of having entrepreneurial education in the university and the content of the entrepreneurial education can be seen. Both elements are important whereby the university could prepare credible entrepreneurial employees and, at the same time, the students should remain open regarding the possibilities to starting their own biotechnology companies. Aligned with R10's view, R17, a professor in the RU, also agrees that the country is still developing, albeit gradually. This is true when R17 says that the biotechnology community in Malaysia is still small.

> **R16, Professor, Head of department, Scientist**
> *Biotech is a small community of scientists, so we all have each other. Everybody knows everyone. So, the same people will go to the same events and so on because we are a small community.*

The quote above reveals that the biotechnology community in Malaysia is not growing as anticipated. This is reflected through R16's experience in having met the same person when attending a biotechnology event held by MOSTI. As demonstrated by R16, the small biotechnology community could be due to a lack of opportunities to enter commercialisation activities.

With the limited entrepreneurship culture embedded among the graduates and academics as discussed above, the number of biotechnology companies remain small. From the data gathered at the Malaysian Science and Technology Information Centre (MASTIC), the largest players of commercialised products/technology are typically from the public institutions of higher learning, government research institutes, private institutes of higher learning and government agencies. These are the players that have commercialisation potential under MASTIC (Mastic, 2019).

**Diagram 6.2: Percentage of product/technology based on the category of organisation**




Source: Mastic (2019)

As shown in Figure 6.1, it is evident that public institution currently has the biggest number of R&D invention in Malaysia. The statistics, as presented in the diagram above, reveal the participation of the biotechnology players involved in commercialisation activity. The data is read as follows: the largest participation in commercialisation activities originates from the public institutes of higher learning followed by government institutes, private institutes of higher learning and government agencies, with 3,554, 451, 344 and 154 product/technology organisations, respectively (Mastic, 2009).

In more advanced biotechnology countries such as the US, the biotechnology sector is driven by the private sector where there are also more venture capital opportunities available and angel investors willing to invest and accept the risks in commercialising research conducted by higher learning institutes. Contrary to this, in Malaysia there are a limited number of venture capital opportunities and virtually no angel investors willing to invest in research conducted at the university level. The only available venture capital is Khazanah National Berhad, the sovereign wealth fund of Malaysia. This agency aims to invests in businesses that have the potential to generate sustainable returns (Khazanah, 2019). At this point, it can be said that apart from entrepreneurial culture, financial support also influences the creation of start-up companies. The lack of financial support could restrict company creation as this sector is complex and costly. Therefore, this explains why the public institutes of higher learning dominate commercialisation activities as they have various types of financial income to support this activity. Apart from the R&D financial budget allocated from the government to them, the universities also have pools of human capital working on R&D that have the potential to be exploited. Despite this advantage, not all of the RUs evidence excellence in agro-biotechnology commercialisation. For example, the industry appears to choose the UPM or public research institute. This point is further raised by R16 below.

> **R15, Professor, Director, Scientist**
> *The industry may not come to the University of Malaya because they are probably thinking of UPM, MARDI or other agencies depending on their problem.* [In Malaysia] *because there are already institutions like MARDI, Malaysia Cocoa Board, FRIM* [Forest Research Institute Malaysia]*, MPOB and others. Those would tend to be the places people will go to. So, there is a lot of competition for the industry in agriculture.*

The quote above outlines the preference of the industry towards biotechnology-based solutions in Malaysia. As an academician, R15 observes that the university needs to compete with other universities and public research institutes to gain collaboration. Most often, industry prefers to go to the public research institutes to seek consultation compared to the RUs. This is due to the complex bureaucracy practiced by the universities.

In the field of agriculture, the UPM is one of the pioneering universities in this area. Starting as the School of Agriculture in 1931 and gaining university status in 1973, this university is one of the leading universities in agriculture research in Malaysia. UPM has bagged numerous national and international awards since its inception in 1931 (Universiti Putra Malaysia, 2020). Furthermore, considering its experience in agriculture, more star scientists have ended up working in this university. These star workers may disproportionately benefit from better matching with industry because they have a larger pool of potential distant collaborators to choose from (Jaffe and Jones, 2015). Due to this, the industry tends to favour this university compared to the other research universities considering its achievement in agriculture research.

Such a condition has resulted in less collaboration opportunities available to the other RUs. Apart from UPM, the other research universities are also facing competition from the public research institutes.  The industry sometimes prefers to choose government research institute due to less bureaucracy practices. The government research institutes can place greater focus on collaboration and knowledge exchange because they do not have to teach and lecture compared to the academic scientists which have limited time for collaboration. There are also possibilities that the inventions created in the university fail to match the problems faced by the industry.

> **R9, Professor, Top Administrator, Scientist**
> *First, the industry is still small – the biotech industry, secondly, we did research which does not meet the industry's needs and thirdly we did not publicise our findings to the industry so that they can take the products.*

The quote further accentuates the problem faced by the university in finding a purchaser for its inventions. Two issues are identified in the above statement. The first is that the research conducted at the university level is not in demand and, second, there is a lack of suitable platforms to introduce the product to industry.

Regarding outdated research, it was found that the R&D products invented by the universities in Malaysia were not completely ready to enter the market. This could be due to the products being too scientific, and thus not applicable to the industry; in other words, the research was for academic purposes only and there was no uniqueness in the product (Ali et al., 2017). Furthermore, the weak university-industry orientation also affected the collaboration between these two parties.

In realising and acknowledging this problem, the universities initiated a 'road tour' by inviting potential industry partners to attend the roadshow. Here, industry players are able to express their interest and views in knowing more about different products. Aside from the road tours, the government has also organised roadshows at the national level to encourage universities and firms to exchange knowledge and ideas. This has included the Bioeconomy Conference, My Commercialisation Year events and the BioMalaysia event. These are held annually with the BioEconomy Corporation as the main organiser together with MOSTI. In addition, there is a special university-industrial division in the BioEconomy Corporation that focuses specifically on the relationship between these two parties.

A further reason to explain the low number of takers from industry may be due to the difficulties and challenges associated with collaborating. Among the challenges are the bureaucracy practices and the nature of the academicians who often seek for perfection, thus taking more time. As in business settings, their focus is on profit, thus demanding all processes and results should be produced faster and on time.

In the universities practices, the process of creating the collaboration agreement takes time given the Standard Operation Procedures (SOPs) that both parties need to adhere to in conducting the research. Additionally, as an academic, the R&D activities conducted in the university also need to follow certain procedures before reaching the pre-commercialisation stage. Here, the results produced are slower compared to industry practice. Moreover, the career development system practiced during the period seems unable to support commercialisation activities among academics. As such, R16 further elaborates on this issue regarding the responsibilities that academics need to adhere to.

> **R15, Professor, Director, Scientist**
> *I suppose the academic, the main focus tends to be teaching and research, commercialisation is generally seen as second or third activities, so it's always going to be a challenge because in this university the main focus now is publication. People may not be focused on the intellectual property aspect but more on research value.*

The quote above highlights the university's focus in executing its roles and functions. R15 believes that for academics, teaching and research remain their top priorities. This is evidenced by the yearly performance evaluation where teaching, research and publication activities carry the highest marks and ranking. Therefore, this shows that performance evaluation is biased against collaboration with industry. The following respondent concurs with this. According to R20, commercialisation consumed more time and did not bring significant marks towards the academic's yearly performance review.

> **R20, Professor, Head of Department, Scientist**
> *I don't think so. As the commercialisation requires more time, more energy, more of everything, and most of the people are not doing commercialisation. Only a few wants to be involved with entrepreneurship. And the KPI is obviously not there.*

R20 also agrees with R15's point of view regarding the performance evaluation of academics. According to R20, the academics were not motivated or inspired to be involved in entrepreneurship because they needed to meet the KPI, which, sadly, did not award high marks for entrepreneurship. This is also aligned with the findings of R24 in section 6.2.1.1 and R19 in section 6.2.2.2 The discussion in each section explains why researchers are not overly keen on engaging in commercialisation activities, despite all the support on offer to them.

**Subsection summary**

In this subsection, the discussion was focused on the readiness level of the country to embrace biotechnology. From the analysis undertaken, it was discovered that country was not ready to speed up the development of a national biotechnology industry. The building blocks of the biotechnology players seemed fragile and were not operating at the maximum dynamic sufficient to enable a successful biotechnology industry. Issues of limited employment opportunities, a small biotechnology community, outdated research, bureaucracy and an unsuitable career development system demonstrated that the country needs a better system to improve the situation. At this point, the conditions showed that the country suffered systemic problem in supporting this sector, starting with the foundation of entrepreneurship in the country. This can be achieved through effective communication between academics, industrial players, investors and government. From here, the researcher will have a better understanding on the industrial needs and tailor their R&D activities accordingly. This includes improving the funding system, system of career development, entrepreneurship education and reducing bureaucratic practices. Due to this, more time is needed for reform. This is because the university, industry and government are still in a phase of adjusting their roles whilst engaging with the biotechnology sector. Apart from the country readiness to commercialisation activity, the readiness level of the technology also plays an important part in determining the pace of commercialisation. The next section will explore this in detail.

#### 6.2.3.2 Readiness to commercialise

As previously discussed, some inventors decided not to commercialise due to workload commitments (Franco and Haase, 2015) and other due to the ownership issue (Hunter, 2015), research is in embryonic stage (Ali et al., 2017). Related to the embryonic stage of research, R12 explained the differences between the consumer-ready and novel innovative product. According to her, the inventions created in the university are instead, a novel innovative product.

> **R12, Professor, Director, Scientist**
> *There's a big difference. Commercial-ready means it is ready for the industry to take and develop into a product. Consumer-ready means it is ready to be sold to the consumers. Generally, I think 90% of our technology is not consumer-ready. They are commercial-ready.*

The above quote is related to the definition of "product readiness". Based on R12's experience, there is a difference in the definitions of novel innovative ready product and consumer-ready in commercialisation activity. As the director of the TTO at the university, R12 agreed that the products of research conducted in the university were mostly novel innovative product. Also, from her observation, more firms are interested in buying the consumer-ready invention compared to the novel innovative product.

The quote above highlighted the 'technology readiness level' of the research produced in the universities. Most of the university research is in the embryonic stage and could not reach the marketplace (Wonglimpiyarat, 2016). In the past many of the university research works were so embryonic with insufficient proof-of-concept and typically, they will require an extensive development before they are ready to be introduced to the market. However, due to insufficient financial support and the reluctance of the industry to provide monetary assistance, the universities are unable to upgrade the internal products from lab scale to the up-scaling level

In revisiting the guideline of grants application by MOSTI, the ministry has allocated two types of grants that specially designed for research that in level 4 of Technological Readiness Level. The Smart Challenge Fund (SMART Fund) is the government's initiatives which is open to businesses and researchers interested in competing for funding opportunities for which the Government has identified the strategic and prioritised needs (new technologies, processes, products) with the expectation that the deliverables will solve national problems and identify long term solutions. Through this scheme, the Government will be investing in pre-commercialisation of technologies, processes, products that are highly innovative which can be translated into marketable output to spur the economy as well as for societal benefit. Technology Readiness Levels is a method of characterising technological maturity from the most basic research (TRL 1) through to full-scale-real-world operation (TRL 9). The SMART Fund covers from TRL4 to TRL6 (MOSTI, 2018).

Such conditions explained that regardless of whether the R&D invention reached the novel innovative product or the consumer-ready invention stage, how the invention will reach the market is more important. As there is often a lack of common communication language between R&D institutions and industry about the level of preparedness of a research project, it leads to a barrier in technology diffusion. Innovation Readiness Level (IRL) can be utilised to measure research and development results in universities or research institute as well as industry.

At this point, the respondents highlighted that it is easier to access the consumer market compared to the industrial market. Consequently, industry purchaser could further enhance the technology in accordance with market demand. Referring to the Pre-Commercialisation grant offered by MOSTI, it is already stated in the eligibility criteria of the commercialisation funds that the research undertaken using these grant should reach the up-scaling of the laboratory prototype or in its commercial-ready prototype (MOSTI, 2016). Having the same though as R12, R13 also agreed that the industry prefers to buy the license of inventions ready to reach the consumer. Accordingly, this can be related to the risk-taking practice of the investor.

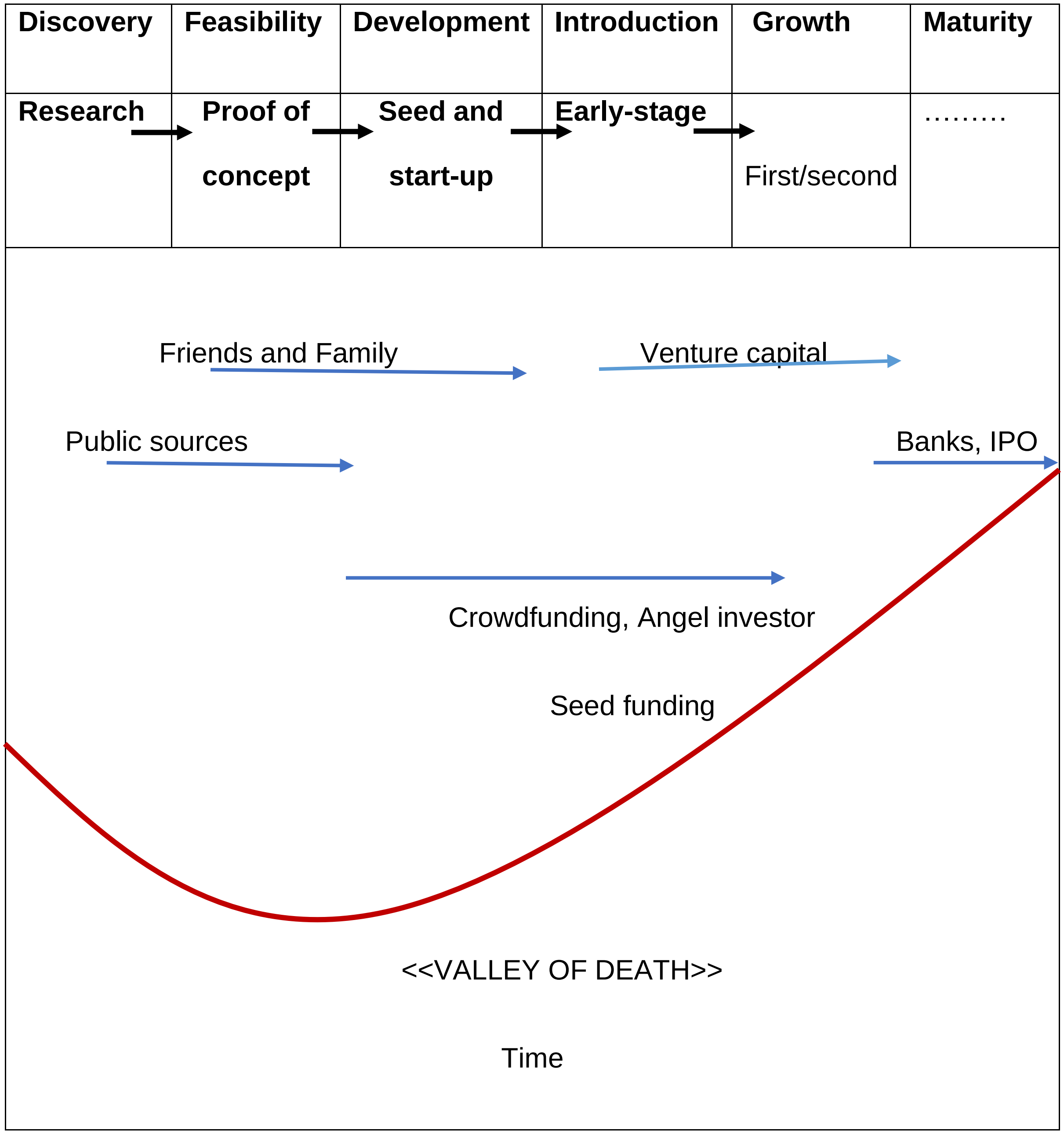
> **R13, Professor, Head of Department, Scientist**
> *But the problem sometimes is that the industry wants the ready product. They don't want to get involved in R&D. There are fewer risk-takers among the industry people. They would like to have a ready product. Like I said before, they just want to do the marketing job. There is very little industry that wants to invest in R&D. The angel investor is not a common practice. Usually, the industry will come to the university to do some work pertaining to their product so it can be marketed, and this also expands the market for their product.*

Aligned with R12, R13 also agreed that the industry preferred the 'consumer-ready product'. By taking the ready product, firms do not need to inject money during the R&D phase. According to R13's experience, the licensee prefers to perform marketing instead of being involved in risk-related activities. Risk-taking is frequently used to describe entrepreneurship and the extent to which managers are willing to make large and risky resource commitments (Swierczek & Ha, 2003). The action involves taking bold action by venturing into the unknown, committing significant resources to a venture in an uncertain environment and may involve borrowing significant capital in pursuing the business. Likewise, the risk-taking activity is also uncertain since it has a reasonable chance of expensive failure. Therefore, such actions explain why many investors are reluctant to invest in start-up companies.

In the context of Malaysia, fewer companies wish to be involved in R&D activities such as joint venturing or acting as a business angels. This preference is mainly due to the low risk-taking culture among companies and investors, thereby resulting in many university products remaining on the shelf. In order for a new start-up company to grow, financial capital such as from an angel investor or venture capitalist are important. Access to finance can be associated with the capability of young and innovative enterprises to seek and obtain the most suitable sources of finance that are applicable to their stage of development.

New ventures, by their very nature, do not have access to the same financial resources as larger or more mature firms. Indeed, for new companies operating in knowledge-based and high-tech sectors, a series of barriers dealing with high uncertainty levels, presence of information asymmetries and lack of successful track records or warranties, limit the ability to obtain funding from traditional sources. Typically, university-based technologies and start-ups are characterised by uncertainty and informational gaps, making it extremely difficult for external investors to evaluate the business potential or monitor the entrepreneurs after investments are made (Munari & Toschi, 2019). The presence of these obstacles and market deficiencies has prompted numerous universities, frequently in conjunction with public and private entities, to initiate specialised initiatives that provide financial aid and support to bolster the investment preparedness of university-based startups and technologies. This, in turn, facilitates their capacity to secure external funding (Munari and Toschi, 2019). Diagram 6.2 shown below depicts the different types of investors during the lifecycle of a new venture.

**Diagram 6.3: Start-up company lifecycle**




Source: Adaptation from (Munari and Toschi, 2019)

The figure shown above presents a different type of investor during the early stage of commercialisation until the maturation stage. In the earlier stage or the embryonic phase, financial funding from public sources is available. In the design phase, it has not yet been incorporated as the project is just a patented idea or invention. Here, the entrepreneurs usually seek financial support from their own personal funds, family and other funding sources if they failed to obtain public funding. Later, in the seed or start-up stage, crowdfunding, angel investors and seed funding are the most appropriate funding sources. Usually, in this initial stage, business angels will play a significant role together with public grants. This phase is also known as the 'Valley of Death', where there are fewer takers who are willing to accept the risk in investing in the project undertaken at the university level. This is the hardest funding stage and many companies fail.

Accordingly, the main reason behind the difficulties in accessing external risk capital can be associated with the risk factors. Many traditional investors prefer to finance later-stage companies compared to early-stage companies. This is due to the start-up companies often associated with high transaction costs, high information asymmetries, high ongoing running costs and lack of exit options. Another reason contributing to lack of investment were due to lack of investment readiness by these companies like a limited understanding of equity instruments, lack of business and commercial competences and experience, poor communication skills, poor quality of businesses and reluctance to cede control. Furthermore, by collaborating with the university, investors are committing to share the risk associated with the project. The process occasionally will take more time than the expected period. This fact was further highlighted and agreed on by R18.

> **R17, Professor, Dean, Scientist**
> Moreover, another thing that we understand is that it is difficult to sell the high-technology product within one or two years. If you sell Tongkat Ali (Eurycoma Longifolia), you can expect that it can be sold by today, but if you do the drug design? It might take years. If a big company, they will spend millions of ringgit to do this. So, the question is, are we willing to spend that much? To invest? And the second question is, are we willing to wait? It is not that simple. But I do agree that we must have the target to go towards that direction.

Here, R17 exemplifies the difficulties in selling the university's R&D product. According to R17, before the product is ready to be marketed, it needs to undergo several processes in order to validate its chemical compounds. This process could take more than a year since it requires several laboratory tests.

According to R18, the production of biotechnology products demanded sophisticated and high-technology processes and is quite time-consuming since it involves many research stages that need significant financial support to conduct the experiments. As such, making it difficult to sell the product in the market within the anticipated time frame. As discussed in Chapter 4 (refer p. 28), the time required for commercialisation may take anything up to eight years to finish the project. The collaborator, who is the profit-oriented company wants to have a quick turn-around or return on investment from the collaboration. Accordingly, this has caused tensions to rise between the goal of the investor and the time needed for the product to reach the market.

**Subsection summary**

In this subchapter, the readiness of the biotechnology product is discussed. Based on the fieldwork and analysis of public documents, it can be concluded that the product invented in the university are still immature. The condition proposes that the market for immature product is still small in Malaysia.  Taking into account that the country is still developing, most of the businesses in Malaysia prefer to buy the consumer-ready product as they could avoid the risk associating with IP ownership, failure during the development phase and long waiting periods during the product development. Without the investment from the industry, the universities are unable to develop the product to fit the current market. Such conditions revealed that there is a missing mechanism in encouraging the industry to invest in the R&D project until it reaches its ‘consumer-ready’ stage. The condition suggests that the ties between heterogenous actors in biotechnology industry are relatively weak.

#### 6.2.3.3 Conclusion

In this subsection, discussion regarding the readiness level of the country and product readiness towards commercialisation activity was discussed. From the analysis undertaken, it can be seen that the government’s initiatives in shaping the biotechnology industry in Malaysia have proven unable to drive the country to its desirable result. It was found that the ecosystem in the country, and in the universities specifically, was unsuitable for the rapid development of biotechnology. The education system, the incentives for company creation, top-down culture and university yearly performance evaluation appeared to insufficiently support knowledge transfer and inovation. In terms of product readiness, the industry tended to favour the consumer ready product, due to the nature of many Malaysian companies that are largely involved in trading activities. Furthermore, the industry was reluctant to become involved in R&D development phases as this involved longer times and was costly. In the larger picture, it was seen that the strategies used at the local level were not able to achieve the aim stipulated in the NBP to spur biotechnology development in Malaysia.

## 6.3 Chapter summary

This aim of this chapter was to identify and explain how the national policy was adapted at the local level. The discussion was focused on the challenges in commercialising university inventions resulting from R&D activities. Here, three key factors, the support mechanism, motivation in pursuing commercialisation and small market of biotechnology business were identified as the main hurdles in commercialising products in the university.

Regarding the support mechanism, two factors were believed to be the main challenges for academic entrepreneurs to commercialise their inventions, due to: (i) lack of university support; and (ii) lack of financial support. In the university setting, it was found that the environment in the university was not ideal for commercialisation activities to expand, evidenced by the weak entrepreneurial foundation, biased performance evaluation and failed human resource planning. University governance seemed to fulfil the aim given by government but failed in providing sufficient attention to the human capital aspect in the university.

Concerning financial support, it was revealed that academic entrepreneurs were overly reliant on public funding as their source of financial support. Furthermore, the workload burden and dual responsibilities as academic entrepreneurs restricted the academics in looking for potential collaborators to invest in the research. Along with this, the incentives offered by the government were incapable to attract investors, thus demonstrating that the incentives were not attractive enough for the industry to accept the challenge.  At this point, it can be seen that the academics are suffering excessive workload and at the same time the system designed to help them with commercialisation is not really functioning.  This is due to the bureaucratic practices and partial autonomy held in universities.  Aligned with this, the limited financial providers and reluctant to invest in university start-up companies has caused difficulties for the researchers to continue to develop their inventions to the next stage.  In most cases, the project will fail or be kept on the shelf.  Due to this, the academics are unable to carry their research into the commercialisation stage.

Regarding the human factor, internal drivers and external resources were considered to be the main reasons for gradual commercialisation activities. Regarding the internal factor, it was felt that academic entrepreneurs lacked internal inspiration and motivation; they were unable to position themselves as both as an academic and entrepreneur. This was due to the lack of support given regarding their workload, incentives and business training, thus making the responsibilities brought about by the dual roles very difficult and complex.

With respect to the external factor, the academic researchers lacked training regarding business knowledge and having resources to expand their research, such as facilities for up-scaling activities or a pilot plant. In addition to this, the weak entrepreneurial foundation in the education system also contributed to the awareness of commercialisation of biotechnology research. This resulted from the new changes occurring at the national level whereby the government decided to place biotechnology as the new growth engine for the national economy. The decision indirectly forced the university to adapt by conducting research until it reached the commercialisation phase. The new responsibilities caused the ineffective planning of mechanisms to support the academic entrepreneurs in commercialisation activities. This demonstrates that the researchers and university governance are disconnected whereby the university is unable to provide the condition suitable for them to pursue commercialisation.

The third factor identified is the small and immature biotechnology market in the country. At the national level, it was found that the biotechnology ecosystem in Malaysia is still fragile and promoting the rapid development of biotechnology in this sector is difficult. This was evidenced by the slow growth in the creation of the companies in this sector, the excessive top-down culture and administration, and the biased performance evaluation process for academics. Such conditions demonstrated that the government, industry and university are still in a phase of adjusting their respective roles in accelerating biotechnology development in the relevant institutions. Regarding the readiness to commercialise, it was revealed that there was limited demand from industry to take up university R&D products. Moreover, industry appeared to be more interested in consumer-ready products compared to novel innovative products. This situation reflected the low risk-taking culture embedded amongst investors and potential industrial developers. In addition to that, the time frame needed for product development was also lengthy, which could cause a slow turn-around and return on the investment. This was due to the nature of Malaysia, namely that the country is heavily involved in trading activities rather than developing innovative products. Moreover, there was no encouragement such as incentives offered to the companies who were willing to invest in university R&D activities.

Overall, it can be said that the governance of the university was complex regarding commercialisation activities. The universities remain lacking in providing resources and systems such as facilities, training, workload and evaluation processes to the academic entrepreneurs. Improvements in these areas would increase the internal motivation of the academic entrepreneurs to be further engaged in this activity. Concurrent with this, intervention from the government is much needed to improve the mechanisms used in attracting the industry to invest in university products.

These observations explain the lack of commercialisation activities in the RU. The analysis showed that the institutions played a big part in shaping the university governance in pursuing commercialisation activities. The actors are bound by the institutions and it is difficult to challenge the current bureaucracy practices held in the university. This also explained why autonomy is still subject to debate when it comes to university governance. In terms of actors and networking, the discussion in this section referred to the non-market interaction which is between the researchers and the university governance. At this point, it can be seen that the university overlook on the aspect of support mechanism such as the workload burden, individual supports and lack of clarity in explaining the changes that will take place in pursuing commercialisation. The failure of effective communication has resulted the academics unmotivated to involve more in these activities. Along with this, the relationship among the university and financial provider also weak as the firms are reluctant to take risk in financing the R&D. However, in this analysis, the knowledge alone is not enough to excel in commercialisation. It must be equipped with tacit knowledge too. Although the National Biotechnology Policy aimed to see the commercialisation from the university, this cannot be easily achieved taking into account the systemic challenges exist in the universities.

In this chapter, the process of translating the NBP into the university setting was discussed. It is anticipated that this chapter will bring about a greater level of understanding and appreciation on how this policy affects the university environment in pursuing commercialisation activities. In the next chapter, the discussion regarding the biotechnology industry is undertaken. Chapter 7 will complete and achieve the main aim of this thesis, which is to explore how national policy and local practices support the knowledge transfer and commercialisation of biotechnology in Malaysia.

# Chapter 7

# The Challenges facing SMEs in accelerating biotechnology commercialisation

## 7.1 Introduction

In the previous chapter, the roles of research university in supporting the biotechnology agenda at national level were discussed. This includes the challenges the academics faced during pursuing the commercialisation activity. Therefore, this chapter attempt to discuss the challenges faced by the company managers who have collaborated with the academic scientists. This chapter determines company managers' views on the effect of implementing the National Biotechnology Policy (NBP) and university local policies and practices on commercialisation activities.

The chapter also aims to answer the third research question on how the implementation of the NBP along with the university policy affected the commercialisation activities among the university start-up and non-university start-up companies. This chapter comprises three sections. Section 7.2 concerning the challenges faced by the companies involved in farming activities and Section 7.3, companies that are related to non-farming activities. In Section 7.4, the summary of the whole chapter is presented.

## 7.2 Findings from agro-biotechnology company managers related to farming activities

In this section, the view of company managers regarding agro-biotechnology in farming is analysed and discussed to further understand the role of the NBP in supporting commercialisation among the SMEs. Hence, this research identified four main factors affecting the commercialisation activity among managers of farming companies:

i) Financial Constraints;

ii) The Infant Biotechnology Industry;

iii) Insufficient Government Support;

iv) Lack of University Support.

### 7.2.1 Financial constraints

Generally, finance plays a key role in supporting the development of biotechnology commercialisation activities. There are various governmental and private agencies in Malaysia that provide grants to aid research and development until it reaches the Commercialisation stage. Nevertheless, it is crucial to note that all of the grants and loans provided differ according to the stage of the research as discussed in Chapter 6 (refer to diagram 6.1, pg.61) However, the rate of commercialisation of university products is still low (Ali Hassan, 2012). In Chapter 6, the limited financial support caused the discontinuation of R&D, but in this chapter, the lack of this factor caused difficulties in upscaling activities. In line with this, the following sections set out the views shared by respondents regarding the notion that limited financial assistance is one of the reasons that dampens the commercialisation process in Malaysia.

> **R37, Operation Manager**
> Money is the first barrier. It needs to be 10 times bigger than the actual money invested in the research stage. It is the most critical. The first reason is that the technology is new. So, we need the MTDC, SME Corp., and Peneraju to help these small companies. In some cases, the companies are not entitled to apply for a grant since they cannot fulfil the required criteria. For example, in my case, I need to wait for the sample [from the university] and this takes more than a year.

According to the response given by R37, who owns a prawn farming company, the procedures involved in applying for a grant are strict and do not support the whole sector. This case is evident from the process R37 had to go through before he could apply for a pre-commercialisation grant. In the application process, he had to provide complete data about his project including samples tested in fieldwork.

As a company manager, R37 is aware that a great sum of money is required in order to expand his business to reach the Commercialisation stage. He is also aware that, apart from his own capital, he could also apply for the MTDC commercialisation grant. In this case, R37 described his experience by stating that, more often than not, small companies are unable to apply for the relevant government grant due to unmet requirements such as insufficient paid-up capital. For example, to apply for a Smart Challenge Fund, the applicants must have a minimum paid-up capital of RM10,000 (US$2,400) (MOSTI, 2018). Moreover, the limited number of venture capitalists and angel investors has caused research activities to grow slowly because most of these research activities have to rely on government grants.

In terms of applying for a public grant, it has been shown here that the applicant must provide accurate and sufficient data. The application form requires the applicant to show the project technology, as well as its commercial potential, financial impact, and how the project impacts social, economic, and environmental aspects in Malaysia..

As for the limited collaboration with venture capitalists and angel investors, these investors are more likely to support more experienced start-up companies Virick (2015). Furthermore, venture capitalists and other investors prefer investing in serial entrepreneurs who have more start-up experience. The VC is often attracted to a company which is also patent-active. When a company is patent-active, it indicates that it has strong innovation potential. Besides that, R&D expenditures and R&D staff levels such as the CEO's education level are also both strong predictors of VC investment. Venture capitalists often invest in larger firms compared to smaller ones because the very small firms are typically more opaque. In addition to the above, VCs also typically avoid tapping into start-up companies that have a long product development time (Lahr & Mina, 2016). These reasons explain why start-up companies often head into 'the valley of death' or are unable to survive in the market.

> **R31, Operation Manager**
> *So, UPM provides the technology and MTDC provides the funds. If I don't have the funds, how am I going to buy the expensive machines and others? So, the tricky part is to set up the company. But once we start, it will become much easier. The difficult part is to get the money. Because of this programme, we can run the business and can produce the products. Although it takes time, it is okay. We can produce the product. Since our project involves financial support from MTDC and UPM, the product development took about six months. But, if we did it ourselves, it could have been done in a month. In this case, two entities were involved, so it took us longer.*

R31 believes that a lot of money is needed to set up a biotechnology-based company. This includes obtaining financial support to run and manufacture the product. Although R31 managed to obtain a grant from MTDC, the procedures involved before the money is released to the company took quite some time. R31 further added, the slow procedures caused a delay in setting up the company and buying equipment to speed-up the product manufacturing time. Furthermore, collaboration with the university also slowed down the process of forming the company. Nevertheless, R31 is grateful to the MTDC Symbiosis programme (initiated by MTDC) because it successfully helped him to start-up the company.

Although R31 is also grateful for the financial support, the time involved to obtain the grant meant that the company had to find another source of financial assistance. Moreover, the effect of insufficient financial support also hindered the company from buying more powerful equipment to fulfil the demand from users. According to R31, the demand for the product was there, but the company could only cater for a small number of orders. This situation reflects the slow production of the product in meeting customer demand. Hence, the company is reluctant to advertise their product because they know that they cannot fulfil all the orders from clients. The situation resulted in a slow return on investment for the company and due to this, it was unable to reach its target to apply for BioNexus status from the Biotechnology Corporation. The BioNexus status enables a company to get privileges such as tax exemptions from the Biotechnology Corporation but the company needs to apply for it within 5 years with its Return on Investment (ROI) RM 250,000 (USD 60,200.00). There was a similar challenges with next respondent, R32 who shared his experience in obtaining public grants. According to R32, he revealed that there are limited grants available for SMEs on biotechnology:

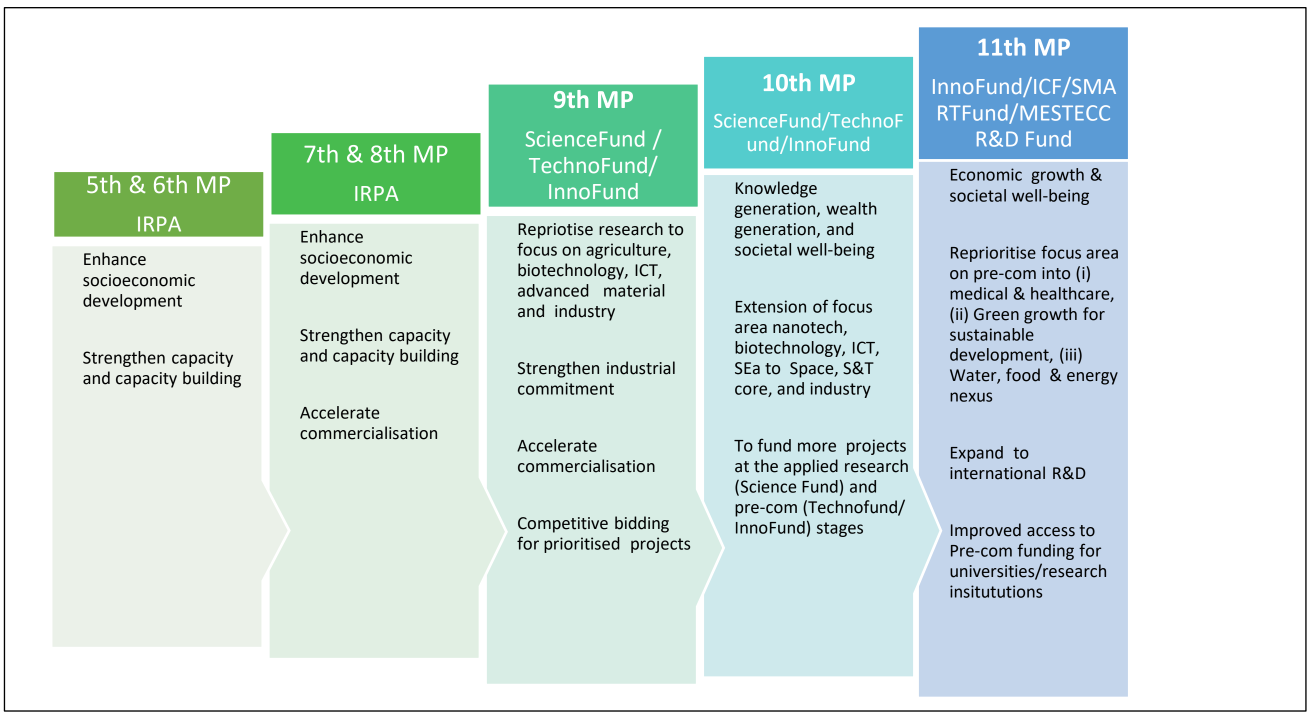
> **R32, Managing director**
> Of course, I'm looking for financial aid. I have access to soft loans and grants that I am looking at right now. At the moment, the government is not going to finance my company's R&D or livestock. Plus, the National Feedlot Corporation scandal has made the loan provider reluctant to assist farmers.

R32, who is involved in cattle farming, seemed to agree that financial capital was an important factor that must be considered in developing a business. Moreover, the limited source of financial support has forced him to look for another alternative to fund his cattle-breeding project, particularly with respect to buying more livestock. In this case, R32, who is the company manager, needs to have a contingency plan if the company fails to obtain a grant from the government.

On a more important note, R32 stated that during the period of applying for a loan, the country started focusing more on agriculture commodities, including the National Feedlot Corporation (NFC) (BiotechCorp, 2009). The National Feedlot Programme was expected to produce 276,000 cattle through the integrator feedlot, commercial farms, and 310 satellite farms. The commercial and satellite farm contracts were only given to selected entrepreneurs that fulfilled the criteria set by the NFC (Department of Veterinary Services, 2013). Due to this mega-project, less financial assistance is allocated to the company managers involved in cattle breeding.

Furthermore, the changes in political leadership and transition to the new Malaysia Plan (11th Malaysia Plan) also affected the funding available for biotechnology-based research. The diagram below represents the evolution of R&D funding starting in the 5th Malaysia Plan to the 11th Malaysia Plan.

**Diagram 7.1: Evolution of R&D funding**




Source: MESTECC (2019)

Figure 7.1 shows the changes to available public funding over time regarding the Malaysia Plans. As can be seen, NBP started in the 9th Malaysian Plan. During this period, research was focused on agriculture, biotechnology, ICT, and advanced materials and industry. The NBP was launched at the end of the fifth Prime Minister (PM) and was carried out by the sixth PM. However, in the 11th Malaysian Plan, the focus changed to medical & healthcare, green technology and water, food, and energy. These changes limited the funding allocated for biotechnology research. However, this is aligned with the phases planned in the NBP but targeting in more specific area such as green technology.

**Section summary**

From the above evidence, it can be seen that financing is important to ensure company growth and sustainability. Clearly, the government plan such as the Symbiosis Programme has given a positive effect in the creation of new start-up companies. However, there are more issues to getting the financial assistance in supporting the operation of the start-ups. Regarding this factor, it is found that the difficulties in getting financial support are due to the strict and lengthy procedures involved in applying, and granting of the money to the companies, and the changes in political leadership. Thus, it can be seen that financial barriers are a critical issue for start-up companies.

However, in this analysis, the companies that collaborate with universities found it difficult to get a grant mainly due to the bureaucratic red tape existing in universities and government agencies in Malaysia. This includes the rigid requirement to apply for financial facilities. Furthermore, the transition phases of NBP to the next phases force the government to be more selective in giving public grants. Another factor is the infant level of the biotechnology industry. Due to this, investing in new start-up companies is not commonplace considering the risks that comes with it. Hence, it is important to note that these two factors are interrelated because the infant level of the biotechnology industry influences the amount of financial support available in the country. This point is elaborated in Section 7.2.2 below.

### 7.2.2 The infant biotechnology industry

The above discussion concerns the financial constraints faced by university start-up companies and SMEs in Malaysia. One of the possible reasons Malaysia lacks financial support is because of its infant biotechnology industry. This makes it unlikely to attract foreign direct investment and venture capitalists to invest in the country. Combined with the weak biotechnology policy framework, this limits the growth of the biotechnology industry. For example, the policy is unable to control the monopoly activities of larger firms, thus restricting the growth of smaller biotechnology companies in the chilli market.

> ***R40, Company Manager***
> *What I can see is market penetration. Because in this industry, we do have the 'big boys' or the big bosses and when we want to bring in a new product, yes, it is very challenging.*

R40, who is involved in chilli farming activities, explains that the market is dominated by a chilli tycoon, thus making entrance into this market difficult. R40 believes that rather than trying to compete with the chilli tycoon, she should find alternative routes to selling the chillies. This decision led her to sell the chillies directly to end-users such as restaurant owners. According to R40, the chillies produced by her company could not enter the market as they were not the standard size.

Referring to public documents relating to chilli commodities, no such standard size specified by FAMA was found as a requirement to enter the market. The chillies are classified into three types: fresh chillies, dried chillies, and bird's eye chillies. Therefore, this situation suggested that a monopoly system exists in the market. The monopoly in the chilli market reflects the inability of policy to provide equal opportunities to SMEs. Importantly, this evidence further suggests that healthy market competition barely exists. From the experience of R40, the situation portrays weak policy enforcement in providing opportunities for start-up companies to join the market. Apart from a lack of enforcement of policy to control the monopoly market, the slow development in this sector is also influenced by low consumer acceptance. This is further elaborated by R31 below:

***R31, operation manager***
*The main problem is the 'consumer' because they are used to chemical fertilisers. So, all the fertilisers for crops are chemical-based. So, it is difficult to change from chemical- to biotech-based… and I think that is the main challenge.*

According to R31, who is involved in various fertiliser businesses and from his observation the users such as farmers preferred to use conventional ways to fertilise crops. In his opinion, it is hard to change the previous practice.

The reluctance to adopt biotechnology techniques is one of the characteristics revealing that the country is not fully engaged with biotechnology. This further explains why Nitrogen (N), Phosphorus (P) and Potassium (P) or also known as NPK fertiliser is still preferable compared to biological fertilisers. In line with this idea, it should be noted that the culture of using NPK fertiliser started in 1979 when the government introduced it to help farmers increase crop yields. Two possible reasons explain the wide use of NPK fertiliser over biological fertiliser. First, the NPK fertiliser is given to the farmers under the fertiliser subsidy for Malaysian paddy/rice (Abdul Rahim & Ismail, 2017). Second, the usage of NPK fertiliser can positively impact yield provided that other fertilisers such as urea and compound fertiliser remain unchanged (Ramli, Shamsuddin, Mohamad & Radam, 2012). Compared to synthetic fertilisers, organic fertiliser is more expensive, has slow progress and uneven nutrient distribution to the plant. However, in the long term, this fertiliser will improve the soil structure and is more environmentally friendly.

The use of inorganic or organic fertilisers alone has both positive and negative effects on plant growth, nutrient availability, and soil. Organic fertilisers improve the physical and biological activities of soil but have comparatively low nutrient content, so a larger quantity is required for plant growth. Therefore, causing incurred cost for the farmers. The inorganic fertilisers are cheap and effective but will cause environmental pollution if use excessively (Roba, 2018). Hence, it is expected that a long period will be needed to educate farmers to use safer fertilisers and for the government to realise the importance of improving the ecosystem. In the same vein, R37 also believes that a lack of understanding of biotechnology could hinder farmers from adopting biotechnological innovations in their business:

***R37*, Operation manager**
Companies do not understand the essence of biotechnology. A well-established company applies biotechnology, but SMEs, since they don't understand it, have a low acceptance rate. For example, the public-listed companies, the RM1 and RM2 million (USD 240,000) capital-worth companies, surely use biotechnology but those RM100,000 and RM200,000 (USD 48,000) capital-worth companies refuse to use it. One of the reasons is because of the cost. They do not see the return. I agree that awareness is still very low.

R37 pointed out that that low awareness regarding the potential of biotechnology amongst smaller companies has led them to refuse to adopt biotechnology techniques. The company managers possess limited capital to invest, considering the high investment costs involved in adopting biotechnology techniques.

As discovered by Moschini and Lapan (1997), although technology will improve agricultural input to the market, if the cost is too high, farmers would not adopt it. Farmers can always use conventional ways, although the trade-off will be low output. Furthermore, NPK is significantly cheaper than biotechnology-based fertilisers. The same result is echoed by (Pray and Naseem, 2003), who found that farmers would adopt a new technology if it can increase their profits or welfare (Pray & Naseem, 2003) considering there is no difficulties in terms of the cost. This case reflects the farmers' dilemma in Malaysia whereby their average income is less than RM2,000 (per month (USD 480) (Malaysiakini, 2017) and they could not afford to adopt this technique.

**Subsection summary**

In this section, it was found that the biotechnology industry remains in its infancy due to the existence of the monopoly system practised in the country, the habits of using conventional ways of farming and the high cost involved in investing in the new technology.  At this point, it can be seen that policy governing the biotechnology activities is unable to boost the growth of the biotechnology sector. Just like 'the chicken and the egg' scenario, the crop owners are unable to purchase biotechnology techniques due to cost and the biotechnology companies are unable to generate their income if the crop owners are unable to purchase the technology even if it could benefit the crops. Therefore, one important point found here is that the government role is important to support biotechnology companies. The infant biotechnology sector is also interrelated with government support. Next, Section 7.2.3 discusses the lack of government support to facilitate SME commercialisation activities.

### 7.2.3 Insufficient government support

The Malaysian Government has attempted to provide a wide range of support for technology-based firms in the form of technical expertise, training, dissemination of information, and financing (Ajagbe and Ismail, 2013). Despite all these initiatives, the respondents still feel that the government should do more to help SMEs. The following discusses the views of respondents involved in SMEs on the effectiveness of these initiatives.

> ***R39, Senior Operations Manager***
> *We also surveyed the Malaysia Agriculture, Horticulture, and Agrotourism* [MAHA] *event, and according to our respondents, the government did not help those who already have full facilities. Just like us. The reason is either you already make a lot of profit or you just started, and you are not qualified to get the help.*

The long response by R39 describes her experience. As a Senior Operations Manager, she felt confused regarding the facilitation given by the government. From her experience, the company she is working at is not entitled to get the help from the government in terms of facilities. It goes the same with the companies who just started the business. Such conditions left R39 puzzled as she does not know what exactly the criteria being evaluated are by the government in entitling them to get the facilities.

From the above response, it can be seen that R36 is having difficulty finding information on the route to applying for help from the government. This situation indicates that there is no clear information or guidelines on the criteria for farmers to seek help from the Ministry of Veterinary Services or how their application is being evaluated in order to get support. According to the official website of the Ministry of Veterinary Services (DVS), it is the responsibility of the DVS to distribute livestock based on farmers' applications. Moreover, there are three types of applications offered by DVS:

i. Technical consultation and intensive training of livestock expanding programme;
ii. In-kind contribution; and
iii. Special financing business expanding package.

In applying for support from the DVS, the applicant must provide documentation related to farming activities such as a certificate related to livestock breeding. In other words, the applicant must meet all the criteria set by the DVS and provide sufficient information such as the e-permit. These criteria are important to determine whether the applicant possesses adequate experience and appropriate sites before being granted support (Department of Veterinary Services, 2017).

From the above observation, it can be seen that the information is given through the website however, lacking in its dissemination process. Such conditions suggest that communication breakdown occurs whilst disseminating the information. This communication breakdown has prevented the government's facilitation and support from reaching the farmers and SMEs.

However, despite the fuzziness of getting the information and the guidelines regarding applying for support, the government still provides support to companies that are facing problems.

> **R39, Senior Operations Manager**
> In the biotechnology market, we make the product available. In 2010, we had a doctor. We also had a good project going on. We even brought cement and did the AI (artificial insemination) there. However, without enforcement from the government, the farmers did not know about our project, and the farmers did not want to take up the product although it is good. So, we had an abundance of stock and had to stop providing our services because there was no demand for it. So, we talked to the government and the government agreed to solve one of our problems.

R39 showed the surplus of stock produced by her company. Apart from livestock breeding, R39 was also involved in providing frozen semen and Artificial Insemination (AI) services to farmers. However, and similar to the case of synthetic fertiliser, the farmers were reluctant to spend their own money to buy and use AI services. Hence, R39 sought the government's help to deal with their abundant semen stock.

The government later bought the products produced by R39's company and passed them to farmers under DVS. According to Hashim (2011), the National Agro-Food Policy (2011-2020), among others, aims to increase the efficiency of the ruminant industry. This initiative includes increasing productive ruminant populations through effective breeding services (Serin and Fadhilah Annaim Huda, 2010).

The situation above shows that the government is committed to help companies provided that the government also needs the companies' services to achieve the objectives of the National Agro-Food Policy (NAFP). This case is aligned with the principal objectives and strategic direction of NAFP, of which there are three: (i) to increase food security and safety; (ii) to make agro-food a competitive and sustainable industry; and (iii) to increase the level of income of agro-based entrepreneurs. The commitment showed by the government through their action of buying the semen stock from R39 shows that the government is serious in creating a sustainable industry by facilitating and encouraging agriculture-related business activities (Bakar, Hashim, Mohamed Radzi & Songan, 2012). Apart from governmental intervention to help agriculture companies to solve their problems, the government also provides other facilities to support research activities through its technology transfer offices (TTO) and Higher Institution Centre of Excellent (HICOE). Despite these facilities, R31 expressed his disappointment regarding the TTO and the HICOE.

> **R31, Operation manager**
> Since we want to outsource the process, we have surveyed Technology Park Malaysia to use the bioreactor machine over there but they said they don’t have it. So, we tried another agency. This agency is under MOSTI. I forgot the name. I called them but, unfortunately, they also use the same bioreactor machine. So, there is no place that we can go to outsource it. So, they advised me to use the facilities in university

R31 highlighted that there are facilities provided by the government. He further added that the facilities are inadequate and incapable of meeting all the demands of the scientists although there are five HICOEs (as 2014 data) in Malaysia. As a result, R31 had to find other alternatives to outsource the service.

At this point, it can be seen that the facilities provided by the government through government agencies and HICOE are insufficient to support commercialisation activities among SMEs. Previous research has also found infrastructure issues as the most significant factors that impede research commercialisation (Vanderford and Marcinkowski, 2015). In most cases, investors, such as shareholders, venture capitalists, and banks, are reluctant to provide capital to buy equipment that is used only incidentally for testing and validation. While it is true that high-technology start-ups may require access to these facilities, it is important to note that investors do not necessarily see the acquisition of such equipment as a top priority. The investor exhibits a preference for allocating funds towards new product development, marketing and sales initiatives, as well as strategic location investments, as opposed to acquiring equipment for the purpose of evaluating claims and confirming research outcomes. (Hulsink and Scholten, 2017). Hence, there are limited facilities available for SMEs to lease, and although facilities are available, the cost of leasing is very expensive. As a start-up company cannot buy the equipment, they need to use the facilities available in research institutions or HICOEs, but the mechanism to encourage SMEs to use these facilities is missing.

**Subsection summary**

This section discussed insufficient government support. Throughout the analysis, it was found that the government indeed offered financial supports, facilitation services and infrastructure facilities. However, in terms of financial help such as grants, it was noted that the government favoured middle-class farmers. The situation suggests that there is a structural problem in the provision of support such as grants. In terms of facilities, it was noted that the government had indeed created various facilities for SMEs but was still unable to cope with the demand from the users. Furthermore, there are no incentives offered as the price of the services is quite expensive for using the government facilities. These two factors are believed to have slowed down the commercialisation activities among SMEs. This revealed that the facilities and support offered are insufficient to assist start-up companies to further commercialise their activities.

### 7.2.4 Lack of university support

Apart from the support from the government, the start-up company also need the university support to sustain and expand their business. Therefore, the concept of entrepreneurial culture is seen as a tool to encourage activities in commercialisation. The idea of ‘entrepreneurial culture’ emerged in the economic literature in the 1960s. Entrepreneurial culture is regarded as a complex notion that refers to values, beliefs, and attitudes shared in a society that values, supports and rewards entrepreneurial activities. The current research explored the extent to which entrepreneurial culture exists among government entities and universities. The following responses provide examples of the lack of entrepreneurial culture in Malaysia within universities.

> **R31, Operation manager**
> Universities are not very helpful. This is my humble opinion. There is less effort to help companies. They [universities] as the biggest shareholder should help with promotion, place (to market), and everything, but the reality is that they are less helpful. So, many of my friends feel that company managers are blocked from doing things that would be in their best interest. They (company managers) are full of ideas, but in the end, they refuse going forward because they feel that the university will terminate them if they don’t follow their rules. So, they are not free to make changes. Scientists must follow the rules and guidelines provided by the university.

From the viewpoint of the company manager, R31 expressed his frustration over the support received from the university. According to him, being tied to collaboration with the university hindered him from freely making his own decisions. His friends experienced the same situation when they collaborated with a university partner. He further added that some of his ideas were rejected because they were against university guidelines. He also mentioned that his career could end if he refused to follow the rules.

The above response describes the insecurity of R31 regarding university practice in treating start-up companies. The tension between the companies and the university is obvious and could be because there is no common practice aligning both parties. For example, the difficulties in achieving the mutual agreement on strategies and plans proposed by the company manager. Due to this rejection, the company manager might feel undervalued, thus causing them to hesitate to contribute their full ideas to the university. To secure a job in the company, the company manager had to follow the business plan provided by the university.

At this point, the situation seems to suggest that the university showed less appreciation towards this group. This example also shows that university does not fully engage in entrepreneurial activities as they are unable to be flexible towards the ideas from the company manager. From the analysis in Chapter 6 regarding the challenges of commercialisation the university is still bound by its traditional roles. The university encourages academics to focus on teaching and research over commercialisation activities. This is evidenced by the yearly evaluation performance that academicians undergo. Therefore, the situation has forced academicians, who are also collaborators with the company manager, to focus on research over commercialisation activities. This situation mirrors university policy regarding academic researchers engaged in commercialisation activities, which is in contradiction with the aim of the NBP to intensify the creation of more spin-off companies from universities. This lack of a supportive culture is highlighted by both R32 and R37:

> **R32, Managing director**
> My issue today is more on the contribution of the scientist. They are very nice people but because of the policy, if they want to go out, they have to first get permission from their bosses.

As a company manager, R32 is frustrated with the commitment given by academics. He mentions that the university rules restrict academics from becoming further involved in commercialisation. He also mentions that the culture practised by the university is less friendly towards business activities. For instance, the academic scientist needs to obtain the university's consent before they can meet their business partner. This situation exemplified the institutional barriers:

> **R37, Operations Manager**
> My friend, who is also the advisor of my company, cannot travel to my farm because he is not given any money for travel expenses. Besides, it is quite a distance from the university to the farm. The university said that they will undertake everything—the license and everything, but now they say things differently. How are we going to proceed from here?

Similar to the experience of R32, R37 also faced difficulties with university governance. According to R37, the academic, who is a technical expert from the university, is unable to visit the farm frequently, as he has no travelling expenses. The unclear guidelines on travelling expenses have caused difficulties in the collaboration between the academics and industry.

Unclear guidelines on travelling expenses have also caused difficulties in determining who should bear the expenses. This situation had caused tension between both parties, thus affecting the collaboration. The situation mirrors the lack of university governance on this matter. Referring to the public funding offered by MOSTI, travelling expenses are not covered in the provided grants. The scope of funding covers equipment, materials, market testing, product documentation, and consultancy only. There is no allocation for transportation for site visit purposes (MOSTI, 2017). Without clear guidelines on the expenses, it would likely cause internal conflict between the university and the company manager once the collaboration take place.

**Subsection summary**

In this section, it could be seen that the university governance of entrepreneurial activities is lacking. This is evidenced by the experience of the respondents above who expressed their frustration over the university's support in promoting commercialisation activities. The company managers explained that the university was inflexible in encouraging its staff to engage in commercialisation activities. Furthermore, the commercialisation-related policy designed at the university-level restricts both parties (the academics and the company manager) from moving freely. This is resulted from the bureaucracy practices practiced in all government agencies in Malaysia. Due to these practices, the interactions between the universities and their company managers becomes inflexible. Furthermore, the analysis also showed that there is a blurred guideline of responsibilities carried by the company manager and the university. The unclear guideline had caused the conflict between the universities and company managers when it comes to take up the responsibilities such as the travelling allowance issue.

### 7.2.5 Conclusion

In this section, the discussion was focused on the challenges faced by company managers while pursuing collaborations with universities. For the company managers in the agro-biotechnology business, four main factors were observed that influenced commercialisation collaboration activities. It can be concluded that the ecosystem to encourage biotechnology commercialisation among start-up companies involved in farming activities is still lacking. This is demonstrated by the limited financial assistance in this sector. Second, the biotechnology industry in Malaysia is still in its infant stage as the policy is unable to break the monopoly system and promote the growth of new biotechnology start-up companies. This has limited the creation and survival of new companies. Third, insufficient government support showed that the facilities and support offered were unable to sufficiently assist start-up companies to become further involved in commercialisation activities. Fourth, it was also noticed that the university's governance structure was lacking as it was unable to provide clear guidelines regarding the responsibilities to enable collaboration. These factors showed that the biotechnology ecosystem is not well enough developed for those start-up companies involved in farming activities to flourish. At this point, it can be seen that the structural problem exists in the biotechnology ecosystem and as a result causes slow development in this area.

## 7.3 Findings from the interviews with agro-biotechnology companies' managers related to non-farming activities

The previous section discussed the problems faced by company managers concerning farming activities. In this section, non-farming activities, which refer to the production based on agro-biotechnology including health drinks, supplements, and culture cells, are discussed. The analysis managed to identify three main barriers that contribute to the slow progress of the agro-biotechnology commercialisation of non-farming activities in Malaysia, as below:

(i) Consumer Market;

(ii) Barriers to Market Entry;

(iii) Monetary Support to Run R&D for Commercialisation.

### 7.3.1 Consumer market

In most western countries, the public perception of biotechnology has received a great deal of attention in recent years. There have been numerous surveys on the public perception of biotechnology in Europe, the USA and Canada (Gaskel et al. 2003), but there have been few similar studies in developing countries. General consumer awareness about biotechnology varies depending on the country and the type of biotechnology applications or questions asked. For example, the farmers accept biotechnology techniques due to clear advantages to them.

Consumer attitudes on biotechnology take into account many factors, including information, trust, beliefs, risk and benefit perceptions, and develop against the background of a complex set of personal values that today largely dictate that external information is processed and evaluated (Lucht, 2015). As posits by R38, the discovery of biotechnology can solve a lot of problems, thus making this technology in high demand. As for R38, he uses biotechnology to expand his culture tissue business. However, since the technology is new, the acceptance of the user is quite challenging:

> **R38, Chief Operating Manager**
> *Since this thing is new, one thing is that the product going out to market needs to be novel. So, the main hurdle is public acceptance. That is one, but I think that it is a very minor problem because the biotechnology itself solves a lot of issues that we face.*

The above response exhibits the use of biotechnology in everyday life. According to R38, he is very positive that his product could easily penetrate the market because it is considered to be a pioneer in the sector. Involved in the culture tissue business, he believes that his product could solve problems that people face in the planting sector.

As mentioned by R38, it is important to ensure that the biotechnology product can provide a solution for the user. This case implies that for the product to get sold, the company managers must be able to convince the users that the product could solve the problems and be beneficial for their business. The different studies carried out on the social acceptability of biotechnology all underline the absence of perceived utility as one of the determining factors for the opposition to biotechnologies, regardless of the field of application (Amin et al., 2014). Therefore, selecting the right product for commercialisation is important for the company managers. Choosing the right product which have high demand will increase the probability to sell in the market.

Previous research has also found that the acceptance of biotechnology is dependent on gender, level of education, and political stance (Rousselière & Rousselière, 2017). At the same time, R38 believes that it is important to have the ability to predict any problem that might occur in the future. This situation recalls the discussion in Chapter 6 whereby researchers are encouraged to conduct R&D that is demanded in the market (refer to Section 6.2.2.1). Therefore, R38 believes that for the product to get sold, the company managers must demonstrate its benefits. The next respondent (R38) also echoes the same views:

> **R33, Managing Director**
> For example, for wellness products, health awareness plays an important role as well. As for this product, the consumer will only buy it if they realised they are sick.

According to R33, who is a company manager, he believes that consumer awareness of health supplements can influence their buying habits. He further adds that, from his observation, people will not buy health supplements if the person is not sick. The idea of maintaining a healthy and nutritious lifestyle and diet is well entrenched in the minds of most Malaysians. In general, Malaysians already have the basics of health and wellness in place. Most have some knowledge of traditional wellness and herbal medicine that is usually passed down through the generations. Thus, purchasing modern functional foods is not commons.

In the western countries, supplements are taken to prevent the disease, part of the treatment regime and for supplementing the diet (Lentjes, 2019). Nearly half of the adult population in the USA and European countries reported consuming dietary supplements due to maintain and promote personal health as well as part of their healthy habits (Bailey et al., 2011). In Malaysia, the prevalence of dietary supplements usage among adult was considerably lower than findings in other countries.

Research conducted on dietary supplement users found only one third of Malaysian adults took the supplements. Many reasons could explain this. The preference to use health supplements has been influenced by the level of socioeconomic status, education level, and gender. The consumer market is limited and price-sensitive due to family income (Mohd Zaki *et al.*, 2018). As a middle-income country, Malaysia is comprised of: 20% top income (T20); 40% middle income (M40); and 40% bottom income (B40). As the majority of Malaysians are from the middle and bottom-income group, thus price of the product plays an important factor in determining the purchase of the supplement product. Therefore, it is important to make sure the product invented has a reasonable price. This is further agreed by R29, who is knowledgable about the target market and believes it is important to ensure there are potential buyers, especially in the business-to-consumer market (B2C):

> **R29, Scientist**
> *If the cost is high and the selling price is inexpensive, it won't work. For instance, the consumer can't afford to buy expensive products. They can only afford to buy a product within a selected range but at the same time, the cost of production is too high.*

As a scientist that works on health supplement products, R29 is aware of the buying trend of health supplements in Malaysia. According to R29, although her product is beneficial, only selected groups could afford to buy it. She further added that the product that she invented is quite expensive, so this could be one of the reasons people do not buy it. Although she realises the situation, R29 cannot reduce her price because the biotechnology product has undergone many stages to ensure that it is safe and effective. According to a report prepared by Khazanah Malaysia Research Institute (2016), the cost of manufacturing health supplement products is mainly incurred from the processes it has to go through.

Apart from the price factor, R29 also believes that market segmentation will help the company to increase its sales. One of the important areas of market research involves the identification of small firm customers and business areas. Many people that go into business do not know who their customers are or their business area. Through research, businesses can get valuable information such as location, race, income bracket, occupation, and educational level. This information can be very useful for businesses to enhance their sales as well as to expand their market (Hashim, 2011). R29, who during the interview had not finished her research, believed that it is important to have a target market because it allows company managers to establish effective marketing communication strategies.

**Subsection summary**

In this section, it can be seen that the consumer market for non-agricultural products is still small. It is exemplified by the findings above where only small group of people have the capability to buy biotechnology-based product. Although the biotechnology products seem to offer benefits to its user, some users are unable to purchase it due to their socioeconomic status and their views on biotechnology product. Aligned with this, the product should be sold in a market place where middle-income people would go shopping and should not be directly marketed to younger consumers as they may consider this supplement are irrelevant to their lifestyle and age. Therefore, it can be seen that market identification is important in connecting the product to the consumer. Without understanding the nature of the consumer, it will be hard to tackle their needs. Although the target market is important, company managers often face challenges in entering it. Therefore, the next discussion will focus on this.

### 7.3.2 Barriers to market entry

Referring to the official website of SME Corporation Malaysia (SMEcorp), start-up companies and SMEs could benefit from the programmes and initiatives offered by this agency. The same goes with MTDC. Although the agencies offer many different forms of support to these companies, they are still unable to penetrate the market. there are several barriers to the market entry. The first informant (R29), in her experience believed that knowledge about marketing is important to sell the product.

> **R29, Scientist**
> I have heard that to put your product on the shelf, you need to pay a certain amount of money, around thousands of Ringgit Malaysia [MYR], just to display your product. There are many requirements that you have to fulfil to enter the market. It is not easy to enter the market. That is what I heard. I never experienced it for myself though.

R29 expressed her confusion regarding the procedures to get the product into a retail store. Involve in health supplement products, she is quite worry about how she will market the product. From what she had heard, there were many procedures involved in bringing the product onto supermarket shelves. As a new entrant to this sector, R29 felt nervous about getting her product into the market.

While there is still debate about whether entrepreneurs are born or bred, there are some researchers who agree on the important contribution of entrepreneurship education to students (Othman, Hashim and Wahid, 2012). Entrepreneurship education is useful in a situation where university graduates may need to consider self-employment in small firms, as the number of graduates increases while vacancies in large firms decrease (Iwu *et al.*, 2021). These entrepreneurial qualities can be positively influenced by educational programs Furthermore, it was shown that the most successful companies tend to be those that combine education and experience (Ahmad, 2013) . With this in mind, the Ministry of Entrepreneurs and Corporate Development also wants to encourage graduates to become entrepreneurs. Self-employment can reduce the number of unemployed graduates and more business opportunities arise from a growing economy.  At this moment, entrepreneurial training is not a compulsory subject that need to be taken while pursuing education in university, however, it is offered as an elective subject.

From R29's impression, it can be said that she had limited knowledge on market access. This could be due to little or no exposure on entrepreneurial activities during her third education level.  Although there are other alternatives such as short training offered by government agencies such as MTDC, SME Corporation Malaysia, NIBM and others.  However, in R29 experience, she had difficulties in finding the right training and limited time to underkate the training.  Similar to R29, R33 also shared the same problem regarding market entrance:

> **R33, Managing Director**
> *Well, yeah. The competition is very tough. Furthermore, when we want to put our product in retail stores, I am not sure if we have to pay for it. But I am sure that it is consignment-based, which means we will have to wait until 3 months to get paid.*

R33 also mentioned the confusion of entering the market. He was unsure about the procedures involved to get his product into stores. There are three issues that R33 and R29, namely a lack of knowledge on how the supply chain in retail stores works, the difficulty to get direct payment after putting their product in retail stores, and how the product can be promoted.

In discussing the challenges identified by R29 and R33, it is noted that both of them have limited knowledge on market access. The slotting allowance for instance is one of the components in entering the market. The one-time payment is made by the supplier to the retailer to secure some shelf space in the retailer's store (Thompson *et al.*, 2003). Another consideration to enter the market is the capability to supply the product in large quantities. At the same time, the company manager must ensure the product has attractive and informative labels to attract the customers such as certificates or logos, bar codes, ingredients and nutrition facts (if relevant) (Ministry of Domestic Trade and Consumer Affairs, 2018).

Among the agencies responsible for helping the SMEs in marketing their product is SMECorp. The agency acts as the central point of reference for research and data dissemination on SMEs and entrepreneurs and provides business advisory services for them throughout the country. Apart from the SMECorp, BiotechCorp also helps biotechnology companies to market their products. To this end, the BioEconomy Corporation has come out with the BioShoppe idea. The BioShoppe is a shop specially designed for BioNexus status companies to sell their products. As of 2019, only four shops exist and these are situated in select shopping complexes all over Malaysia with one having an online database. However, other companies lacking a BioNexus status have to devise their own strategy to sell their products. At this point, it can be seen that the government only supports selected groups of biotechnology companies. This situation could affect the overall growth of the biotechnology industry in Malaysia.

As discussed above, the logo and branding are important to influence purchasing activities. The next respondent discusses how the logo or the certificates from the National Pharmaceutical Regulatory Agency (NPRA), could affect the sales of the product.

> **R35, Operation Manager**
> *It was stated that there is no cure for cancer. We want to convince the consumer. We cannot call the patients and ask them to try our product. Even the doctor I am working with cannot ask his patients to do so. So, we call them as the customer. We cannot identify our product as a cure. It is wrong.*

As for R35, he could not freely put his product into the market although the product has proven results in curing cancer. He also said that one of the reasons he could not sell the product in the open market was due to not getting approval from National Pharmaceutical Regulatory Agency (NPRA). When the interview took place, the product of R35 have been rejected once by the NPRA. Therefore, R35 decided to take more time in getting approval from NPRA.

The NPRA is a government agency to implement regulationof pharmaceutical products. The agency responsible of ensuring the quality, efficacy and safety of pharmaceuticals through the registration and licensing scheme (npra.gov.my, 2021). Therefore, the approval from NPRA serves like an assurance from the NPRA to the buyers. Without the safety approval from the NPRA, he is not there is no access to the market.

The experience of R35 posits that it is hard to get regulatory approval from the NPRA. This is because the procedure is very hard for someone who does not have an understanding of the entire biotechnology development process.

One of the reasons R35 would like to get certification is to obtain the trust of his customers. The approval from NPRA indicates that the product is safe to consume and does not contain harmful ingredients that would affect the health of the user. In the case of pharmaceutical products, the product sold should have a registration number such as the MAL to ensure that the product is safe for sale and use in Malaysia (National Pharmaceutical Regulatory Agency, 2017). The product also needs to have adequate information on its label before it can be legally sold in the market to prevent it from being confiscated and fined. Apart from that, individual citizens are selective in buying products that require the manufacturer to provide adequate information and verification to ensure trust and for them to be convinced that the product is safe and effective.

The situation highlights the importance of having the skilled, experienced and knowledgeable company managers in ensuring the product reaches the market as soon as possible. The missing knowledge regarding biotechnology could cause the certificate application process to be rejected and, in turn, cause a delay in marketing the product. Apart from the certification process, the government procedures are also barriers that slow down the process of bringing the product to market.

> **R41, General Manager**
> *Last time, I brought my product to the table but there were so many comments. The government wants to have a Bumiputra company manufacture the product and such a company could go further in the international market. They gave too many comments. So, I think it is better for me to just export it on my own. I bring the product to the Bumiputra Committee to get the funds and everything. But when things turn out like this, I said, that's it. I don't need them. When there are too many screening procedures and too many comments, the invention will just remain on the shelf. That is why I did not tell them that I had exported my product to the outside market. I did it silently.*

As a company manager, R41 believed that the government does provide assistance through Bumiputera Exporters Development Programme (BEDP) in helping the SME to export the product internationally (Malaysia External Trade Development Corporation (MATRADE)

(2017). Through the programme, the product will be audited and assessed by panels from various entities such as MARA, PUNB, TERAJU, MITI and MATRADE. They will provide comments and input whether the product is ready to be exported internationally or needs to be improved. However, his previous experience with government assistance programmes caused a delay in the product marketing process. Reflecting on the experience of R41, the regulation imposed by the programme on products produced in Malaysia is burdensome for companies to export the product internationally.

The Government of Malaysia has initiated several schemes and funds to ensure the growth and expansion stage of SMEs, including SME Go, Fund for Food, and EquiBumi (SMECorporation Malaysia, 2018). However, the procedures involved in getting the product into the global market are rigid. Therefore, R41 decided not to overly depend on government support to further export his product and expand his company. The intermediary agency established by the government to ease the commercialisation process also proved to be ineffective, as it was unable to ease R41's journey towards product commercialisation.

However, for those who do not have much experience, they might choose to simply give up altogether. Such a situation could lead to the slow development of local companies to reach the international level.

**Subsection summary**

It can be concluded that the barriers to enter the market still exist for start-up companies regardless of whether they are a university start-up or not. This case is demonstrated by the low level of market knowledge among company managers in university and non-university start-up companies. Hence, they did not know what to expect in the next part of the value chain after getting the product ready. This missing knowledge would affect the type of marketing strategies that they use. Furthermore, facilitation to navigate the procedures for obtaining product approval is still lacking especially for the inexperienced company manager, thus causing delay in marketing the product. Another problem related to barriers to market entry involves the rigid procedures imposed on the company that wants to become involved in business activity under the government programme. This is evidenced by the difficulties in getting access to exhibitions and the procedures involved in exporting products through the government agency. This situation has resulted in less growth for start-up companies and threatens the ability of companies to expand internationally. Apart from market access, financial issues also affect commercialisation activities. Hence, Section 7.3.3 expands further on this factor.

### 7.3.3 Monetary support to run R&D for commercialisation

Similar to the funding issues discussed in Section 7.2.1, the company managers in the non-farming activities also admitted the importance of the availability of funding to ensure the sustainability of their company. Research indicates that SMEs businesses tend to have a higher failure rate compared to large organisations. These failures are often due to resource limitation, which includes financial insufficiency. To start the discussion, R33 shared his experience below. He said that without funding, his company was unable to increase production:

> **R33, Managing Director**
> *It goes back to funding because if there is not enough funding, we can't do anything. If we want to put the product to the market, we need a large number of funds to help us do mass production.*

As the above extract explains, the first and most important resource issue is access to finance. R33, who is in charge of a new start-up company involved in health drinks, admitted that they had difficulty in manufacturing their products on a large-scale. As they are new to the industry, they could not afford to buy equipment to increase their production.

Having equipment to increase production is one of the aims of R33. By having a powerful machine, production can be done at large scale and the company can, therefore, market its product extensively all over the country. However, due to insufficient capital, R33 was unable to buy the up-scaling machine. This condition refer to the early stages of innovation, at the transition between original scientific research and the commercialisation of associated technologies (Ellwood, Williams and Egan, 2020).

The term Valley of Death originally referred to the lack of financial resources in the transition from the invention stage to the innovation state (Auerswald and Branscomb, 2003). This circumstance exists during the earliest stages of technology development, at the juncture between scientific discovery and the proposal of a viable commercial opportunity (Ellwood, 2020). According to R33, due to insufficient financial support, he is unable to produce the health drinks in sufficient amount to penetrate the market at a large scale.

In struggling to cross the ‘valley of death’, there are many reasons that contribute to the situation. It is well known that in the early stages of science-based innovation, both the technology and the markets are hard to understand and that the basis for investment decisions is never secure (Beard *et al.*, 2009)

This situation demonstrates that start-up companies need to have steady financial support to survive. In a similar vein, R38 also perceives funding as important for running research projects. In the case of R38, who is also involved in health drinks, he needs a financial injection to increase product manufacturing. Insufficient capital is, therefore, a hurdle preventing him from speeding up his R&D and product manufacturing:

> **R38, Operations Manager**
> It is about funding. It needs a long gestation period. Not to mention the equipment used in the industry and the research involved. At the same time, the funding requirement is high. We have established our lab with MTDC-UPM, but the rent is high. So, this is usually a barrier. We, in our long-term plan, can find cheaper, better facilities. Right now, we are still with UPM-MTDC. So, when we expand, we would like to have our premises rather than renting them out.

R38 revealed that a high level of investment in research and a longer time is needed to ensure that the research can be converted into a viable product. Along the way, the equipment used in this process could be quite expensive. Furthermore, the rental that is imposed on the start-up company is also one of the company's biggest financial liabilities. R38 concluded that funding support is important especially for a new start-up company to help it expand its business. Therefore, such conditions explained that the facilities provided are expensive and incentives are lacking to encourage start-up companies to use the facilities provided by the government.

In most cases, young biotechnology firms do not have the resources needed to buy or lease expensive facilities they need to validate their research results. Without owning or having access to research equipment, these start-ups cannot demonstrate their scientific results effectively and are unable to seize the claims and opportunities following their disclosures (Hulsink & Scholten, 2017). Because they often lack collateral, a track record, stable cash flow, and/or operational profits, science-based start-ups have to find alternative sources and channels of finance. As biotechnology start-ups often require large R&D investment, they need external finance. However, biotechnology start-ups typically cannot rely on bank loans because of the uncertainty in R&D and information asymmetries between entrepreneurs and creditors (Honjo & Nagaoka, 2018).

Realising this situation, the government has provided labs that can be rented by start-up companies. For example, Agriculture Biotechnology Institutes have three specific blocks that allow experiments to be performed. Although there are universities and government agencies that provide leasing services such as the HiCOE, the price is still considered high. Further, the facilities do not offer any special rates for new start-up companies to encourage them to use the facilities. As the result of financial insufficiency, the companies need to find the cheapest rental facilities and equipment to increase their production. The situation reflects a gap in accessing facilities for SMEs to expand their research from the R&D stage to the manufacturing stage. Similar to the situation of R33 and R38, R35 also faced insufficient financial sources, which have led to delay in the validation of the research results for his product:

> **R35, Company Manager**
> In my situation, we can only research if we have the funds. Like our product, it took 6 years to develop together with the box. At this point, I don't know how much more time it will take.

According to R35, he has been in a research project for the past six years. The process of commercialising the project was 'on-off' due to inconsistent financing available to support the project. At the time of the interview, the project was ready with packaging, but R35 was still in the process of applying for a certificate from NPFK. Shadowed by his previous experience, R35 expressed his ambiguity regarding the time required to continue to the next step, which is the validation test.

In R35's experience, the R&D process of the product will be continued when financial support is available. Being a new science-based start-up company, they are lacking customers and financial support thus restricting them to conduct more market testing. Furthermore, the regulatory approval of new products or treatments may only be provided after several rounds of lengthy experiments and clinical trials, altogether taking years or even decades (Atherton, 2013). Therefore, this condition explained the situation faced by R35 in getting the product into the marketplace.

Without secure and stable cash flows, young companies such as R35 often have difficulties in obtaining financial support from external debt and equity providers as they are unwilling to engage in strategic funding deals (Berger and Udell, 1998). For instance, R&D facilities in biotechnology are often single-purpose technologies (e.g. designed to test prototypes or validate research results and proof of principle), making them both very expensive and obsolete within just a few years (Hulsink and Scholten, 2017; Steen, Ortt & Scholten, 2010). While it is true that high-tech start-ups require advanced facilities, it is important to consider the perspective of investors, who may perceive substantial investments in extra equipment as a potential hindrance to their future prospects. Investors tend to prioritise new product development, marketing, sales, and strategic partnership over testing claims, confirming research results, and acquiring dedicated research and technology equipment for these goals. This financing gap between investors and investees may have severe repercussions, as the lack of funding for research and testing equipment may impede the early growth of biotechnology startups (Hulsink and Scholten, 2017).

**Subsection summary**

In this subsection, it is believed that monetary support influences the operation of the start-up companies. Through the analysis, it has been discovered that financial availability affected the product manufacturing and R&D process. Small start-ups can face significant challenges in both sustaining themselves within local clusters and securing investment to support their product pipelines (Tian, 2009). Currently, these emerging enterprises find themselves at a critical juncture whereby they are transitioning their research concepts into viable commercial ventures. To successfully navigate this challenging phase, substantial financial resources are required to overcome the significant obstacles and sometimes referred to as the 'valley of death'. At present, the financial resources allocated to this stage are multiple times greater those allocated to basic research (Jamil, 2017).

According to Ford et al. (Markham, 2002), the valley of death refers to a critical phase characterized by a significant decline in funding conditions mostly attributed to government and corporate finance policies. Insufficient financial resources, including angel financing and venture capital financing, provide limitations on the effective commercialisation process (Wonglimiyarat, 2014). Along this line, the availability of financial resources appears to be among the most crucial factors for traversing the valley of death (Jamil, 2017).The discussion above revealed that there is limited amount of monetary support available, and there is limited stimulus in encouraging start-up companies to use government facilities.

### 7.3.4 Conclusion

In this section, the centre of the discussion was on the challenges faced by start-up company managers engaged in non-farming activities. The result of the discussion showed that three main factors influenced the commercialisation activities among these SMEs: (i) Consumer Market; (ii) Barriers to Market Entry; and (iii) Monetary Support to run R&D activities.

From the analysis, it was further discovered that knowledge about target market, marketing and sufficient financial assistance were the major factors that influenced commercialisation activities among the company managers related to non-farming activities. Having sufficient knowledge about the target market and market supply chain is important as the company managers are dealing with individual consumers. Knowing about the target group of the consumer is important as it provides information on how to market the products and to whom. Therefore, greater knowledge about the market will assist the company managers with business planning and marketing. Here it can be seen that the role of the company manager is not just promoting or marketing the product, but choosing the right partner with the right product to be commercialised.

On top of that, the company managers need to possess qualities of a good businessman which includes the knowledge about market and supply chains. Obviously, the government wants to encourage commercialisation activities by implementing NBP and various policies, however, the education systems are not preparing the graduates with entrepreneurial traits. Furthermore, the limited participation from government and industry in investing in start-ups companies has contributed to the slow growth of the biotechnology industry. In line with this, financial assistance and incentives to encourage industry participation in start-ups are important to increase the survival of the start-up companies during early commercialisation activities. It can be summarised that the biotechnology start-ups in non-farming activities have difficulties to commercialise their product due to lack of sufficient business knowledge and monetary support from the government and participation from industry. It shows that the government efforts such as the implementation of the NBP is still lacking.

### 7.4 Chapter summary

This chapter had discussed the challenges faced by the company managers in pursuing commercialisation activities. This discussion is divided into three sections. The first is the introduction of the chapter, second section focusing on the challenges in farming companies and the later section is focusing on companies related to non-farming activities.

In the second section, it was discovered that the main factors hindering the commercialisation activities among start-up farming companies are as follows: (i) Financial Constraints; (ii) the Infant Industry of Biotechnology; (iii) Insufficient Government Support; and (iv) a Lack of University Support. This demonstrated that the ecosystem is not yet ideal to spur commercialisation activities among the farming companies.

In the third section of this chapter, the discussion was focused on companies engaged in non-farming activities. Quite similar to the findings in Section 7.2, three factors were found to influence commercialisation activities in these MSMEs (i) Consumer Markets; (ii) Barriers to Market Entry; and (iii) Monetary Support to Run R&D for Commercialisation. This revealed that the company managers are inexperienced in the marketing environment, and how limited financial resources have interrupted the R&D&C process.

As discussed above, similarities between MSMEs involved in farming and non-farming activities can be observed and can be grouped according to financial constraint, consumer awareness regarding biotechnology benefits, and the rigidity of the systems of governmental support. All of the respondents in this group agreed that they faced financial constraints while pursuing their product development especially in up-scaling and validating the result. Furthermore, the procedures in the government sector, including the university, for applying and getting grants are too rigid and inflexible for start-up companies. It could also be noted that both groups believed that financial barriers restricted the buying power of the consumer. This situation has slowed down overall business activities related to biotechnology.

In terms of dissimilarity, it can be noted that start-up companies involved in farming activities are more attached to collaboration with universities due to the needs of these companies to obtain supervision and technical expertise (academic scientists) from universities. The situation suggests that the overall operation of companies is affected by both the regulations and local practices of universities. Meanwhile, SMEs involved in non-farming activities are less attached to the university structure, as they require minimal supervision or technical expertise.

In summary, start-up companies that collaborate with universities face more barriers in pursuing commercialisation activities. The support for entrepreneurial activities is not embedded strongly at the university level. This case is demonstrated by the policy practised in the universities, where the academic scientists are controlled via strict policies and are not given much freedom to pursue links with the private sector. In addition, they are not rewarded for it in their KPI and have few financial resources outside of formal grant conditions (e.g. a lack of travel funds). Taken together, this situation has resulted in few incentives and a culture of bureaucratic control, mainly due to the rules and regulations that the technical experts need to follow, which in turn affected collaboration and business activities to commercialise the product. As a consequence, the biotechnology sector is facing a number of structural problems. First, at the national level, the steps in getting the funding are too long and involve strict procedures. This is the same with the public funding offered by the government agencies. This is due to the bureaucratic culture practiced in the country. Secondly, at the university level, the same problem occurs. The academics need to follow certain procedures when collaborating with the business manager in running the company. Thirdly, the company managers themselves are lacking in bringing the product into the market. It is true that the government has tried to solve this by providing incubators and training through various government agencies, but these efforts have only had limited success.

With the implementation of the NBP, this analysis discovered that the policy itself is a generally well designed although there are a few flaws here and there which can be improved over time. The problem with its implementation is that the policies (referring to NBP and university policies) is largely influenced by the bureaucratic practices held in the government. Although the discussion in this chapter is focused on the companies but they are still bound by the bureaucratic practices embedded in the universities when it comes to manage the commercialisation activities.

# Chapter 8

# Conclusion

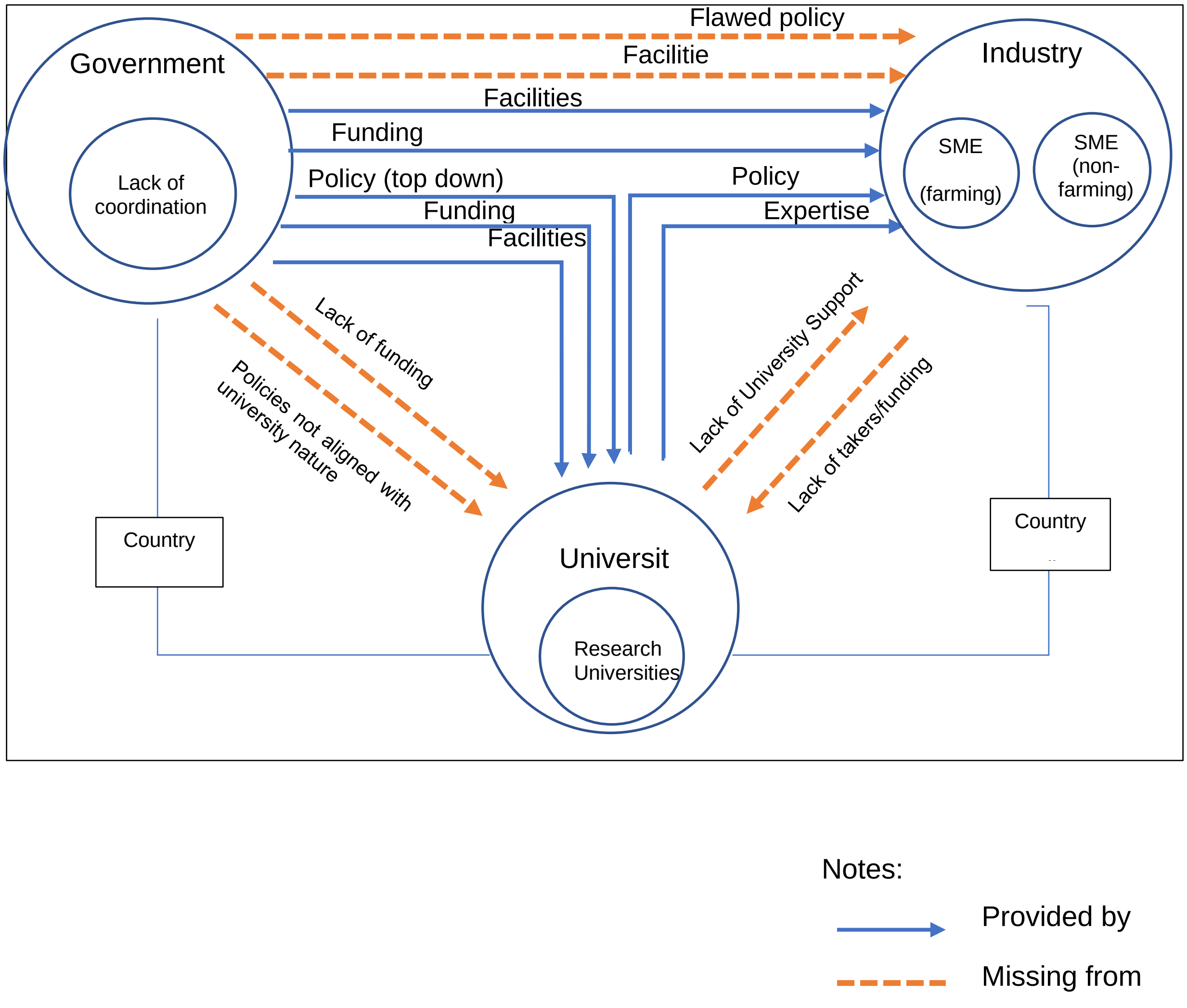
## 8.1 Introduction

The study set out to explore the concept of commercialisation in the context of the biotechnology industry in Malaysia. The thesis builds upon comprehensive discussions of the debate on the nature of the National Biotechnology policy and in particular, the sustainability of the start-up companies in the biotechnology sector. This has involved examining the different categories of respondents at the national, university level, and spin-off company levels. The study has applied the Triple Helix Model to address the relationship between the government, university, and industry in practicing the NBP. This study aims to discover how the NBP affected the national, university and spin-off companies while pursuing commercialisation. To do this, a few smaller research questions have been set up to help the researcher to discover the aim.

## 8.2 Empirical findings

The main empirical findings are summarized within Chapters 5, 6 and 7. This study's primary focus is discovering the roles of national and local policies in supporting the biotechnology development in Malaysia to become ahigh-income country. Through analysing narratives of key participants and scrutinizing public documents, the implementation of the National Biotechnology Policy is used to understand the collaboration between the government, university and industry. To have better picture of the whole findings of the thesis, the below figure will illustrate the connection of the three actors in implementing the National Biotechnology Policy.

**Diagram 8.1: National Biotechnology Policy implementation**




The above figure demonstrated the range of connection between the university, industry and government while implementing the National Biotechnology Policy with a focus on knowledge exchange and commercialisation of biotechnology. The details of the diagram will be explained as the researcher answer the research question below.

## 8.3 Answering the research questions

This section seeks to answer the research questions set at the beginning of the study (see chapter 1). The main aim of this PhD is to examine the reasons behind the slow development of biotechnology commercialisation among the research universities in Malaysia. To do this, four research questions has been set to discover the reasons behind commercialisation activities and consequently answering the main aim of this research. The research questions are set as below:

I. What are the issues faced by biotechnology actors at the national level in enabling knowledge exchange and commercialisation of biotechnology in Malaysia?
II. How do universities translate the National Biotechnology Policy (NBP) into local practice?
III. How do these local practices support knowledge transfer and the commercialisation of biotechnology?
IV. How might the successes and limitations of national and local policy be conceptualized in terms of the Triple Helix model of innovation.

### 8.3.1 The fragmented coordination at national and local level in pursuing commercialisation

This section is particularly seeking to answer the first research question. The first research question is set to help the researcher to understand the roles of these agencies in supporting the biotechnology agenda in the country. One of the main roles of these government agencies is to help to intensify the commercialisation among spin-out companies. Therefore, this research question is aimed to answer the issues faced by the biotechnology agency in Malaysia whilst pursuing the activities.

The Malaysian Government truly recognises the need to enhance innovation in every sector of the country. Inspired by Vision 2020 (Biotechcorp, 2011), driving Malaysian economic growth will require the transition from a low to a high-income nation which in turn requires the development and application of new technologies. Realising this, Malaysia launched the NBP in 2006 to generate new source of wealth. This incorporated 9 policy thrusts to be implemented over 15 years with the main goal to contribute 5% towards Malaysia's Gross Domestic Product (GDP) and create 280,000 jobs by the end of 2020. The government's agencies continue to play a central role in accelerating the biotechnology agenda.

The government established a number of agencies to facilitate the development of start-up companies in pursuing these activities. The national research institutes alongside these agencies continue to play a central role in accelerating the biotechnology agenda (Arujanan and Singaram, 2018) through the NBP. The agencies connect with the universities and industries in order to get them to work together in pursuing commercialisation activities while the NBP served as a bridge to encourage the university and industry sectors to collaborate.

However, from the analysis undertaken here it can be seen that the government agencies are working in silos and are fragmented. This is not unusual as the nature of administration in Malaysia is very bureaucratic, evidencing a control culture and top-down governance style. Due to this, the situation has affected how it interacts with universities and industry. The control culture has limited the interaction among each government agencies in the 'government spiral' of the Triple Helix, and things are more difficult when interacting with others within the spiral as they have to cross institutional and political boundaries. This is not to say that there is no interaction between these three spirals but the procedures involved when dealing with other agencies either inside or outside the spiral is difficult, as a result of the bureaucratic practices long embedded in the Malaysian state (Haryono and Khalil, 2011).

As discussed by (Etzkowitz, 2008), although the Triple Helix is focused on the relationship between university, industry and government, it also focuses on micro circulations which refer to the internal interactions in each spiral. Micro circulation, in this context, means the circulation of interactions that take place within a particular helix. Specifically, micro circulation among the government agencies is not connected or not functioning reciprocally.

In this research, for example, the internal conflict that occurred at the agency level also contributed to ineffective service delivery by the government agency towards other agencies and actors. The change in the organisation of agencies made by the government affected how the employees felt, forcing them to resist a number of policy initiatives. Such a situation has delayed the function of the agency in delivering its services. This is also true when engaging decisions made at the national level can be slow as it involves various stages before reaching a final decision and subsequently being passed onto actors in the other spirals. Decision making concerning the provision of public grants is one example of how bureaucratic practices have affected commercialisation activities in the country. For example, in order for a university start-ups company to apply for a public grant, approval from university top management is needed.  It is important to note here that the meeting at the top management is not held very often and this has affected the speed of commercialisation.

With a focus on biotechnology, as a new-comer, it can be seen that Malaysia adopted the ‘Statist Model of the Triple Helix’. In this model, government plays the coordinating role and is expected to take the lead in developing projects and providing the resources for new initiatives. These are clearly exemplified by the establishment of multiple agencies, allocating finances and formulated through the NBP to support biotechnology activities. However, although these initiatives appear well designed, the research findings and analysis show otherwise. The statist model relies on specialised organisations linked hierarchically by central government. It is also characterised by specialised basic and applied research institutes including sectoral units for particular industries. Notably, the universities are largely teaching institutions and distant from industry (Etzkowitz, 2008).

As previously discussed, there are many government agencies and various stakeholders supporting the development of the biotechnology industry. The three main stakeholders in biotechnology development consist of public sector, private sector and academia. Most of the time, the public sector acted as a facilitators and funding provider especially in the early operation of the companies. Among them are MOSTI, MARDI, MITI, Technology Park Malaysia, NIBM and Malaysian Biotechnology Corporation. Under each ministry, there are specific agencies to offer different services towards biotechnology development. For example, under MOSTI, there are the National Biotechnology Directorate, MABIC, Malaysian Biotechnology Corporation, NIBM and more agencies are being established. Taking the NIBM. This agency is responsible for the performance of three research institutes namely ABI, MGI and I-Pharm. Each of these institutes focuses on different type of biotechnology. ABI focuses on agriculture, MGI focus on genome sequencing and I-Pharm on pharmaceutical research. These three agencies have been corporatized in 2011 but are still under the purview of MOSTI. There are more agencies established to cater different needs of biotechnology development.

While other countries might have problems in terms of funding, insufficient natural resources or lack of government commitments, Malaysia seems to have bigger challenges. In ensuring all the initiatives run smoothly, the government decided to establish more agencies to facilitate the growth biotechnology development focusing on different aspects such as funding bodies, import-export activities and more. This has caused fragmentation while implementing the policy. With too many agencies established, some of them have overlapped function and are often in competition to get recognitions from the government. As to date, there are more than 10 ministries and central government bodies supporting the development of biotechnology commercialisation in Malaysia. They are divided on their functional lines such as facilities, facilitation, university commercialisation, funding, import-export and private-partnership projects based on different ministries. The embeds competition among the government agencies and causes massive coordination problems and duplication of efforts in delivering the NBP. The situation demonstrates the fragmented overall nature of the Malaysian state and its systemic problems.

**8.3.2 The challenges of translating national policies at the universities level**

In this section, the researcher is aimed to explore how the research universities adapt with the National Biotechnology Policy in supporting the national agenda. The implementation of NBP in year 2005 have shaped these universities to become responsive to biotechnology research. Therefore, the second research question seek to answer what are the challenges in translating the NPB into local practices.

Since the implantation of the NBP, it has directly impacted how the research universities have worked on their R&D activities. Special provision was made in terms of the grants given to RUs to expand R&D activities until the commercialisation stage was reached, and simultaneously to encourage the universities to generate their own income. However, during the time period when this research was carried out, many structural challenges were identified in translating the NBP at the university level.

Due to the nature of bureaucracy and top-down governance in Malaysia, the RUs genuinely did not possess full autonomy of their university governance. In other words, the RUs were only able to make a few decisions as the rest of the power (autonomy) was held by the central government. For example, the decision to employ accountants, lawyers, office managers and business development manager staff in the technology transfer office. This office is very important as it deals with grants, IP, licensing etc, so it is questionable why these posts were not offered as permanent due to central government policy. Moreover, there is a flaw in terms of university support towards its staff. The work burden issue was not tackled properly where the evaluation system for yearly performance remained underdeveloped. This meant that the university lacked sufficient incentives to encourage its staff to be involved in knowledge exchange and start-ups companies. This situation arises because the universities were unable to change the evaluation system since they remain under the control of the Ministry of Higher Education. Due to this, academicians focus more on other components in the evaluation system such as publications and research rather than exploring the knowledge they produced. This clearly demonstrates how bureaucracy and top-down governance has limited the freedom of universities in making decisions.

On top of this, universities have also faced difficulties in establishing collaboration with industry as they (industry) only favoured inventions evidencing a higher technological readiness level. Most of the inventions from the university have not yet reached that stage of development. This is partly a result of the commercialisation related grants having limited availability. This situation suggests that the market for novel inventions remains small and that industry seems reluctant to invest in products with a lower technological readiness level. At the same time, the university sector is also facing competition from the public research institutes. One of the reasons may be due to a reduction in bureaucratic practices in the public research institutes compared to universities. Generally, it can be said that commercialisation policies are helping, but are unable to provide sufficient focus on staff development.  This is apparent in the academicians lacking of experience and freedom in running the start-ups companies. Without proper support in this area, it is likely that universities will be unable to sustain their start-up companies.

In relation to the Triple Helix, the function of university is not just as a place for knowledge generation but also to promote knowledge exchange and collaboration. The capitalisation of knowledge sits at the heart of a new mission for the university and involves networking more closely with knowledge users and to establish the university as an independent economic player. By becoming an entrepreneurial university, it is thus expected to take on the roles of others as highlighted in the Triple Helix model. Ideally, the entrepreneurial university is an academic institution that is under the control of neither government nor industry. However, the results from the analysis here showed otherwise. Being Malaysian public universities, it is hard to eliminate the bureaucratic, top-down and controlled culturing embedded at both national and local level in relation to the university's governance. Etzkowitz (2008) highlighted four pillars that strengthen the functions of the entrepreneurial university: (i) academic leadership; (ii) legal control over academic resources; (iii) organisational capacity of transfer technology; and (iv) an entrepreneurial ideology embedded among administrators, faculty and students.

Among the four pillars mentioned above, it can be said that the RU possessed pillar number one: academic leadership. From the analysis, it can be seen that most of the academics regardless of their position agree that the universities are doing their best in helping the scientists to pursue their R&D until the commercialisation stage. However, the results of this are still limited. The second pillar highlighted the university governance over academic resources. For this point, it can be said that it is only partially true. The findings show that the universities only have partial autonomy over their governance, as demonstrated by the inability to create a permanent position in the technology transfer office. Furthermore, the universities lacked the authority to adjust the reward structures to accommodate the expansion of traditional university roles into those needed for an entrepreneurial university.

The third pillar focuses on the university capacity to transfer technology through patenting, licensing and incubation. Despite the existence of various agencies at the national level (e.g. BioMalaysia Corporation) and university level (e.g. technology transfer office and Symbiosis Programme), the process of technology transfer appears difficult due to the existence of a bureaucratic, top-down and controlling culture embedded within universities. The fourth pillar highlights a need for the same entrepreneurial spirit across all levels within universities. It can be said that university staff are aware of this notion. However, the lack of university support (e.g. workload burden) has hindered the ability of academics to further engage in this activity. At worst, researchers seldom see real benefits from their labour because the incentives for industrial partnerships and the commercialisation of research outputs is always skewed to benefit industry and government (Sarpong, Abd Razak, *et al.*, 2017).

The universities have tried to evolve from their traditional role to become more entrepreneurial institutions by engaging in knowledge exchange, creating start-ups companies and developing public-private partnership.  However, this mission is very challenging considering that universities are bound to follow all the government-set guidelines relating to their traditional role in education. Although the research universities attempt to participate in knowledge exchange and starting companies, but this does not qualified them to be viewed as entrepreneurial universities    As they only partially possess the four pillars that strengthen the functions of the entrepreneurial university as identified by Etzkowitz (2008).

### 8.3.3 The roles of university and national based policies in supporting the commercialisation activities of start-up companies.

The previous subsections (8.3.1 and 8.3.2) have discussed the roles of national agency and research universities in supporting the national agenda to spur biotechnology commercialisation. Therefore, in this section, the question is set to investigate how do these local practices support knowledge transfer and the commercialisation of biotechnology?

In answering this question, one of the things that should be understood is that the start-up companies are located in a different spiral from both government and university, it is indeed the bridge connecting government, university and industry. This means that the start-ups are parts of the industry. They are the small players and the subset of the industry.

The interview participants felt that the most crucial aspect in getting a product into the market is financial support. Without sufficient investment it is difficult for start-up companies to engage in upscaling activities. In most cases, the start-up company could not afford the cost of upscaling their product(s). Regardless of whether the company is university-based or not, the root problem is the same when it comes to investment. The wider industry is reluctant to invest in university products and collaborate with start-up companies. This may be explained via two possible mechanisms: the commercialisation process itself; and barriers in communication.

Firstly, the process of getting the product into the market involves various stages some of which are lengthy. As mentioned previously, financial support is the biggest hurdle in pursuing scaling up activities. Most of the time, the procedures involved in applying and obtaining grants are rigid and time consuming (Cirillo, Breschi and Prencipe, 2018). This is due to the bureaucratic culture embedded at the national level, this slows down the entry of university biotechnology product reaching the market. Secondly, the goals of university and industry are different when dealing with commercialisation. The university placed the emphasis on obtaining full data on of the product such as the result of tested in field trial, while the fund provider or investor valued the income generated from the product (Al-Tabbaa and Ankrah, 2016). Although their goal is to make profit from the R&D product, the university and industry have different ways of how things should be done in generating the income. That is why some big companies choose public research institutes as they are less bureaucratic compared to universities.

On top of that, the small market for biotechnology product also slows down the activities. There are only small group of citizens consumer who can afford to buy products based on biotechnology such as the supplements considering the price of the product. Therefore, buying expensive product is not usual. Furthermore, Malaysian is a middle average income country, thus explaining the small market of citizen consumer. For industry consumer, the same is true as most farmers have limited resources and are reluctant to invest in biotechnology.

In answering the third research question, it can be seen that both national and local policies on commercialisation are not really helping the commercialisation activities. The policies seem to be working on paper but in reality, it does not produce a positive impact. The policies are unable to work effectively due to bureaucratic practices and the command-and-control culture. Indeed, the policies seem to make the procedures more difficult for academics to further explore in knowledge capitalisation and the start-up companies to speed up their commercialisation activities. The overall weakness of the Malaysian biotechnology industry and the lack of other sources of finance mean that entrepreneurs and starts up are totally dependent on government support.

Etzkowitz (2008) highlighted three sets of factors deemed essential to the development of knowledge-based firms and growth: (a) human capital factors; (b) material factors; and (c) organisational factors. Human factors emphasise the importance of having: (i) a critical mass of scientists and engineers linked through social networks; (ii) research groups in areas of potential commercialisation; and (iii) a pool of scientist and engineers interested in forming their own firms. For the first point in the human factor, although Malaysia has a critical mass of scientist and engineers in universities, but they are not connected with others from the industry. This setting demonstrates that the scientists and engineers are connected through cluster but limited in their own environment. The second and third aspects are fulfilled by the function of RU where universities are regarded as knowledge generators and have the interest to exploit the knowledge. As a matter of fact, the research universities have a large number of experienced scientists working on biotechnology topics that have the potential to be exploited. However, this factor alone unable to guarantee the successful sustainable university start-ups.

The second factor regards material resources. In order for firms to functions smoothly, they must have the: (i) availability of seed capital from private or governmental sources; (ii) inexpensive and appropriate space for new firms; and (iii) equipment, ranging from multimedia computers to prototype biotechnology plants. From the analysis, the seed capital is available but limited and it clearly demonstrated that start-up companies lack capital and struggle to get financial assistance to support their scale-up activities. In terms of space, the government has fulfilled this through its ‘Symbiosis Programme’, which serves as an incubator for new university start-up companies. The companies also suffer in finding the equipment necessary to run their up-scaling activities. Since it involves high capital costs, such companies have to rent the equipment but it seems that the equipment available in universities and government agencies is often limited or unsuitable. Within industry, the company manager cannot delay production, but they have the ability to decide to outsource the process. However, high costs will be incurred if they continue to rent in a long period. Furthermore, the requirement to obtain 'BioNexus' status forces the product to be processed with 'GMP' status is quite a burden for new start-up companies.

The last enabling condition relates to organisational factors. There are four conditions here namely: (i) opportunities to learn business skills; (ii) flexible university policy design; (iii) facilitation from the research institutes; and (iv) residential community to attract a skilled population (Cai, Pugh and Liu, 2015). This research shows that the universities and national agencies in Malaysia offer four out of the five of the conditions listed above, but there is still room for improvement. The opportunities and facilitation to learn business skills exist, but different company managers require different forms of training. This is the same with the academics involved in these activities. Although facilitation is given, company managers still lack experience. This is one of the biggest hurdles faced by them. In terms of university policy design, it is clearly demonstrated that the current policies are inflexible. The company managers are not given enough freedom when it comes to commercialisation strategies and this has discouraged innovation to happen. When the policies are too rigid, procedures become too tight and it is hard for the start-up companies to keep up with these requirements. The fourth factor explaining the cultural, scenic and/or recreational resources that can attract and hold a population who are willing to work in the start-up company. This last condition is not discussed here as it is not directly related to the research.

In short, it can be said that the policies at national and university level are unable to support the research university in creating more start-up companies. The policies are unable to provide a framework that is flexible enough for the research university to explore biotechnology industry. From the overall analysis, it is clearly demonstrated that Malaysia has good quantity of scientist and engineers but they are not connected to government agencies, universities and the biotechnology industry. The networking activities are limited to their own institutions and this suggested that the biotechnology network as a whole is weak. In terms of material factors, the government has provided seed funding, research equipment and incubators but these are not enough to cater for the needs of university start-ups companies. The government has strict procedures in giving the funding and at the same time has established high regulations of these start-up companies. Due to this, the start-ups are having difficulties in up-scaling their business. In relation to the last condition, it is found that the university is unable to formulate a commercialisation policy that suits the need of its academic staff.

### 8.3.4 How might the successes and limitations of national and local policy be conceptualized in terms of the Triple helix model of innovation.

The Triple Helix model consist of three actors: government; university; and industry. From the previous discussion, it can be seen that the government is the prime mover of commercialisation activities in Malaysia. It is the government that provides financial support, facilities, and facilitation to the start-ups, while the research universities act as a knowledge producer and source of human capital. The third actor is industry but biotechnology firms are generally small and immature in Malaysia. Each of these actors have their own main roles in commercialisation activities and their own unique characteristics which distinguish them from one another. Although they are different, according to this model they have the capability to take the roles of each other. The below diagram (diagram 8.2) shows how these three elements of the Triple Helix connected and can take on the roles of other.

**Diagram 8.2: The interdependencies of government, university and industry**

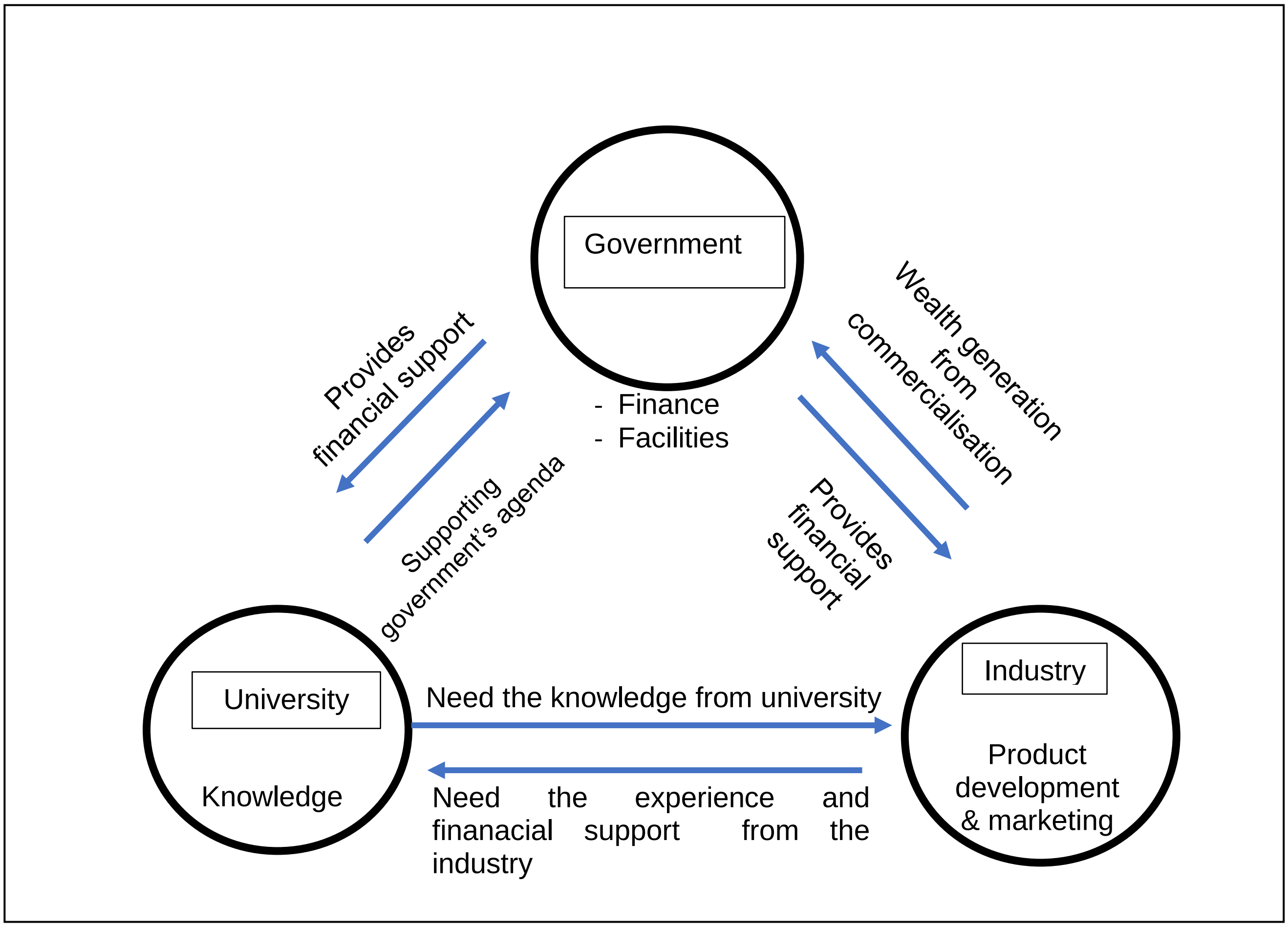



Diagram 8.2 shows the interdependence of each actor towards the others in supporting the biotechnology agenda. The above discussion has portrayed the interdependencies of these three actors in spurring biotechnology activities. The government provides finances support and facilities to universities and industry through grants and the establishment biotechnology related agencies. In return, the universities will continuously support the government agendas and the industry will repay the government initiatives through tax payment from product sales. In a different angle, the universities as a knowledge generator will provides human capital and knowledge to fulfil the employment in government and industry. It is also important to note here that the university does not only provides the human capital but also provide consultation

and facilities for the industry related to advanced knowledge in specific area. This is because, not all firms in the biotechnology industry have their in-house labs. For those SMEs, they will need the expertise from the universities in running their R&D activities. In return, the industry will provide funding to support the university's R&D activity.

As can be seen, the government provides an environment suitable for commercialisation, but lacks the knowledge for capitalisation and skills to run a business and this dearth can be filled by universities roles and the creation of the start-ups. The university has the knowledge but lacks infrastructures and skills necessary to capitalise on the knowledge. This explained the need of government in providing the infrastructure and experience in product development from the industry. The third element is the start-up company; they are good at exploiting knowledge but lack in terms of facilities and knowledge. Therefore, the start-up companies need support from the government and universities. As clearly demonstrated in the above discussion, the connection of G-U-I in Malaysia resembles the static model of the Triple Helix. This emphasized the roles of government in navigating the biotechnology activities in the country.

The overview represents the connection between the three actors but to determines the key structural features of the Malaysia Triple Helix, the strength and weaknesses of each actors need to be analysed. This is done in Table 8.1 below.

**Table 8.1: The strength and weaknesses of the actors related to Triple helix in biotechnology commercialization**

| Actor | Strengths | Weaknesses |
|---|---|---|
| **Government Providing commercialisation environment** | - Monetary provider<br>- Provides infrastructures and facilitation<br>- Diverse network<br>- Command-and-control administration<br>- Owns the natural resources<br>- Full autonomy on policy planning | - Bureaucracy<br>- Top-down and controlling administration<br>- Fragmented structure and coordination<br>- working in silos |
| **University Source of knowledge** | - Knowledge generator<br>- Pool of talented scientist<br>- Experienced scientists<br>- High-quality control working culture<br>- Special R&D monetary support<br>- Incubation facilities<br>- Technology Transfer Office | - Partial autonomy<br>- Top-down administrative culture<br>- Workload burden<br>- Underdeveloped incentives system<br>- Inflexible university governance |
| **Industry** | - Business expertise<br>- Profit generator<br>- Fast working culture<br>- Owns capital<br>- Eager for successful result<br>- Willing to learn | - Immature industry of mainly small firms<br>- Undercapitalised<br>- Small market for products and some monopoly<br>- Focus on trading with limited risk taking |

The table above highlights a number of key systemic and structural features that are a feature of the Malaysian Triple Helix. The government plays the central role and has made a major commitment to developing biotechnology. It is able to do this given the highly centralised nature of Malaysian government. Policy is comprehensive but implementation is hampered by the fragmented structure of state agencies and the competition between them. The top-down command and control culture makes it difficult for central authorities to respond to local needs, making it difficult for firms and academics to fully benefit from the resources supplied by the government. In contrast, other countries (e.g. UK) with a more co-ordinated and flexible policy culture are better able to support local innovators.

The research universities reflect a serious attempt to change the culture in Malaysian higher education to support entrepreneurship and many initiatives support this strategy. However, the lack of full autonomy and the authoritarian and centralised administrative culture limit how effective these policies are. This is reflected in the problems industry managers have in working with Rus. The weakest element of the Malaysian Triple Helix is the biotechnology industry. Its small size and immaturity mean that it is limited in its capacity to commercialize university research. The small markets (consumer and agricultural) also limit the capacity of firms to profit from their products and lead firms to prioritise market ready products. However, the most important feature is the lack of private finance, making the biotechnology industry dependent on the government.

The interactions between these three actors are therefore shaped by these structural features of the Malaysian state, the organisation of universities and the limited size and capacity of the industry. From the analysis, it can be seen how these three actors accept, process and react to the biotechnology agenda. Undoubtfully, these three actors have fully accepted the agenda sets by the government, however the lack of entrepreneurial foundation, inflexible policies, unattractive incentives and limited investment from the industry had cause difficulties in producing desirable result such as generating the wealth. This condition had cause academics, company managers and industry to become less motivated to involve in biotechnology commercialisation. The most affected actors in this framework are the academicians as they received pressure from the government and industry. The academics are forced to involve in knowledge exploitation activities without they themselves having right business foundation and experience. At the same time, they are encouraged to tie a collaboration with the industry as part of their yearly performance evaluation although the mechanism in determining the marks in commercialisation activities are still underdeveloped.

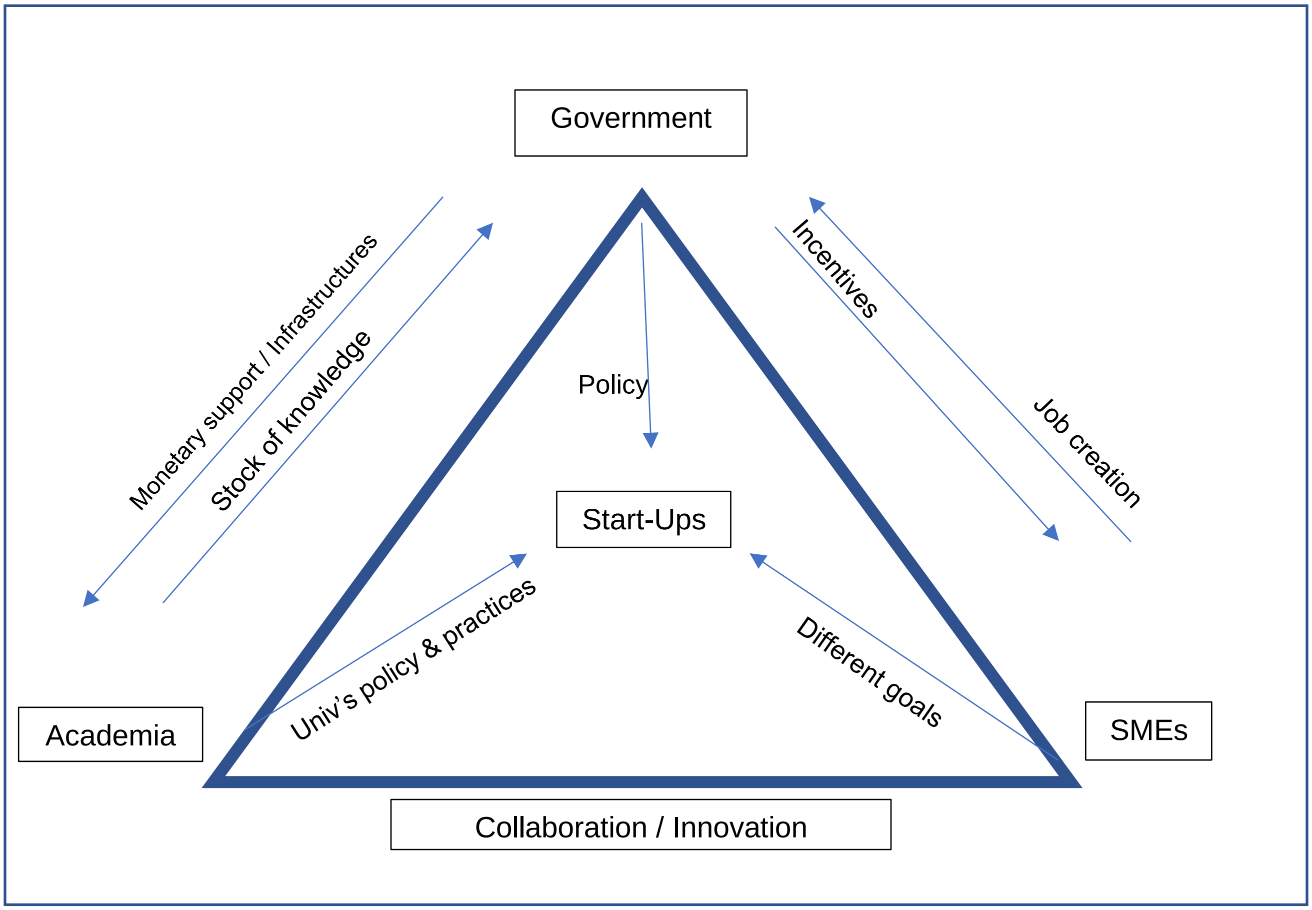
The industry reluctant to invest in the spin-out company as they carry high risk of failure. Furthermore, there are only little or no incentives offered by the government for investing in these spin-off company.  Thus, from the analysis, it can be highlighted that the basic foundation of entrepreneurship is weak at the national, university and industry level.

**Interaction between the helices**

Collaboration between industry and university faces significant challenges. While universities are primarily driven to create new knowledge and to educate, private firms are focused on capturing valuable knowledge that can be leveraged for competitive advantage. Furthermore, universities are becoming increasingly proactive managers of their collaborations with industry, seeking to create valuable intellectual property to foster technology and knowledge transfer.

Interaction between university, industry and government is key to innovation and growth in a knowledge-based economy. Ideally, the successful Triple Helix, will work when the university-industry-government closely interacts with each other and this is facilitated by intermediaries such as venture capital firms, incubators, and science parks. These social inventions are hybrid organisations that embody elements of the Triple Helix in their DNA. Universities, firms, and governments each take the role of the other in Triple Helix interactions even as they maintain their primary roles and distinct identities. The university takes the role of industry by stimulating the development of new firms from research, introducing the capitalisation of knowledge as an academic goal. Firms develop training to ever higher levels and share knowledge through joint ventures, acting a bit like universities. Governments act as public venture capitalists while continuing their regulatory activities. Diagram 8.3 shows the ideal interactions of G-U-I and their roles.

**Diagram 8.3: Interactions of government-university-industry as evidenced in this research**




As they take on the role of each other, each institutions maintains its primary role and distinct identity. The government is expected to intervene into the system only when an activity cannot be provided by the market. It is on the basis of this argument of market failure that the government may provide funds to the university to support research because the private sector will not meet that need (Etzkowitz, 2008). Since it would not take place otherwise, it is accepted that this is an important role for government. The universities keep their traditional roles of teaching and research but also devotes effort to enable the capitalisation of knowledge, patents, and start-up companies, while firms continue to produce goods and services and also act as a source of funds for small companies such as the university start-ups.

At this point, it is clearly demonstrated that Malaysia adopted the Statist model of Triple Helix where the government is the prime mover of biotechnology development. In this context, these results suggest that the slow development in commercialisation was also a result of poor enabling conditions that facilitate the Triple Helix interactions of government, university and industry. These conditions are either tangible (in the technical environment) or intangible (in the institutional environment) (Cai & Etzkowitz, 2020).

There are four elements of tangible conditions to ensure the smooth interactions between G-U-I. These are: (i) competencies of universities in knowledge and technology generation and diffusion; (ii) absorptive capacity and demand of industry and innovator for knowledge and technology; (iii) supportive infrastructures including policy and fiscal measures; and (iv) visionary leaders. Looking back at the analytical findings in Chapters five, six and seven, it can be seen that the most obvious missing condition is supporting infrastructures, referring to policy set at the national and local level, and appropriate fiscal measures. The policies would work better if the bureaucratic hurdles in both government and university actors were reduced and there was better co-ordination. The policies set at the national and local level are inflexible in encouraging more academics to become involved in commercialisation and allowing business managers to fully commercialise the university invention(s).

The second condition in the Triple Helix is its intangible conditions. This refers to seven logics that are aligned with the activities of a balanced model of the Triple Helix (Cai, Pugh and Liu, 2015). These logics are: (i) shared beliefs in knowledge as a key to economic growth; (ii) market oriented organisational culture (but limited in most universities); (iii) effective intellectual property protection system; (iv) strong sense of competition; (v) process management in knowledge production; (vi) civil society; and (vii) democratic policy making (Cai, Pugh and Liu, 2015) .

Out of these seven logics, the most striking element that reduces commercialisation activity is democratic policy making. Due to the command-and-control culture and bureaucratic practices in both government and university governance, fully democratic policy making is most unlikely to happen. The bureaucratic practices result in procedures consuming a large amount of time and resources, thus delaying progress to ensure compliance with all government requirements involving the funding and regulating body (Al-Tabbaa and Ankrah, 2016).

## 8.4 Contribution of the study

This study has contributed to the existing body of literature on commercialisation. This study aims to address the gaps in the current body of literature on commercialisation by investigating the main success characteristics that are thought to impact the success of commercialisation research in the specific context of Malaysia. The comprehensive identification of all essential variables has significant importance, as prior studies (see Arujanan and Singaram, 2018; Afzal *et al.,* 2017; Basarudin *et al.*, 2016) only primarily focused on examining individual success factors in isolation when assessing the success of commercialisation endeavours.

The current study addresses the existing research gap in the field of knowledge transfer as previously identified by multiple scholars who recommended greater investigation in the realm of commercialisation. The primary area of interest for many researchers has been the inadequate execution of the NBP policy (Ahamat, 2013; Amin *et al*., 2011). Their investigations revealed that the exchange of knowledge between government, universities, and industry is crucial for the attainment of a developed nation through the commercialisation of biotechnology.

Previous researchers have identified several factors contributing to the sluggish progress of biotechnology commercialisation in Malaysia. However, limited research has been undertaken to investigate the dynamics between the government, universities, and industry in their efforts to facilitate biotechnology commercialisation specifically within research universities. The present study has provided a theoretical contribution to the existing body of literature by producing a conceptual framework that connects the Triple Helix model with biotechnology. Therefore, the first contribution is this study examines the interplay between the government, university, and industrial sectors in Malaysia with regards to their collaborative efforts in facilitating knowledge transfer and promoting the commercialisation of biotechnology. This study significantly contributes to the comprehension of the empirical data regarding the interplay among government, universities, and industry.

Secondly, the present study's findings have brought attention to certain systemic weaknesses pertaining to the interactions among the three primary players, a subject that has not been previously explored by researchers. The presence of systemic problems in the country's communication is attributed to the prevalence of a top-down governing style and a command and control culture. The manner in which governance is administered has had an impact on the interagency dynamics at the national level. The contacts pose challenges due to the need to navigate across institutional and political barriers. This observation indicates a lack of effective coordination and a fragmented approach in the pursuit of commercialisation, as various agencies are engaged in competitive behaviour with one another.

Thirdly, the present study addresses an important gap in the field of policy creation. As elucidated in section 8.3, the sluggish advancement of biotechnology commercialisation can be attributed to the inadequacies embedded in the NBP design. Several factors contribute to this issue, including the absence of adequate support mechanisms at the university level, limited government support, and financial limits. The policy was formulated with ambitious intentions to generate wealth through biotechnology over a span of 15 years, although the country is still new and immature in terms of its market, capital, capabilities and facilities in biotechnology.

Moreover, this study contributes to the existing body of research on policy implementation. Given that the NBP did not meet the objective outlined in the blueprint, according to the research findings of this study, it appears that the policy's implementation was only partially successful. This research indicates that the NBP evidenced limited success in getting academics to effectively translate their knowledge discoveries into commercial products. Additionally, firm managers expressed a lack of motivation to actively pursue commercialisation activities. This attributed to the weak policy design that failed to recognise the significance of start-up enterprises in facilitating biotechnology commercialisation in Malaysia. The current policy and regulatory framework, as well as the institutions tasked with aiding the industry, appear to exhibit a bias towards existing companies at the expense of start-up enterprises. The findings of this study contribute to the existing body of information about commercialisation, knowledge transfer, and the interactions occurring during the three stages of implementation: national, university, and industry.

This study offers insights from the viewpoints of the government, universities, and start-up enterprises. The combination of perspectives from various stakeholders has facilitated an enhanced understanding of the process of commercialisation within the context of start-up enterprises. This is yet another important contribution made by this study. The extant body of scholarly work (see Arujanan, 2016; Saruan *et al.*, 2015; Abuduxike, Aljunid and Sulong, 2012) primarily concentrated on investigating universities, research institutes, or the industry, while neglecting the investigation of national biotechnology agencies and their involvement. The aforementioned approach has been regarded as a constraint in previous studies, particularly due to the significance of incorporating perspectives from both sides, as they are actively engaged in generating the results of the study (see Teo and Tat, 2019; Mokhtar and Mahalingam, 2017; Nordin *et. al*, 2016). Hence, it is believed that this study has made a theoretical contribution to the existing body of literature.

The aim of this research is to improve the current NBP to promote biotechnology commercialisation, including encouraging close relationships with the actors, i.e., government, university, and industry. Biotechnology agencies such as BiotechCorp, National Institutes of Biotechnology Malaysia (NIBM), Agro-Biotechnology Institute Malaysia (ABI), and Malaysian Technology Development Corporation (MTDC) will benefit from this research as it provides feedback from academic researchers and start-up company managers regarding NBP implementation. This bottom-up approach could provide the best mechanism for the biotechnology industry to grow. At the university level, the top management of the research universities and Ministry of Higher Education (MOHE) could use this research to revise current governance practices to fit with the national biotechnology agenda. It is also expected that there will be more products and spin-off companies from the research universities once the barriers to commercialisation activities have been reduced.

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In order for biotechnology commercialisation to grow and add to the national economy, Malaysia needs to develop a strong model based on multiple attributes where innovation in terms of collaborations, support mechanisms, accessibility of funding, government policies, and market needs should be made. Failure to improvise on the slow development of this sector will only delay the country's goal to go global as stipulated in the NBP and generate the biotechnology industry as the third wealth engine of Malaysia.

### 8.4.1 Policy contributions

This approach in this thesis is complementary to other studies (Ahamat, 2013) that attempt to illuminate the barriers to entrepreneurial activity within a nation. Furthermore, at the policy level, this study offers a coherent summary of evidence regarding interventions that stakeholders can use in assessing and considering whether to introduce and/or redesign government policies to enhance biotech research and commercialisation activity among scientists and others. This thesis highlights not only what is known but also what is unknown concerning government intervention. This is made possible from the data of the respondents' interviewed. This information can be used by those who seek to shape policy, particularly

Malaysians themselves, including scientists, and by scholars who seek to understand the nature and impact of government's intervention. Additionally, this study contributes by providing opportunity to gauge the extent to which government policies have coevolved, conflict and/or complement each other. Many countries including Malaysia are now contemplating what else they need to do to promote a vibrant entrepreneurship culture. Most entrepreneurial development initiatives continue to be built around programmes to enhance individuals' competency skills, integrate entrepreneurship into national economic development efforts, use the education system to encourage future entrepreneurs, incubate entrepreneurial firms, invest in diverse sources of activities as well as creating the infrastructures and a competitive tax policy and regulatory climate.

## 8.5 Recommendations

When examining the commercialisation activities in research university in Malaysia, this study identified weak implementation of commercialisation policies as a main area of concern. This included the implementation of the policy at national and university. This has caused slow commercialisation activities at research university particularly. Given this finding, I would like to suggest recommendation to the three main actors in the Triple Helix involved in this research.

### 8.5.1 Government

As discussed in Chapter 5, Malaysia has a unique and complex structure of government agencies. The Ministry of Science, Technology and Innovation had established many government agencies in supporting the agenda of creating wealth through biotechnology commercialisation. In addition to lack of awareness, coordination is found to be limited which leads to sector fragmentation with overlaps, inefficiencies and redundancy. Given this, it is difficult to ensure the engagement and coordination among the biotechnology agencies at the national level. As a consequence, the agencies are unable to deliver its good support services at both national and local (university) level.

As a recommendation, there should be a massive reorganisation of the biotechnology-related national agencies. At the moment, there are so many agencies at national level, various initiatives and programmes aimed at biotechnology companies and universities. Due to many ministries and agencies involve, this has causes massive coordination problem. First, in order to address these issues, the government should reduce its centralised control model in the administration of innovation policy. Previously, the government had established PEMUDAH (Malay translation: Pasukan Petugas Khas Pemudahcara Perniagaan) or the Special Task Force to Facilitate Business to help the SMEs in empowering their activities. Among the values of PEMUDAH is providing proactive public-private sector collaboration, providing facilitation, reducing the unnecessary regulations and practicing zero tolerance for corruption (PEMUDAH, 2022). However, this agency is dealing with SMEs and established companies but is not specifically aimed at start-up companies. Therefore, it is recommended to have special unit focusing on start-ups in this agency to help the MSME (micro, small and medium enterprises) in sustaining their business. Here the emphasis would be on supporting new firms to get access to the resources provided by the government.

Secondly, in terms of engagement and coordination, the government should convince the agencies related to biotechnology commercialisation activities to make the transition into the corporatize companies as proposed in previous policy. The Ministry of Science, Technology and Innovation should communicate and explain why this transition is needed and how it will impact the employees. The employees should be given the opportunity to express their worries to their senior management and management should seek ways to achieve mutual agreement between the new roles of corporatized organisations and the needs of the employee.

Thirdly, in term of coordination, it is suggested that the government should reduce its bureaucracy practices. As previously known, biotechnology is a cross-cutting disciplinary activities, and when it comes to research and commercialisation, it requires the participation from more than one agency to monitor the project. The engagement between government agencies is difficult due to the bureaucratic practiced in each of the agencies. This would help reduce the extent to which agencies work in silos and reduce redundancy in handling the commercialisation activities of start-ups or companies. The coordination is a good thing to coordinate the agencies into concerted efforts for biotechnology, however, take into account that Malaysia administration system is highly centralised control, thus having too many ministries and agencies cause a lot of fragmentation in terms of cooperation and coordination among the agencies. Therefore, it is suggested that all these agencies are listed and group into their similarities. This can reduce redundancy among their roles and as number of agencies are reduce, this will improve the coordination issues.

### 8.5.2 Research universities

In research university settings, there are three main challenges in pursuing commercialisation activities. They are the academic work burden, the evaluation of the current reward system and the centralised control model practices in the university. In terms of academic work burden, the university should provide two different modes of planning. Those who are interested in doing commercialisation can choose a commercialisation mode that allows more time flexibility in handling research and knowledge exchange and their work burden for teaching should be decrease. This option will allow those who are interested in commercialisation to be evaluated more fairly. However, reducing the academic work burden alone is not enough to spur biotechnology knowledge exploitation activities. The university should improvise their reward system in the yearly performance evaluation. Both these changes will require the approval from the central government. To enable this the government should grant universities greater autonomy when pursuing commercialisation.

### 8.5.3 Start-ups companies

Firstly, the finding of this research showed that company managers have limited experience in the biotechnology sector and knowledge of the market. However, managers involved in the Symbiosis Programme are being equipped with such commercial knowledge making them able to better develop their companies. To address this, the training offered by the Symbiosis Programme should be expanded to cover all firms. Secondly, the university must better value the contribution made by staff involved in managing company. This means that, the academics and the university should discuss together the decisions of how to operate the business. Much greater freedom should be given to the company managers without the interference of academic scientists and university managers. By granting them the power to make decision, they will feel the company and university values their work in knowledge exchange.

As to address the limited funding available for the new companies or the spin off companies, it is suggested that the government proposed new funding mechanism that will be applicable to all Malaysians public HEIs. This study suggests further that companies in this pre-commercial industry are too depending on governments funding. Therefore, it is suggested that the government initiate a development fund aim specifically at providing long term grants and loan for new firms. This development fund would be a highly appealing option for new companies with limited operating history, which are too small to raise capital in the public markets and not sufficiently mature to secure a bank loan or complete a debt offering. To increase innovation speed, entrepreneurs have to generate positive cash flow streams to be able to repay the capital they obtained. All of these characteristics increase the start-ups entrepreneurial orientation and make them more competitive.

### 8.6 Limitation of the study

This research is subjected to number of challenges that restricted the effectiveness of the research techniques used and therefore on the reliability of the research findings. Firstly, the research was carried out as a cross-sectoral study. This study examined a particular phenomenon at a particular time. If this research was carried out as a longitudinal study, this research could collect more information on the effect of the policy before, on and after the implementation of the National Biotechnology Policy. Secondly, the sample size of the interview session is not proportionate. Although the semi-structured interview only needed a relatively small number of respondents, this can bias the findings. This was largely due to difficulties in getting access to and cooperation from the government agencies such as the policy makers involved in NBP planning and the directors of the Biotechnology Corporation. Thirdly, there are limited respondents from the research universities except for the University of Putra Malaysia. For the University of Science Malaysia, the inventions produced by the university staff are being commercialised by USains- the corporate arm of the university. During the correspondence phase with the university, the marketing manager of USains did not allow the researcher to conduct interview with the academic scientists. For the other universities such as the University of Malaya, University of Technology and National University of Malaysia, their expertise is not in agri-biotechnology.

## 8.7 Future research directions

This study has provided a good benchmark in understanding from the researchers' perspectives the requirements for a successful commercialisation of research. In conducting the future research of this study, attention should be given to each of the commercialisation key issues. Since this study is more descriptive and evaluative in nature, future research would need to validate and clarify the role of reach of these factors in contributing to the success of research commercialisation. Research in areas similar to the Malaysian context would be a good starting place.

First, a follow up studies can be conducted to bringing up to date the new findings from the agrobiotechnology sector. As this research is conducted in 2015, therefore it is expected more agrobiotechnology spin-off companies can participate in the future research. Secondly, this research can be replicated to the other biotechnology sector such as the healthcare and industrial. By conducting research on the other two sectors, a complete commercialisation biotechnology framework can be drawn. Lastly, it is also worth to investigate the financial supports provided at firms' level. By understanding types of financial supports available, the result of the study can provide a guideline for the start-up companies during grant application. The result of the study could improvise the current methods in granting the grant.

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# APPENDICES

## Appendix A

Operational Definitions

**Micro Enterprises:** Stands for micro, small and medium enterprises. The micro enterprise company is defined as a company with sales turnover of less than RM300,000 or having less than five employees.

**Small Enterprises:** Enterprise with sales turnover from RM300,000 to less than RM15 million or having between 5 and 75 employees.

**Medium Enterprises:** Enterprise with sales turnover from RM15 million up to RM50 million.

**Start-up company:** Refers to a very young company in the early stages of its development.

**Spin-off Company:** Refers to a company founded by university staff where its technology is developed by a university.

**Citizen Consumer**: Consumer who makes and purchases goods and services for personal use.

**Industry Consumer:** Also known as industrial consumer. The consumer purchases the products with the intent of using those products in the course of operating a business.

**Appendix B**

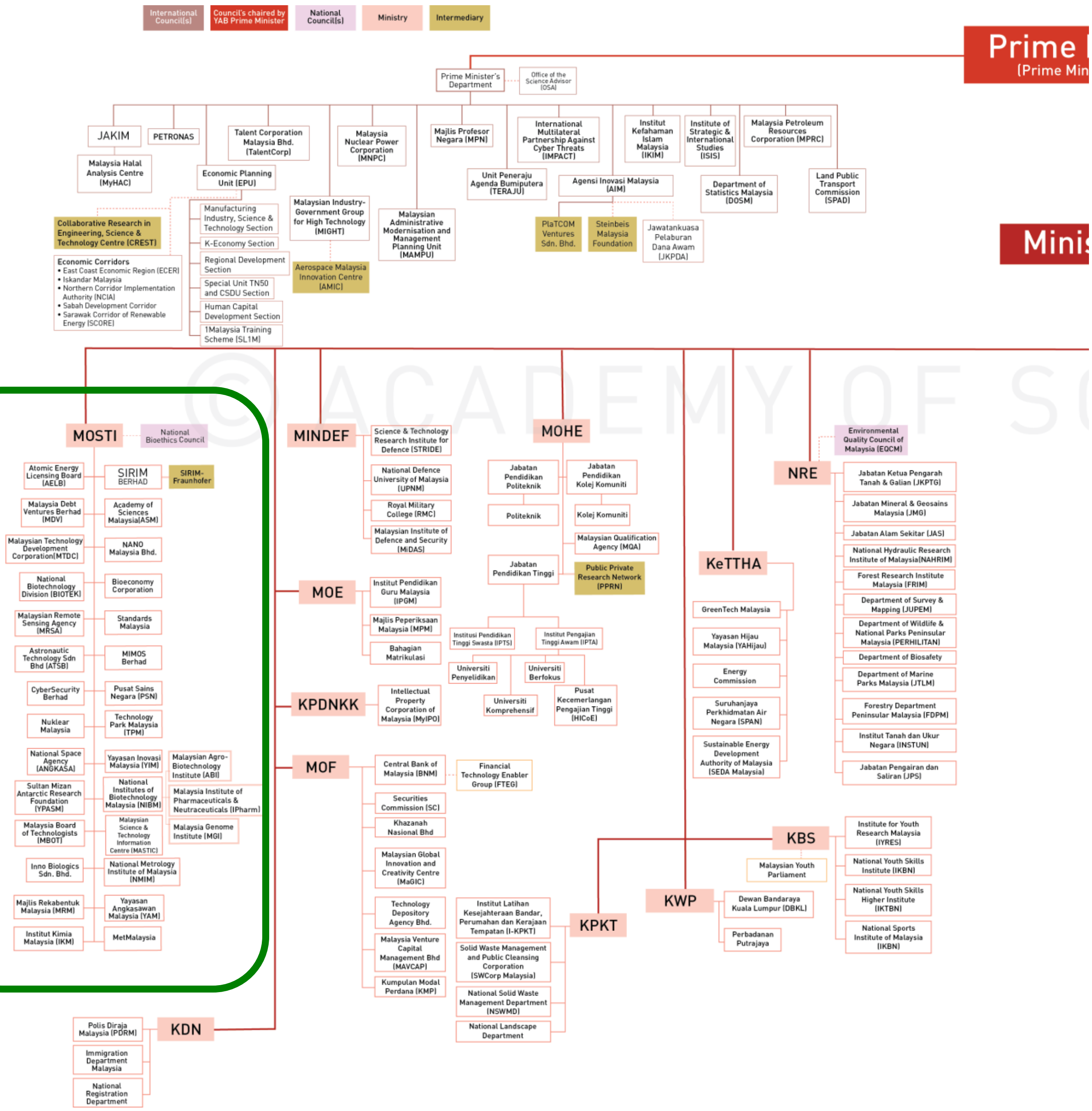
Data of informants

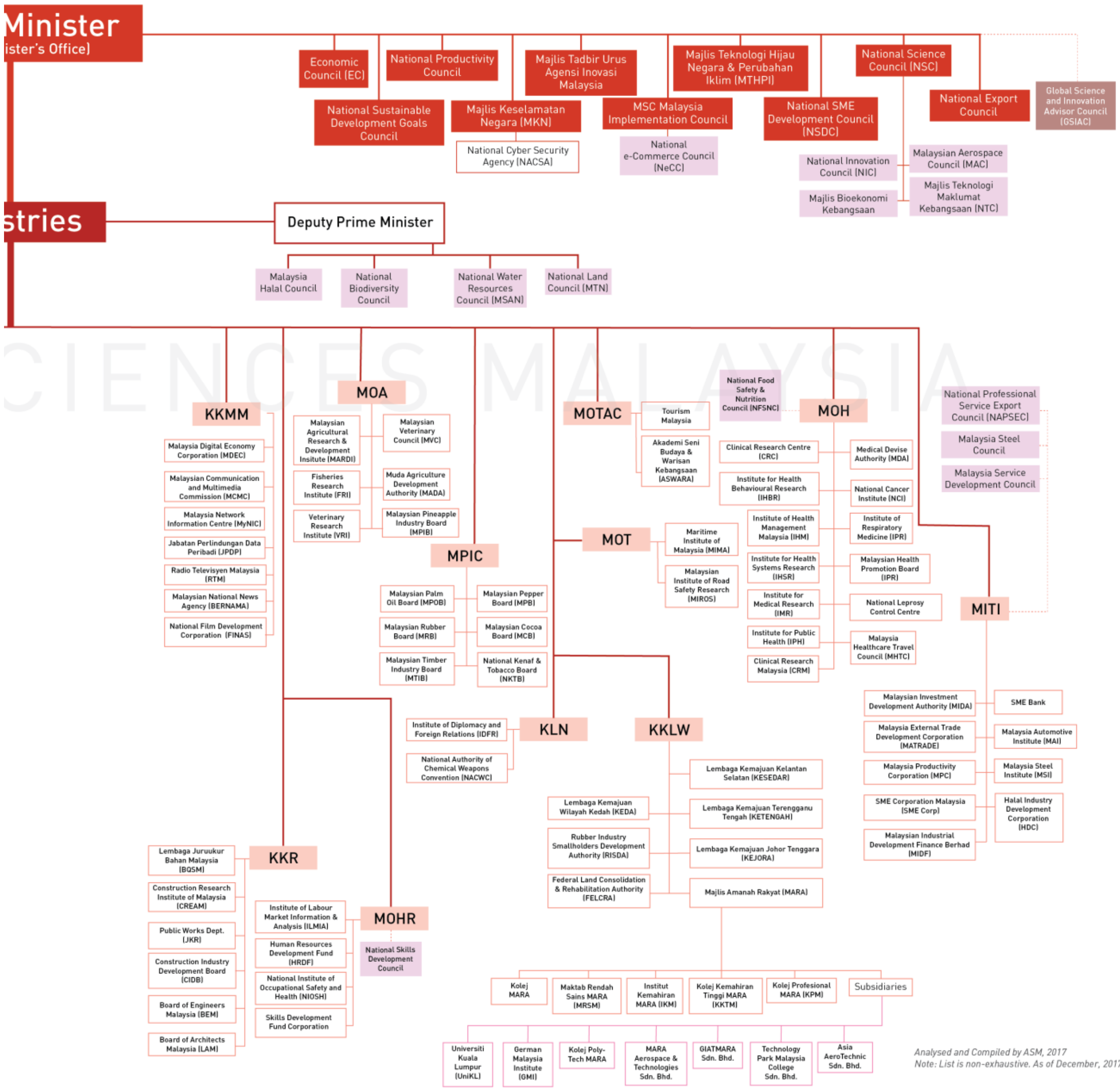
| Informant's coding | Position | From |
|---|---|---|
| R1 | Chief Assistant Secretary | MOSTI |
| R2 | Manager, Corporate Planning, Corporate Services Division | Biotech Corp |
| R3 | Business Development Manager | Biotech Corp |
| R4 | Business Development Manager | Biotech Corp |
| R5 | Director | ABI |
| R6 | Chief Operation Manager | NIBM |
| R7 | Business Development Officer | NIBM |
| R8 | Senior Vice President, University-Industry Partnership | BiotechCorp |
| R9 | Professor, Director of Research and Innovation Center | University of Technology Malaysia |
| R10 | Professor, Director of Research Management Center | University of Technology Malaysia |
| R11 | Professor, Director, Scientist, Start-up company owner | University of Technology Malaysia |
| R12 | Professor, Director, Scientist | University of Malaya |
| R13 | Professor, Head of department, Scientist | University of Putra Malaysia |
| R14 | Professor, Director of Research Management Centre, Head of Laboratory, scientist | University of Technology Malaysia |
| R15 | Professor, Director, Scientist | University of Malaya |
| R16 | Professor, Head of Department, Scientist | University of Putra Malaysia |
| R17 | Professor, Dean, Scientist | National University of Malaysia |
| R18 | Professor | University of Putra Malaysia |
| R19 | Associate Professor | University of Putra Malaysia |
| R20 | Professor, Head of Department | University of Putra Malaysia |
| R21 | Associate Professor | University of Putra Malaysia |
| R22 | Group Business & Marketing Officer | Usains |
| R23 | Technology Manager Coordinator | University of Science Malaysia |
| R24 | Technology Manager Coordinator | University of Science Malaysia |
| R25 | Senior Manager Technology transfer & commercialisation | National University of Malaysia |
| R26 | Research Officer | University of Putra Malaysia |
| R27 | Innovation Manager | University of Technology Malaysia |
| R28 | IP Manager | University of Technology Malaysia |

| | | |
|---|---|---|
| R29 | Scientist | NIBM |
| R30 | Head, Veterinary Service Division | University of Putra Malaysia mvp |
| R31 | Operation Manager | University of Putra Malaysia-mtdc |
| R32 | Managing Director | Palmgen |
| R33 | Managing director | Germibran |
| R34 | Operation Manager | HCA |
| R35 | Operation Manager | Herbal Primer |
| R36 | Director | Diversatech |
| R37 | Operation manager | Neurich |
| R38 | Chief Operating Officer/ Director, Business Development & Operations | Orchid Life |
| R39 | Senior operation manager | Al-Raudah Farm |
| R40 | Chief operating officer | CiliBangi |
| R41 | General manager | Fasclone |

**Appendix C:**

Organisational Chart of Prime Minister Office

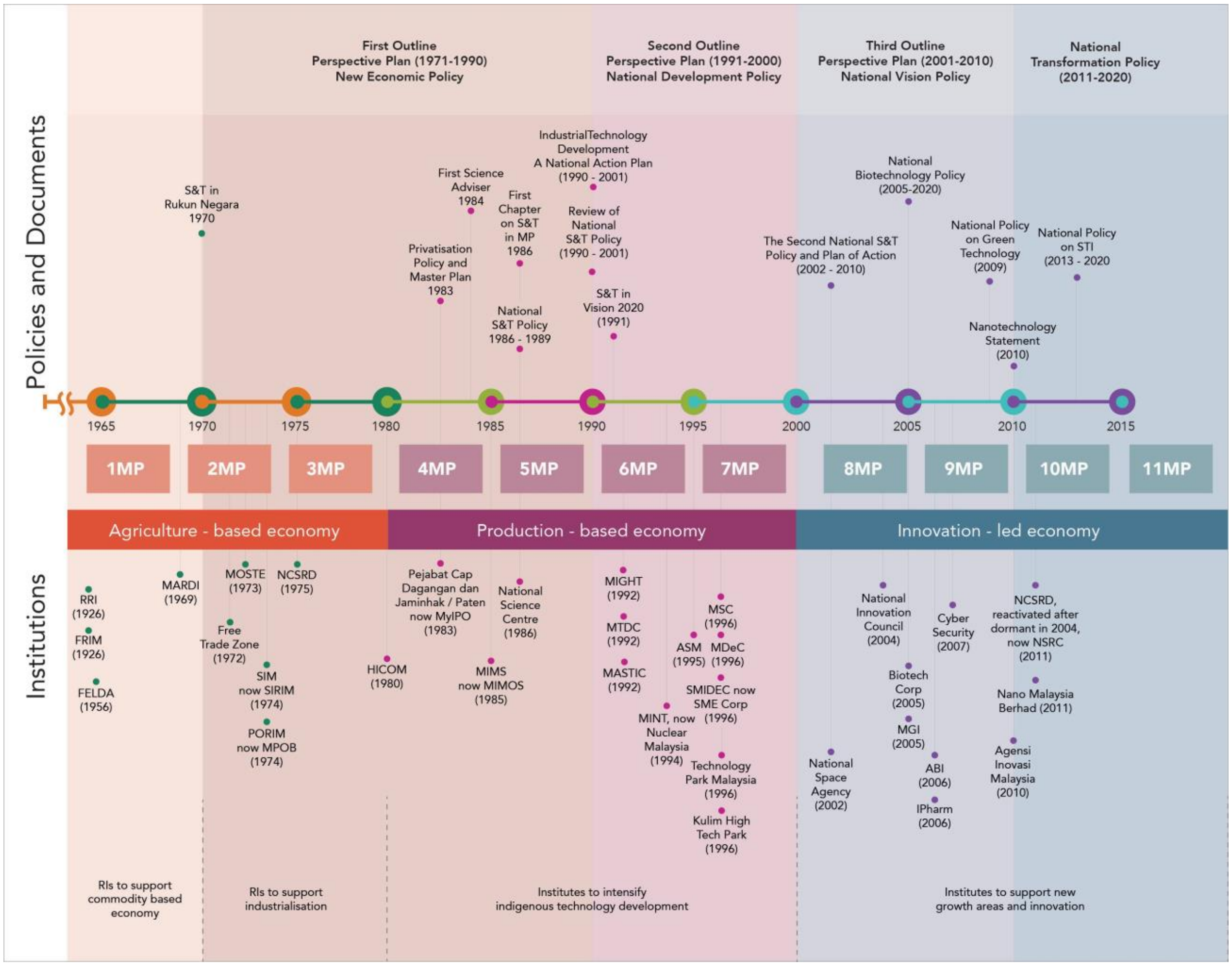





Source: (Academy of Sciences Malaysia, 2018)

## Appendix D

Malaysia's development plans from 1st MP to 11th MP




Source (Academy of Sciences Malaysia, 2017)

## Appendix E

Introduction Letter for Field Work Interview Activity in Malaysia (In Malay language)

The University Of Sheffield.

**Noor H Zainol Abidin <nhzainolabidin1@sheffield.ac.uk>**

# Kebenaran Menjalankan Kajian PhD di Mosti

14 messages

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**Noor H Zainol Abidin** <nhzainolabidin1@sheffield.ac.uk> 4 June 2014 at 23:06

To: jamil@mosti.gov.my, khalidah@mosti.gov.my

Assalamualaikum,

Y. Bhg Dato' Mohd Jamil b. Maah
Puan Noor Khalidah bt. Md Khalid,

Salam sejahtera.
Saya, Noor Hanis binti Zainol Abidin pelajar dari Universiti of Sheffield ingin membuat lapangan kerja di Malaysia pada bulan Julai 2014.

Untuk makluman Y.Bhg. Dato' dan Puan, saya merupakan pelajar tahun kedua doktor falsafah di University of Sheffield, United Kindgom. Kajian saya bertajuk 'The roles of national and local policy and practices in support knowledge transfer and commercialisation of biotechnology in Malaysia' yang akan mengupas isu-isu tentang masalah pengkomersilan R&D yang dihadapi oleh syarikat terbitan universiti (spin-offs company) di Malaysia. Kajian ini juga akan mangkaji sejauh manakah polisi di peringkat nasional atau universiti dapat membantu syarikat terbitan universiti ini berjaya dan berkembang. Oleh itu, pandangan daripada penggubal dasar sangat penting bagi kajian ini.

Bersama-sama dengan ini saya lampirkan pengesahan etika, proposal dan juga lembaran maklumat tentang kajian ini untuk rujukan pihak Y.Bhg. Dato' dan Puan. Bersama-sama ini saya lampirkan:

1) Surat memohon kebenaran untuk menjalankan kajian Ph.D di Malaysia
2) Pengesahan Etika dari pihak University of Sheffield
3) Proposal kajian
4) Lembaran maklumat tentang kajian

Saya boleh dihubungi melalui alamat email ini atau noorhanisza@yahoo.com atau melalui telefon : +44730 325 361

Segala perhatian dari pihak tuan/puan didahului dengan ucapan terima kasih.

Yang benar,
Noor Hanis binti Zainol Abidin
Department of Sociological Studies
University of Sheffield

## Appendix F

Participant's Information Sheet

| The University Of Sheffield. | Participant's Information Sheet |
|---|---|

**Title: The roles of national and local policy and practices in support knowledge transfer and commercialisation of biotechnology in Malaysia'.**

Background and aim of the research:

Malaysia is among the late-industrializing countries but recently changed its direction to become 'fast follower'in innovation strategy. Various policies, programs and initiatives have been implemented to achieve the high income nation status by the year 2020. Believing biotechnology sector will become the new growth engine forthe nation, this study will explore the roles of National Biotech Policy and National Science and Technology Policy 2 in supporting the commercialization of biotechnology industry in Malaysia. In this project, focus will begiven to the biotechnology products commercialized by spin-offs and start-ups companies in Malaysia. In short, this project is interested in reviewing the policy area and identifying the critical issues found in its implementation.

Participation recruitment:
The participant will be chosen based on the position, experiences and length of services in the policy making process. During the interview session, the participant can choose not to answer, or withdraw the participation at any time without having giving any reason for it.

Information needed from the participant:
Among the needed information including what is the implicit reasons of choosing biotechnology sector as newwealth generator, the current condition of biotechnology industry in Malaysia and how the National Biotech Policy can fits the national aim to become a high income nation by the year 2020. It is estimated the interview session will take around 40 minutes to 60 minutes for each session.

What will happen to the results of the research project?
To further address this question, the researcher will be sensitive in handling the participants' information. The recorded information will be anonymised, transcribed, and kept confidentially in accordance with the University ethics principles and the British Sociological Association's code of ethics. Instead of usinganonymised name, the researcher will address the participants by using standardized job titles to protect theirinvolvement in the project. Particular segments will be deleted if the information leads to the identification of the participant. Approval from the participants will be sought if the researcher has an intention to use this information for further project (eg. Journal publication or conference).

Impact of the project:
It is hoped the result of this project will able to identify the critical issues for debate and reform in the implementation of the policy either at national and local level. The suggestions resulted from the research will be propose to related agency for improvement.

Ethics committee in overseeing the project:
The project will be ethically reviewed and approved via Sociology Department's ethics review procedure.

Contact information


| | |
|---|---|
| Name : Noor Hanis binti Zainol Abidin<br>Position : Lead investigator<br>Email Address : nhzainolabidin1@sheffield.ac.uk<br>Phone Number : (+44) 7730 325 361 | Name : Paul Martin (Professor)<br>Position : Main supervisor / Director of research<br>Email Address : paul.martin@sheffield.ac.uk<br>Phone Number : 0114 222 6414 (external), 26414 (internal) |

# Appendix G

Example Participant Consent Form

Title of Research Project:
The roles of national and local policy and practices in support knowledge transfer and commercialisation of biotechnology in Malaysia'.

Name of Researcher: Noor Hanis binti Zainol Abidin

**Participant Identification Number for this project:** **Please initial box**

1. I confirm that I have read and understand the information sheet/letter (delete as applicable) dated *[insert date]* explaining the above research Project and I have had the opportunity to ask questions about the project. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without there being any negative consequences. In addition, should I not wish to answer any particular question or questions, I am free to decline. *Insert contact number here of lead researcher/member of research team (as appropriate).* ☐

3. I understand that my responses will be kept strictly confidential (only if true). I give permission for members of the research team to have access to my anonymised responses. I understand that my name will not be linked with the research materials, and I will not be identified or identifiable in the report or reports that result from the research. ☐

4. I agree for the data collected from me to be used in future research ☐

5. I agree to take part in the above research project. ☐

| ________________________ | ________________ | ____________________ |
|---|---|---|
| Name of Participant<br>(*or legal representative*) | Date | Signature |

______________________  ______________  _________________

Name of person taking consent   Date   Signature
(*if different from lead researcher*)
*To be signed and dated in presence of the participant*

______________________  ______________  _________________

Lead Researcher   Date   Signature
*To be signed and dated in presence of the participant*

Copies:

*Once this has been signed by all parties the participant should receive a copy of the signed and dated participant consent form, the letter/pre-written script/information sheet and any other written information provided to the participants. A copy of the signed and dated consent form should be placed in the project's main record (e.g. a site file), which must be kept in a secure location.*

**Appendix H**

Acceptance of becoming respondent (In Malay language)

Penerimaan Pelawaan Sebagai Responden Kajian Projek:

**'The roles of national and local policy and practices in support knowledge transfer and commercialisation of biotechnology in Malaysia'.**

**.**

Saya, Datuk/Dato'/Prof.,Prof. Madya/Dr./Tuan/Puan ____________________________________ dengan ini bersetuju/tidak bersetuju untuk menerima pelawaan sebagai respondent bagi kajian projek seperti yang tertulis diatas. Saya juga bersetuju untuk ditemuramah oleh ketua projek (Noor Hanis binti Zainol Abidin) pada :

Sila pilih tarikh dan nyatakan masa yang sesuai untuk sesi temuramah ini:

| | |
|---|---|
| ☐ | 25 Julai 2014, Masa: ________________ |
| ☐ | Tarikh lain yang sesuai, Masa: ________________ |

Antara hak-hak saya sebagai responden adalah:

- Saya boleh menarik diri dari kajian ini tanpa perlu memberi apa-apa penjelasan kepada ketua projek dan penarikan diri ini tidak akan menjejaskan reputasi saya pada masa hadapan. Saya juga bebas untuk tidak menjawab soalan yang dikemukakan jika tidak selesa untuk mengulas tentang isu tersebut.
- Saya faham bahawa maklumat yang diberikan akan dikawal dengan ketat dan akan digunakan untuk tujuan ilmiah sahaja.
- Saya bersetuju data yang diperolehi boleh digunakan oleh ketua kajian untuk kajian di masa hadapan.
- Saya bersetuju untuk menandatangani lembaran borang persetujuan sekali lagi pada hari kejadian untuk menyatakan kesudian saya sebagai respondent kajian ini.

| ________________________________ | ________________ | ________________ |
|---|---|---|
| (Nama responden) | (Tarikh) | (Tandatangan) |

## Appendix I

## Semi-structured interview questions

<table>
<tr><th>No.</th><th>Questions</th></tr>
<tr><td rowspan="2">1.<br>National level</td><td>Research Question 1:<br>What is the role of Biotechnology Policy in enabling the creation and sustainability of university spin-off companies?<br>Group: Government agencies</td></tr>
<tr><td>I. What are the biggest problem facing the biotechnology sector in Malaysia?<br>II. What are the Malaysia ambitions in global market? Locally and internationally.<br>III. What are the overall aim, vision and mission of NBP?<br>IV. Are there any specific phases in NBP?<br>V. What are the elements or parts of NBP is designed to support commercialization?<br>VI. Are the policies encouraged the creation of new biotechnology company? - based on the trends/report on biotechnology sector.<br>VII. What are the strategies used by the government to encourage the creation of new biotechnology company?<br>VIII. How NBP able to solve this problem? How the Government supports the commercialization activities in Malaysia?<br>IX. What are the supports given by the Government to support commercialization activities in the creation of new biotechnology company?<br>X. Focusing on the commercialization in the university level, what are the supports given by the Government to encourage the creation of spin-offs company?</td></tr>
<tr><td rowspan="2">2.<br>University level</td><td>Research Question 2:<br>How do universities translate the National Biotechnology Policy (NBP) into local practice?<br><br>Group: Top level management of RU<br><br>Research Question 3:<br>How do these local practices support knowledge transfer and the commercialisation of biotechnology?<br><br>Group: Academic scientist</td></tr>
<tr><td>I. How the university can be the player in biotech industry?<br>II. What is the role/s of university in contributing to the development of Malaysia biotech industry?<br>III. Can you summarize how the NBP affected the university?<br>IV. How the university translate the national policy into local practices?<br>V. If there any new policy/amendments made? What are they?<br>VI. How the policy works? Who involves? Who is affected? Will it frequently being revised? How frequent?<br>VII. Is there any specific unit deal with the commercialization activity in the university?<br>VIII. What is the role of Research & Innovation Center in the university?<br>IX. What are the different strategies adopting by the university in furthering the commercialization activities?<br>X. Does the university play an active role in helping the creation of spin-off company? What are the available supports?<br>XI. Focusing on the creation of spin-off company, how the company is formed?</td></tr>
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| | |
|---|---|
| | XII. How many products are actually being commercialized?<br>XIII. How they identified the products has the potential to be commercialized?<br>XIV. What are the supports given by the university for the spin-off company once they are established?<br>XV. How the supports are given?<br>XVI. To what extend the supports are given?<br>XVII. How the university decide when to stop giving the supports?<br>XVIII. What are the mechanisms used to ensure the sustainability and growth of the spin-off company?<br>XIX. How the company is monitored?<br>XX. How it is evaluated?<br>XXI. Is there any other initiatives given by the university? |
| 3. Start-up level | **Research Question 4:**<br>**To what extent do government agencies, national policy and university-based policies help the sustainability of start-up companies?**<br><br>Group: Company managers |
| | I. What is the Malaysian industry facing in entering the biotechnology market?<br>II. What are the main barriers facing the development of biotechnology product in Malaysia?<br>III. How it can be solved?<br>IV. Can you tell me a little bit about your company?<br>V. How it is set up?<br>VI. How long the company is being established? Is it big/small?<br>VII. What area are you involved with? crops, natural products, aquaculture or livestock biotechnology?<br>VIII. How many of your products in the market?<br>IX. How many of your products are still in the pipeline/development process?<br>X. Can you give me any comment on NBP?<br>XI. Is there any other policies related to the formation of the start-up company?<br>XII. How do you translate the national policies into local practices?<br>XIII. Do you have local biotechnology policy?<br>XIV. Can you tell me in short about your local policy?<br>XV. Are the implementation of NBP and other related policies simplifying the process of creating a company?<br>XVI. How the national policies and other related policies regarding commercialization affected your company?<br>XVII. How the establishment of biotechnology clusters can help commercialization activities in Malaysia?<br>XVIII. Do you use the services offered by the cluster?<br>XIX. From your point of view, are the policies effective in playing its roles? |