Gordon Institute of Business Science
University of Pretoria

Challenges to localisation in South Africa: A case study of the molecular diagnostics and reagents sector

Riaan Werner van Wyk

St. No: 96172012

A research project submitted to the Gordon Institute of Business Science, University of Pretoria, in partial fulfilment of the requirements for the degree of Master of Business Administration

6 November 2017

Abstract

Technological innovation drives development, and for developing countries it presents an unique opportunity to not only catch-up to technology leaders in the developed world, but also to leapfrog technology and gain a dominant position in certain markets (Lee & Mathews, 2013). It therefore makes logical sense that emerging should develop the capacity to generate knowledge and innovate. In the South African context, the Bio-economy strategy strives to achieve this goal, but thus far innovation seems to be lacking with few products that are adopted in the market. This is evident in the local molecular diagnostic industry where the reagents that are a big cost component of clinical diagnostic tests and research and analytical services are predominantly imported at high cost by local users.

The objective of this research was to assess what the challenges are to localised manufacturing of molecular diagnostic reagents, and it achieved this through use of a exploratory case study methodology guided by the Technological Innovations Systems framework of analysis. The study also looked at the localisation strategy that should be followed to maximise socio-economic spillover and the role that government should play through policy intervention.

The findings of this research indicate that the inaccessibility of sufficient funding, lack of regulation of imports, and lack of government support for local firms restricts the ability of domestic firms to compete within the local market. Alternatives exist in the export market where there is potential for high earnings, provided that firms leverage their competitive advantage to create an unique value proposition. Government would have to intervene by providing required funding, protection of the local market, coordinate and facilitate collaboration and assist firms in capability building in order to compete in the export market.

Keywords

Molecular diagnostic reagents, Technological Innovation Systems, Innovation policy.

Declaration

I declare that this research project is my own work. It is submitted in partial fulfilment of the requirements for the degree of Master of Business Administration at the Gordon Institute of Business Science, University of Pretoria. It has not been submitted before for any degree or examination in any other University. I further declare that I have obtained the necessary authorisation and consent to carry out this research.

Signed: Date:

Riaan Werner van Wyk

Table of Contents

List of Figures

List of Tables

List of abbreviations

TIS	Technological innovation system
CE/ EC	European committee for standardization
IS	Innovation systems
MNC	Multi national corporations
SME	Small and medium entrerprises
IPR	Intellectuall property rights
OEM	Original equipment manufacturing
ODM	Original design manufacturing
OBM	Original brand manufacturing
PCR	Polymeras chain reaction
TB	Tuberculosis
HIV	Human immunodeficiency virus
NGS	Next generation sequencing
DTI	Department of Trade and industry
DST	Department of science and technology
TIA	Technological innovation agency
THRIP	Technology and Human Resources for Industry Programme
IDC	Industrial development corporation
DTI	Department of trade and industry
CSIR	Council for Scientific and Industrial Research
MRC	Medical research council
SHIP	Strategic health innovation programme
MDMSA	The Medical Device Manufacturers Association of South Africa
SAMED	South African Medical Device Industry Association
FDA	Food and Drug Administration

FDI	Foreign direct investment
BGI	Beijing genomic institute
SOEs	State owned enterprises
GVC	Global value chain
TF	Technological forecasting
GRI/ PRI	Government/ public research institute

CHAPTER 1

INTRODUCTION

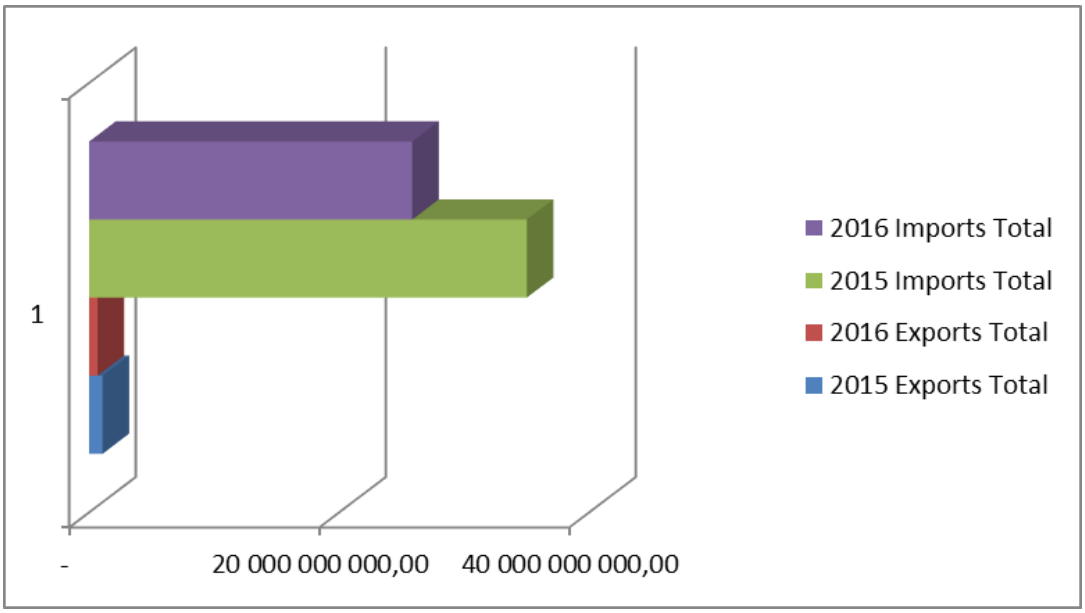
2.2 RESEARCH PROBLEM & PURPOSE

Technological innovation is critical for developing countries to industrialize and achieve economic growth and development (Bento & Fontes, 2015). In an effort to encourage research, development and innovation in South Africa's biotechnology industry the Department of Science and Technology released a number of strategic initiatives, the latest and most prominent being the Bio-economy strategy, and a South African Swedish partnership to locally promote and develop Pricision medicine in 2013. Despite these efforts local innovation in biotechnology remains low with products that are predominantly imported and distributed to users at prime cost. The same is also true in the case of molecular diagnostic reagents, a cost intensive consumable that is used for clinical diagnostic testing, DNA fingerprinting and research, as shown by the import and export figures in Table 1 and Figure 1. This study will investigate the current state of the local molecular diagnostic reagent market in order to assess what the factors are that pose a challenge to localised manufacturing of molecular diagnostic reagents.

Table 1: Trade Statistics for Molecular Diagnostic Reagents

Year	Imports (Rand, million)	Exports (Rand, million)
2015	35 012,81	1 072,58
2016	25 844,35	669,26

Figure 1: Imports and Exports of Molecular Diagnostic reagents



Source: Department of Trade and Industry (2016)

2.3 DEVELOPING COUNTRIES AND TECHNOLOGY CATCH UP

Technological innovation in developing countries have been promoted by numerous international organisations such as the United Nations in recognition of its potential to drive economic growth and assist these countries in adressing the societal problems that they face (Kebede & Mitsufuji, 2017)(Stephan, Schmidt, Bening, & Hoffmann, 2017). To achieve this developing countries would need to build innovation systems that comprise of a number of actors (government, private and academic contributors), networks and institutions that support the innovation of a technology of interest. The challenges these new systems of innovation need to overcome are multifold and include a shortage of skilled labour, weak infrastructure, restricted access to financial resources (Lee & Mathews, 2013).

Less developed countries, also known as technology followers can catch up with their developed or leader counterparts by attaining new technologies, products and managerial structures that were developed by the leader, mastering it and finally adapting it (Lee & Mathews, 2013). Latecomer firms have a cost advantage when adopting mature technologies in that they do not have the burden of carrying costs that are associated with research and

development. Technology transfer takes place from leader to follower countries through the transfer of knowledge. For this process to be successful technology followers would require the necessary absorbtive capacity, influenced by the level of higher education, organisational and institutional capacities. The possibility also exist for latecomers to catch up by leapfrogging technology when adopting a new and up-to-date technology when the previous version is absent (Edsand, 2016). In some cases technology leading firms may tend to hold onto existing technologies in an attempt to recover their returns on investment and because of uncertainty that exist with regards to the new technology (Lee & Lim, 2001).

2.4 INSTITUTIONAL CHANGE AND THE ROLE OF GOVERNMENT

Established technological regimes pose a threat to the new innovation system and would have to be 'unseated' for the new system to gain market access and be sustainable. This can only be achieved through institutional support for the latecomers (Kukk, Moors, & Hekkert, 2016). In the context of this study that implies providing a policy and regulatory framework and national culture that supports scientific development in biotechnology (Manessah, Teresa, & Kerrin, 2015). Government's role is to provide support to latecomers in getting access to markets through subsidies and protectionary measures such as niche creation and assist with research and development (Lee & Lim, 2001). To achieve this government uses a mixture of innovation policies that target various factors for instance technology push and pull (supply and demand) factors. (Kivimaa & Kern, 2016)

2.5 TECHNOLOGICAL INNOVATION SYSTEMS

Carlsson and Stankiewicz (1991) defined technological systems as "a dynamic network of agents interacting in a specific economic/industrial area under a particular in- stitutional infrastructure or set of infrastructures and involved in the generation, diffusion, and utilization of technology" (Kebede & Mitsufuji, 2017). Different to the national innovation systems concept that is defined by its geographical boundries, a particular technology defines a Technological innovation system (TIS). The Technological innovation system framework of analysis has been designed to 'measure' a TIS's performance in terms of seven processes

that are critical for TIS function and development. By following this process system weaknesses are identified to inform policy design and intervention (Edsand, 2016).

2.6 A CASE FOR BUSINESS: BIOTECHNOLOGY & MOLECULAR DIAGNOSTIC REAGENTS

It has been predicted that biotechnology will be the economic growth engine of the future. The GEM report classifies South Africa as being an efficiency-driven economy and “efficiency opportunities” exist within biotechnology in particular in bioprocessing biomanufacturing (Manessah et al., 2015).

Localised manufacturing of molecular diagnostic reagents have the potential to reduce the burden of health expenditure to the country and present an opportunity for South Africa to grow its GDP through export to international markets. The molecular diagnostics market is expected to reach USD 9,333.8 Million by 2020 with growth forecasted at 9.3% compound annual growth rate (CAGR). The market can be segmented into instruments, reagents, software and services of which reagents makes up the largest share of the market and have the highest CAGR. Reagents are based on polymerase chain reaction (PCR) technology, and the global PCR market is expected to reach USD 4.94 billion by 2021 at a CAGR of 8.5% for the next five years (Marketsandmarkets.com, 2015). Infectious diseases such as HIV and Tuberculosis constitutes the biggest share of the medical diagnostic market, followed by blood screening and oncology (Marketsandmarkets.com, 2015).

The probabililty of achieving success and sustainability in efforts made by the Department of Health, Science and Technology to establish a precision medicine ecosystem in the country (Mia, 2015) will greatly be enhanced through localised manufacturing of molecular reagents and has the potential to stimulate growth in South Africa’s ailing manufacturing sector (Baker et al., 2016). Through this sectors that are imbedded in the value chain of the molecular reagent TIS and those that produce complementary goods and services will grow and create employment opportunities. Production of point-of-care testing devices for instance could potentially make affordable decentralised diagnostics accessible to communities in rural areas where access to proper healthcare services are restricted.

2.7 CONTRIBUTION TO LITERATURE

The study contributes to the growing base of literature on Technological Innovation Systems and in particular its application to the context of developing countries. It hopes to create a better understanding of the challenges that firms face in these environments and with it provide insight into what role institutions can play in overcoming similar challenges. The literature on Technological innovation systems have predominantly until now had a technological focus on renewable energy. This study will focus on biotechnology within the context of South Africa. Markard et al. (2015) states that TIS studies conducted within different countries are welcomed and will shed light on the role of institutional context on TIS development.

2.8 RESEARCH SCOPE AND OBJECTIVES

By applying the Technological innovation system analytical framework based on functional pattern analysis, this research will attempt to determine the scale and shape or nature of the local market for molecular diagnostic reagents, the achievements (or lack thereof) of the bio-economy strategy and implemented policies in developing local manufacture of such products, and to suggest suitable policy intervention that will be more successful in growing this sector. During the course of the study the following questions will be answered:

1) Based on the TIS framework, what are the challenges for the localization of molecular diagnostic reagents?

2) What localization strategy could be pursued to maximize the potential benefits of a strong reagent sub-sector?

3) What should the role of government be in implementing such a localization strategy?

CHAPTER 2

LITERATURE REVIEW

2.1 A CASE FOR GOVERNMENT INTERVENTION

Developing countries can greatly benefit from technological innovation and it should therefore be prioritised as a strategy for economic and social development (Lee & Mathews, 2013). Firms within these countries however face numerous challenges, such as market and collaboration failures, assymetrical access to information and dominance of imported products in the local market, which inhibits their ability to be competitive and to gain the necessary skills through learning that will foster innovation and create potential for exports (Ahn, 2017)(Szczygielski, Grabowski, Teoman, & Sinan, 2017). In order to level the playing field and to create a space for learning and development, government intervention is required.

The desirable change can be brought about through a combination of industrial and innovation policies that coherently works together to achieve structural and institutional change that will support learning and skills development. Recently the focus of policy intervention has shifted from mere market intervention that address market failures, to a system focus where gaps in the system known as system failures are identified that negativel affect collaboration and knowledge transfer (Warwick, 2013). Government's role is to through policy intervention address system failures that will result in improved collaboration and knowledge transfer. Besides policy intervention that is required, government needs to play an active role through interaction with industry that coordinate the behaviour of industry actors and align strategic goals.

The next section will look at the evolution of systems literature and its increasing role as a means of informing policy design.

2.2 INNOVATION & SYSTEMS THEORY

The concept of innovation systems focus on two aspects, firstly systems, secondly innovation. Systems comprise of interrelated components that work together to achieve a common purpose (Klein & Sauer, 2016). System components are related to each other and influenced by characteristics of the system. Innovation is defined by the OECD as: "*The implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations."* (*OECD Annual Report*, 2005).

The principle of innovation systems is thus that system components (system actors) work together to achieve a common goal of innovation achieved through sharing of knowledge within the system through interaction among system components. Figure 2 illustrates the influential factors that facilitate and the process of innovation is depicted in Table 2.

Figure 2: The Non-Linear innovation model (Source: DNAbiotec)

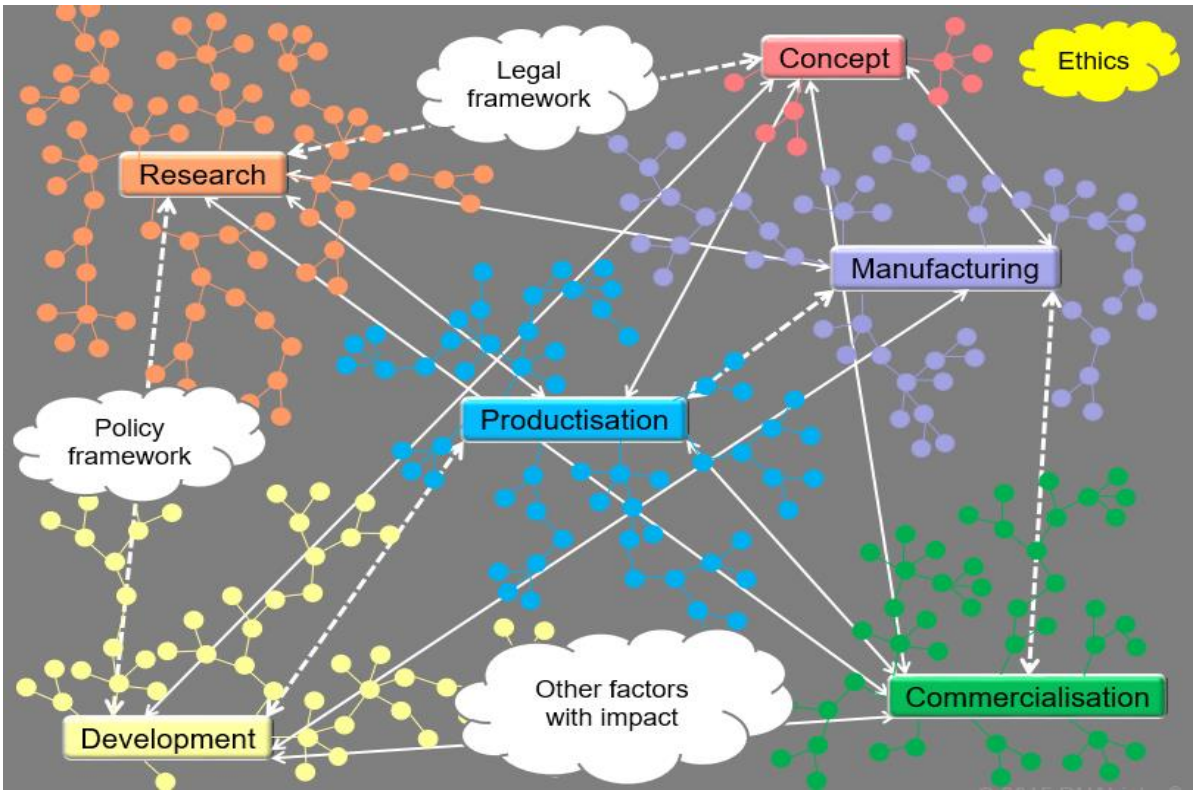


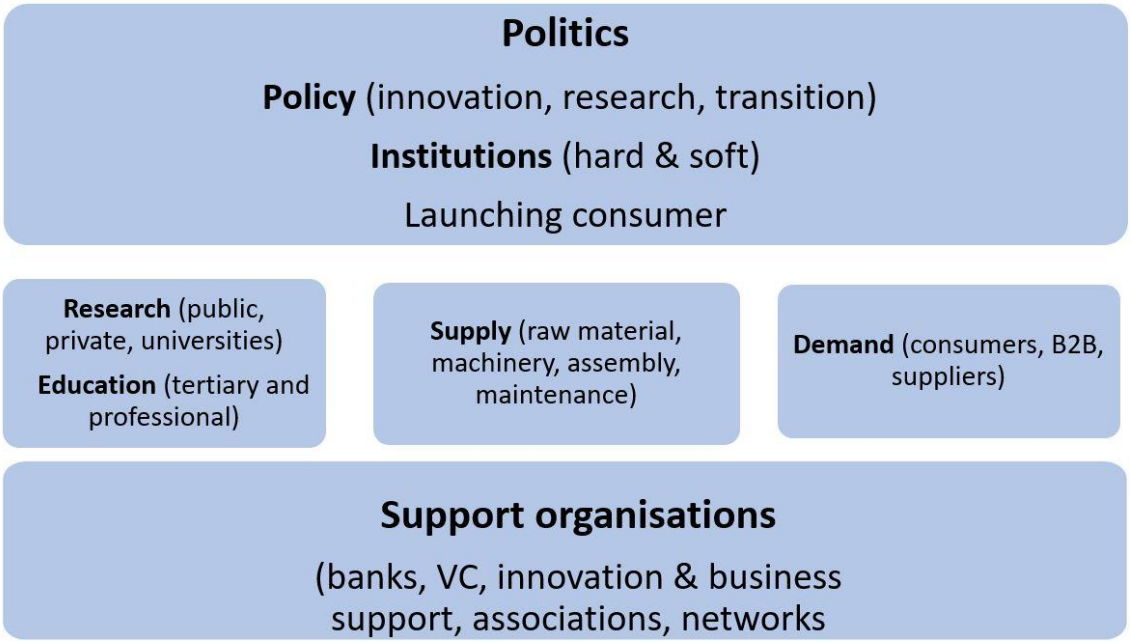
Table 2: Stages of the innovation process (Source: DNAbiotec)

Innovation Element	Input	Process	Output
Idea	• Background IP • Papers • Patents	Idea evaluation	Mature idea
Research	Mature idea	The scientific process	• Valid research result • Invention
Development	Valid research result	• E.g. Testing "fit for purpose" • Etc.	Proof of concept
Productisation	Proof of concept	Transform invention to product	Prototype
Manufacturing	Prototype	• Pilot scale • Full scale	Product ready for sale
Commercialisation	Manufactured product	• Marketing • Sales • Etc.	• Product traded in market • Innovation

Innovation systems (IS) consist of three structural components (Varblane, 2012)(refer to Figure 3), namely actors, networks and institutions. Actors are the constituents of the system and others outside of it that influence development of the IS. They can be categorised as knowledge institutes, educational organisations, industry, market actors, government bodies and supportive organizations (Marko P. Hekkert, Negro, Heimeriks, & Harmsen, 2011)

Networks are formed between actors within the innovation system that facilitates interaction and knowledge and resource exchange. Networks can be categorised as learning or political networks (Bergek, Hekkert, & Jacobsson, 2008) and can be formalised or informal. Networks can be highly orchestrated e.g. standardization networks and others less so e.g. industry – university linkages (Bergek, Jacobsson, Carlsson, Lindmark, & Rickne, 2008). Institutions such as norms, regulation, culture and cognitive frameworks (Jacobsson & Bergek, 2011) direct, influence and align the activities, visions, goals and decisions of actors within the system.

Figure 3: Structure of the Innovation System (Marko P. Hekkert et al., 2011)



Each of these components are interdependent and influence the direction and rate of development of the innovation system. A change in one component can influence the other components and so change the internal dynamics of the system that will either cause the system to further develop or breakdown (Jacobsson & Bergek, 2011).

Later concepts of national innovation systems such as technological innovation systems incorporates a functional approach where processes or functions that are crucial for development of innovation systems are used as criteria to measure the performance of a NIS and determine system weaknesses (Jorg Musiolik & Markard, 2011). Hekkert et al. (2007) states that the limitations of innovation system analysis using only a structural approach to inform policy design, are that it does not adequately explain the internal dynamics of the innovation system. He further states that the framework analyse the role of institutions in innovation system performance adequately, but pays insufficient attention to actions of entrepreneurs on a micro level.

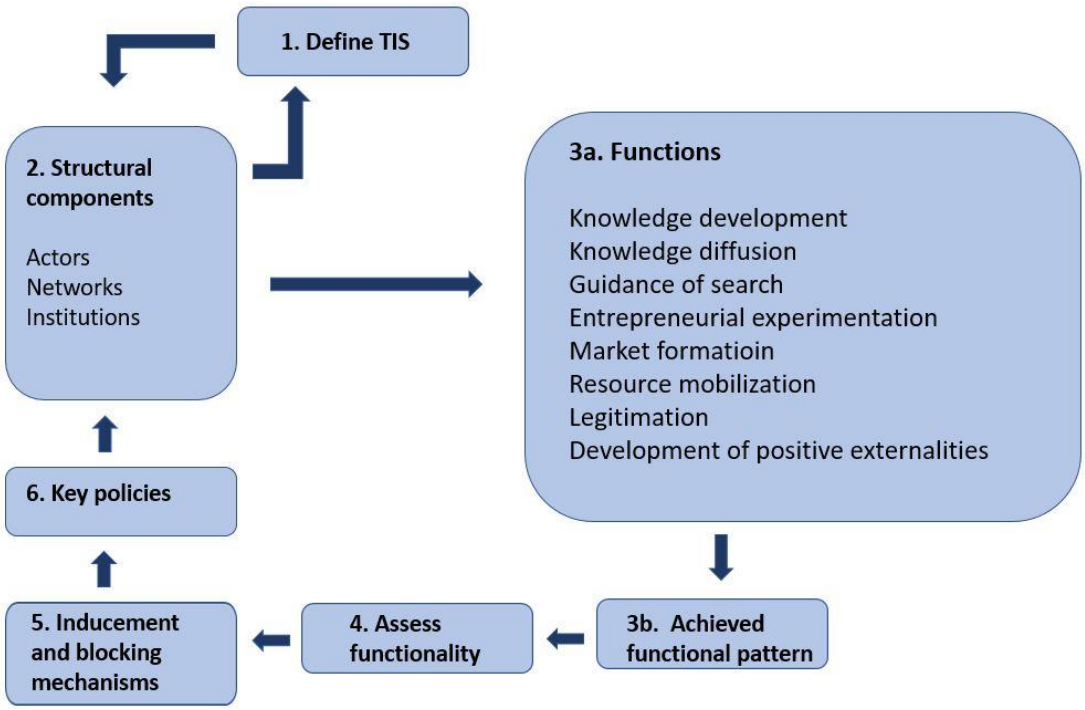
The Technological innovation system framework of analysis present as a solution to this problem through an added step of functions analysis. Functions refer to processes and activities that actors undertake during the process of technology change (innovation).

2.3 TECHNOLOGICAL INNOVATION SYSTEMS ANALYSIS

Technological innovation systems (TIS) are a set of net- works of actors and institutions that jointly interact in a specific technological field and contribute to the generation, diffusion and utilization of variants of a new technology and/or a new product (Markard & Truffer, 2008). TIS theory share many characteristics with innovation systems in general but with an emphasis on technological development. Technology can be viewed as a structural component as well as an output of the TIS (Baker et al., 2016). TIS as a framework of analysis determines system performance and weaknesses based on analysis of seven key functions at a micro level i.e. activities and initiatives of entrepreneurs, in supplement to the structural analysis that gives a macro perspective (Bergek, Hekkert, et al., 2008).

Figure 4 shows a schematic presentation of the procedural process that constitutes TIS analysis.

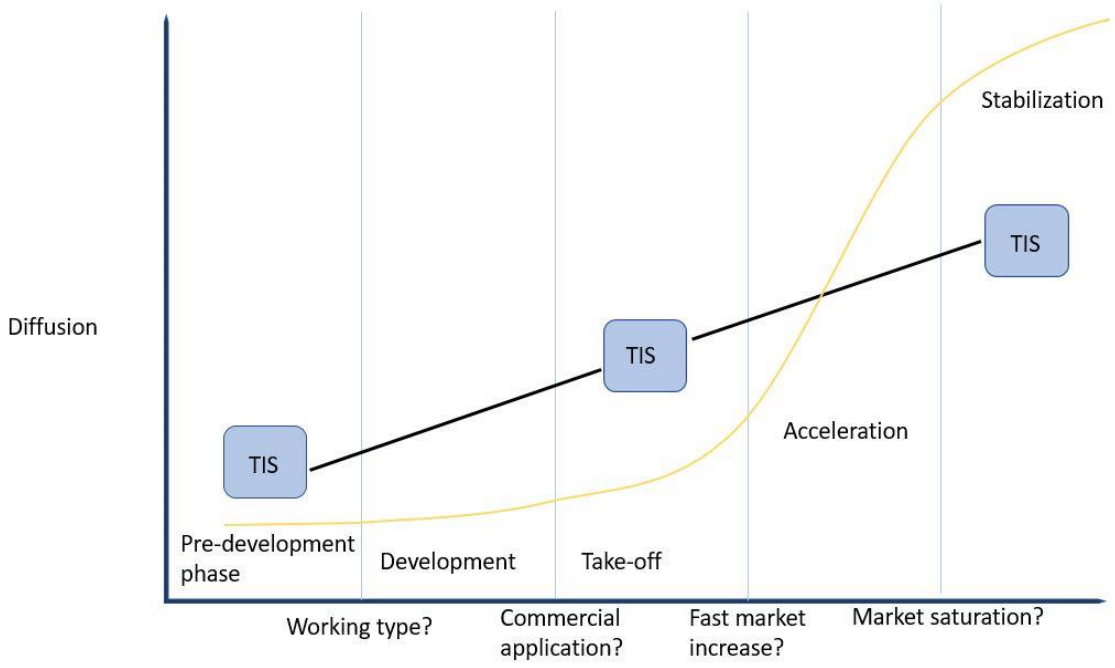
Figure 4: The Technological Innovation System framework of analysis (Gosens, Lu, & Coenen, 2014)



In terms of defining the TIS, Bergek & Jaconsson emphasized the importance of clear parameters to be set for the study of a TIS with regards to its focal point (product or knowledge field focussed), the choice between breadth and depth of analysis and its spatial domain (geographical dimensions). Breadth refers to the aggregation of the study and limitations that are set in terms of product or knowledge field application. The TIS can have a geographical dimension but should include an international component to understand the TIS performance within a global context (Bergek, Jacobsson, Carlsson, Lindmark, & Rickne, 2008b).

The phase of development that the TIS under focus are in should be taken into account during the analysis process (see Figure 5). Structural development will differ and certain functions will be more crucial for development than others depending on the phase (Marko P. Hekkert et al., 2011).

Figure 5 Technological Innovation System phase of Development (Marko P. Hekkert et al., 2011)



During the pre-development phase knowledge development will be most crucial and can be negatively influenced by insufficient transfer of knowledge, resource mobilization and

influence on the direction of search. For the development phase entrepreneurial experimentation will be most critical, though poor performance of other functions can also have a negative impact. Entrepreneurial experimentation and production and legitimation TIS is essential during the take-off phase and requires resource mobilization and market formation to support development. Market formation during acceleration phase plays the most important in driving development of the market and diffusion further (Marko P. Hekkert et al., 2011).

The analysis of structural components of a TIS gives an indication of where in the system value is added to the products or services produced by a TIS. This process is similar to that of other innovation systems of analysis will not be discussed in depth here (for further description see Innovation & Systems theory). Hekkert.et.al (2011) lists the four structural pillars as 1) Actors

2) Networks of interaction and 3) Institutions with an added component of 4) Technological factors namely artefacts, infrastructure and technological trajectories. Technological trajectories refer to a set of technologies that are used during the development of a product or service that evolves over time (Marko P. Hekkert et al., 2011).

2.4 FUNCTIONAL ANALYSIS

Functional analysis forms the core of the TIS framework and is based on seven functions that have been identified to be crucial for innovation system development. It is important to note that these functions do not exist in isolation within the TIS but are influenced by the other functions to create internal dynamics within the system. External factors such as International regulations on trade and standardization will also impact system dynamics (Bergek, Jacobsson, Carlsson, et al., 2008a). Each function will now be discussed in greater detail below:

2.4.1 Knowledge development and diffusion

The development of scientific knowledge and its application to technological innovation is considered to be a key driver of social and economic development and competiveness on a macro-economic level and increases invention quantity and quality on an organisational level (Hohberger, 2016). Lundvall (1992) emphasizes the role of knowledge by stating that “the most fundamental resource in the modern economy is knowledge and, accordingly, the most

important process is learning". Sources of knowledge development within a system are learning by doing (experimentation), learning by using (Foxon & Pearson, 2008), public or firm research and development (R&D) and exchange of knowledge through learning networks between actors which enjoys the centre of attention within innovation systems. For firms that compete in science and technology industries there are high degrees of uncertainty over the direction of innovation that a technology will take, accompanied by continuous problems that needs to be solved on a regular basis (Hohberger, Almeida, & Parada, 2015). It is therefore crucial that learning networks are established in the early development of a TIS, including university - industry and user - producer networks (Jorg Musiolik & Markard, 2011) not only to facilitate flow of technological knowledge for technology development, but also institutional knowledge to create confidence in the market and future technology (Foxon & Pearson, 2008). TIS development also requires access to a strong knowledge base, that should consist of formalised (explicit or codified) knowledge and informal or tacit (experience, skills and know-how) knowledge within a region (Park & Isaksen, 2002). Knowledge flows have the potential to contribute significantly to 'knowledge stocks' and resources within the TIS also referred to as technological capabilities.

While codified knowledge (can be communicated in written or verbal format) are important, a great amount of knowledge that contribute to innovation are tacit by nature. Geographical proximity is therefore important for knowledge spill over to occur, and it is for this reason that knowledge and technology based firms are often observed to cluster (Pietrobelli, 2010). The concept of open innovation is often associated with clustering of technology based firms, where intense interaction and experimentation facilitate the development of tacit knowledge (Binz, Truffer, & Coenen, 2014). Firms that participate in cluster activity gain a competitive advantage through access to knowledge, skills and competencies that would otherwise not have been easily attainable (Wang, Vanhaverbeke, & Roijakkers, 2012)

System weaknesses can act as barriers to knowledge development and diffusion. Network weaknesses will limit interaction and transfer of knowledge, institutional weaknesses in the form of misdirected or incorrectly designed policies and actor weaknesses such as an insufficient knowledge base in parts of the value chain can have severely restrictive effects to development (Jacobsson & Bergek, 2011)

It is the role of Institutions and intermediary associations to not only facilitate development of networks but also to coordinate and construct interaction between actors (Watkins, Papaioannou, Mugwagwa, & Kale, 2015) e.g. knowledge transfer through university-industry interaction. The majority of system policy instruments improve interaction, strategic

intelligence, vision building and experimentation and therefore aim indirectly to enhance system learning (van Mierlo, Leeuwis, Smits, & Woolthuis, 2010). Sufficient regulation to protect intellectual property (IP) and enforcement thereof is essential for knowledge flow to occur (Wang et al., 2012).

2.4.2 Influence on the Direction of Sea

Influence on the direction of search also referred to in some literature as management of expectations (Bergek, Hekkert, et al., 2008) is activities within a IS that creates clarity of technology users' wants and needs and so legitimates further investment and resource allocation into the development of the system (M. P. Hekkert et al., 2007). Bergek and Hekkert (2007) defines influence on direction of search as "a combination of long-term policy goals and regulations by governments and the creation of vision and collective expectations in an interactive process" (Binz et al., 2014). It often involves a process whereby 1) technology producers, users and other actors interact to exchange ideas 2) producers test these ideas through experimentation 3) Success and failures are communicated to other actors 4) resulting in a reduction of uncertainty that create expectation throughout the system (M. P. Hekkert et al., 2007). Examples of these are institutional factors such as incentive structures (Jacobsson & Bergek, 2011), government or industry expectation of the specific application of a technology, prices of products and other factors (Bergek, Hekkert, et al., 2008), beliefs in growth potential, articulation of consumer demand and technical bottlenecks (Jacobsson & Bergek, 2006). NIS development and firms' search for opportunity is pathway dependent and usually local (Jacobsson & Bergek, 2011), and for this reason require careful consideration of the effects of investment and finance on technology and innovation development (Baker et al., 2016). Jacobsson & Bergek (2006) articulates the need to coordinate investment in order to attract a range of firms that supply complementary products and services to secure the formation of a complete value chain.

Heckert (2007) emphasizes the fact that it is not merely a matter of creating expectation through market or government influence. Consumer associations can also be influential on the direction of investment and policy formation by lobbying for consumer rights and interests (Randelli & Rocchi, 2015). Influence on expectations are also not limited to national factors. Global political institutions such as the world trade organisation (WTO), European union (EU), united nations (UN) and other factors like development of TISs in other countries or global socio-technical landscape changes can have an effect on the direction of search. The

implications are that national policy and actors within a TIS's ability to influence expectations are restricted (Binz et al., 2014).

Uncertainty among potential entrant firms are seen as a major barrier that influence the directions of search negatively. Institutional weakness (policy, norms, culture, goals and expectations) can also reduce expectations. An imbalance in political power within the system, where certain actors are more influential to the detriment of other weaker actors (actor weakness can also deter firms from entering the TIS. An example of this is the Swedish State Power Board that aimed to discourage municipal energy companies from investing in facilities that coproduce heat and power. Companies that did so were 'punished' with increased costs and lower prices for power produced where firms that did not build coproduction plants were offered favourable contracts (Jacobsson & Bergek, 2011).

2.4.3 Entrepreneurial experimentation and materialisation

Experimentation plays a key role in the evolution of a TIS during its formative and growth phase (Jacobsson & Bergek, 2011). System actors are faced with high levels of uncertainty regarding which technologies to use, its applications, which markets to enter and uncertainty whether there will be sufficient demand for a product or service. To reduce uncertainties entrepreneurs engage in market experiments that are characterised by high risk in order to develop knowledge of the ability of the technology to perform under different circumstances, as well as how it is perceived by consumers, suppliers, competitors and government (Bergek, Hekkert, et al., 2008). During the course of entrepreneurial experimentation some firms will be successful yet others will fail and as a result contribute to social learning (Bergek, Hekkert, et al., 2008). Entrepreneurs are motivated by the prospect of financial gain that could be achieved through first mover advantage in the case where an experiment is successful (Jacobsson & Bergek, 2006). This will in turn increase competition as other firms are attracted towards the possibility of gain and invest in physical assets such as production facilities and equipment and infrastructure, commonly referred to as entrepreneurial materialization. The importance of this function does however not only relate to new technologies that are introduced into the market, Rodrik (2004) explains: " What is involved is not coming up with a new product or process, but 'discovering' that a certain good, already well established in world markets, can be produced at home at low cost" (Jacobsson & Bergek, 2006).

The strength of entrepreneurial experimentation within a TIS is measured by the number and diversity of experiments that are taking place as well as the amount of new firms entering into

the TIS (Jacobsson & Bergek, 2006). Low levels of entrepreneurial experimentation could be due to actor weaknesses that exist i.e. possibly the inability to experiment, either due to a lack of motivation, knowledge or funds. In the instance where high risk and technological uncertainties persist, risk-averse companies may also be reluctant to invest in long term projects (Jacobsson & Bergek, 2011). Government can lessen the perception of risk and uncertainty through policy intervention that transfer the risk from companies to the larger society. Public funding of university incubators (Figueiredo & Almeida, 2011) creates spaces where entrepreneurs can safely experiment without being exposed to the risks that are associated with failure. Government's failure to deliver the necessary funding for this can be seen as an institutional weakness. Another option is for government to influence the direction of search by use of field augmentation, where selective information is communicated to make firms more aware of new opportunities that exist (Jacobsson & Bergek, 2006). As new firms enter into the TIS entrepreneurial experimentation will increase.

2.4.4 Market formation

Market formation plays a significant role in the innovation process as it allows for diffusion of technology, incentivise new firm entry and lays the foundation for entrepreneurial experimentation to take place (Jacobsson & Bergek, 2011). In an emerging TIS it is often the case that the market is underdeveloped or very likely does not even exist, with unarticulated customer demand and poor price/performance when compared to what is offered by the incumbent system (Gosens & Lu, 2013). Rosenberg (1976) explains this further: "Most inventions are relatively crude and inefficient at the date when they are first recognized as constituting a new innovation. They are, of necessity, badly adapted to many of the ultimate uses to which they will eventually be put; therefore, they may offer only very small advantages, or perhaps none at all, over previously existing techniques. Diffusion under these circumstances will necessarily be slow" (Bergek, Hekkert, et al., 2008).

A solution to these challenges that an emerging TIS face is to create a protected market, known as a nursing or niche market that facilitate further learning and technological development and creates a space where future expectations can be formed. Government can assist in niche formation by playing the role of a launching consumer, or by means of consumption quotas or incentives that favour consumption of the new alternative vs. traditional product / or service (Gosens & Lu, 2013). In a transnational context this implies creating a temporary protected space where local firms are presented with the opportunity to build capacity and capabilities by implementing initiatives such as private firm contracting, tax

incentives, government procurement, localization quotas and subsidies (Jacobsson & Bergek, 2011). Local government and firms should however take cognisance of the trade-off that exist between protectionism and contact with leading technology firms that can aid capacity development and formation of the new local TIS through knowledge exchange (Gosens et al., 2014). In instances where the local market is weakly developed, the TIS has the option to tap into foreign markets (Binz et al., 2014).

Certain requirements exist in order for successful market formation of a TIS. Uncertainties need to be dealt with to influence the direction of search and secure a critical mass of new entrant firms by ensuring that market formation takes place swiftly, new actors are ensured of access to funding, and industry standards are set at an early stage of TIS development. A failure to do this amounts to institutional weakness and will act as a barrier to market formation (Jacobsson & Bergek, 2011). In order to address uncertainties in terms of demand, firms should include consumers to participate during the innovation process. Firms stand to benefit from this when consumers articulate their needs and provide constant critical knowledge throughout the process (Randelli & Rocchi, 2015).

Should niche market formation be successful and further growth takes place, it can potentially develop into a bridging market that are characterised by an increase in volumes produced and the amount of new entrants into the TIS, and after decades of further growth into a mass market that produce large volumes (Bergek, Jacobsson, Carlsson, et al., 2008b).

2.4.5 Resource mobilization

All activities within an innovation system requires critical resources (Bergek, Hekkert, et al., 2008)

During the process of system development and growth, resources are strategically mobilized to different levels within the system. At an organisational level firms contribute to system development through the different resources and capabilities that they possess, some of which are unique and critical to reach network goals. On a network level, resources are accumulated over time that increases the ability of a network to perform a variety of tasks. The role thus of formal networks are to accumulate, control and strategically coordinate organisational and network resources in order to reach goals of system building (Jörg Musiolik, Markard, & Hekkert, 2012) at the TIS level.

Social capital is required to mobilize resources that are used for venture and system formation (Stuart & Sorenson, 2003). These critical resources include human capital (education in entrepreneurship, management and finance, science and technology), financial capital (seed or venture capital and government funding) and assets (network infrastructure, complementary products and services) (Bergek, Hekkert, et al., 2008). In the case of emerging economies where access to capital may be restricted, either due to institutional (e.g. regulatory) weaknesses that exist or actor weakness e.g. universities that are not delivering quality and diverse education, local TIS actors can leverage transnational relations to get access to financial capital and 'internationalize' education and scientific cooperation through university exchange programs (Gosens & Lu, 2013). The success of such initiatives however relies on the return of skilled individuals to their country of origin. To prevent a brain-drain from occurring where skilled individuals migrate to other countries in search of better living conditions or income, local and national governments should offer benefit package that provide aid to these individuals in business start-ups, access to infrastructure and financial incentives (Gosens & Lu, 2013).

2.4.6 Legitimation

Legitimacy refers to social acceptance and compliance or alignment with institutional structures (regulation, norms or values, culture-cognitive frameworks) within a country or region and needs to be attained by a new TIS in order for its actors to gain political strength, for market formation to take place and resources to be mobilized (Jacobsson & Bergek, 2011). Practices become legitimate when it is diffused throughout institutions, propagated by government and other intermediaries and accepted by organizations that can be influenced by normative and coercive pressures (Schøtt & Jensen, 2016)

Innovation system formation is path dependent and institutions, firms and networks become aligned with a technology as the system develops. Actors within the new TIS that are actively seeking legitimacy of the new technology thus have to strategically choose to either conform to the existing institutional framework that supports the 'old' TIS, or 'manipulate' the rules of the game, or to create a new institutional framework that suits its own interest (Bergek, Jacobsson, Carlsson, et al., 2008a). When the choice is made to conform to the existing institutional framework this places the new TIS at risk of lock-in that can potentially stifle its further development (Markard, Hekkert, & Jacobsson, 2015). If the new TIS chooses to manipulate or change the institutional structure it is bound to meet resistance from the existing TIS and those that have vested interest in the current technology and institutional

setup (Jacobsson & Bergek, 2011)(Kern, 2015). The new TIS therefore do not only compete with the existing TIS in the market, but also for institutional influence as explained by Van de Ven and Garud (1989): "…firms compete not only in the marketplace, but also in this political institutional context. Rival firms often cooperate to collectively manipulate the institutional environment to legitimize and gain access to resources necessary for collective survival …" (p. 210) (Bergek, Hekkert, et al., 2008). It is expected then that conflict will ensue and one TIS will win while the other loses.

Institutional entrepreneurs within the new TIS that prioritise system development plays an important role in accomplishing legitimacy (Bergek, Jacobsson, & Sandén, 2008). In order to gain political strength they operate collectively and form advocacy coalitions that lobbies for institutional change and acceptance of the new technology. They aim to achieve this by creating common standards or through education of users, producers and other intermediary actors (Bergek, Hekkert, et al., 2008). As the number of new firms within the TIS increase so does its political power. It now leverages the familiarity and trust that have been gained to further build legitimacy. Legitimacy thus is both a prerequisite for and a result of system building (Bergek, Jacobsson, & Sandén, 2008).

2.4.7 Development of positive externalities

As a TIS evolves circular feedback linkages are formed that connects different functions of a system. When change occurs within the system this then sets off a chain reaction that benefits other constituents of the innovation system or possibly another TIS in the case where structural elements are shared (Bergek, Jacobsson, & Sandén, 2008). These unexpected gains are referred to as positive externalities or free utilities' (Bergek, Hekkert, et al., 2008) in some literature.

New firm entrants plays a central role in the creation of positive externalities as an increase in the number of firms lends momentum to the feedback linkages within the system, reduces uncertainties and the new TIS attains legitimacy as advocacy coalitions gain political strength (Jacobsson & Bergek, 2006). This in turn influence other functions such as market formation, influence on the direction of search, entrepreneurial experimentation and resource mobilization (Bergek, Jacobsson, Carlsson, et al., 2008a). New entrants can potentially thus strengthen the functional dynamics of a system by generating positive externalities, which makes this function an ideal indicator or measure of system dynamics.

Positive externalities however are not a by-product of system development. Actors strategically shape their technological field by introducing new technical standards and practices, new business models and values that influence collective expectations (Jörg Musiolik et al., 2012). These new supportive structures creates positive externalities that benefit the TIS as a whole to gain advantage over established and competing technologies and innovations (Farla, Markard, Raven, & Coenen, 2012). Firms can more greatly benefit from and contribute more significantly to the development of externalities by co-locating e.g. cluster formation (Jacobsson & Bergek, 2006). Further externalities that can arise from such an arrangement can be the development of pooled labour markets, the emergence of specialised intermediary goods and services providers and information spill-overs, all of which is beneficial to knowledge development and diffusion within the system (Bergek, Jacobsson, Carlsson, et al., 2008a).

2.5 BARRIERS TO INNOVATION AND THE ROLE OF POLICY

A key outcome of TIS analysis is that it identifies system weaknesses or failures that in turn informs policy design to address these weaknesses. Systemic failures are barriers in the system that restricts knowledge development and transfer, causes lock-in and hinders system development and can potentially even cause the death of a system (Laranja, Uyarra, & Flanagan, 2008). Four barriers have been identified by literature, namely infrastructural failures (e.g. technology failures),institutional failures, collaboration failures (Warwick, 2013) and capability failures (referring to activities of actors) (Jacobsson & Bergek, 2011).

Other factors such as uncertainty, lack of collaboration and networking, weak political support and lack of trust are also blocking mechanisms to TIS development (Foxon & Pearson, 2008). Laranja (2008) terms the use of innovation system analysis as a rationale for informing science and technology policy design as a ‘systemic institutional’ approach’, where the key focus is on institutions and their networks of interaction that plays a prominent role in shaping the direction and rate of learning and innovation (Laranja et al., 2008). Institutional setup is seen as directly linked to innovation performance and could be formal institutions that coordinate activities such as regulations, technical standards and patenting or informal institutional structures e.g. norms and culture (Laranja et al., 2008). Policy design thus focus on these formal and informal institutions as devices to positively influence knowledge development and interaction along ‘technological trajectories’ (Laranja et al., 2008).

Innovation policy thus aims to address poor functional performance in a TIS either by strengthening current inducement mechanisms and adding new mechanisms or by removing or weakening blocking mechanisms (Ou, 2010).

Typical examples of inducement mechanisms are tax incentives or research and development funding (Foxon & Pearson, 2008). Policy can also aid in creating legitimacy for a TIS for instance by coordinating its compliance with international standards or by creating forum platforms where interaction and knowledge exchange can take place (Gosens et al., 2014). For innovation policies to be effective it should apply technology push and demand pull instruments (Reichardt, Negro, Rogge, & Hekkert, 2014). The policy designer thus use a variety of methods to coordinate and organise actor behaviour in the TIS and it is therefore important that the designer should be knowledgeable of the technical aspects and complexities within a TIS. Gosens et al (2014) stipulate the role that governments should play through policy implementation to support TIS development within emerging countries:

2.6 LOCALISATION STRATEGIES AND OTHER CONSIDERATIONS FOR LATECOMER COUNTRIES

The underlying strategic objective in the majority of developing countries for science, technology and innovation (STI) is to catch up to global technology leaders within industries that have been prioritised for growth (Lee & Mathews, 2013). There are a number of key factors that countries who intend to achieve technological catch-up need to consider. Access to resources that are required for development are restricted and its therefore important that these countries correctly identify and prioritise sectors and segments where catch-up could be most likely achieved. The developmental path through which catch-up could be achieved namely path following, stage skipping or own path creation also needs to be considered.

These choices will be influenced by numerous factors, in particularly the technical capabilities of local firms and the accessibility of external sources of knowledge. The cumulativeness of technical advances and predictability of a technology's trajectory are important factors to consider (Lee & Lim, 2001). High cumulativeness are characterised by frequent innovation, and would imply that more R&D would be required in order to catch-up, and a fluid trajectory makes it difficult to predict the direction that technological development would take, as is usually the case with new technologies.

Follower regions should also consider the technological cycle time of sectors that are prioritised for development. Cycle time refers to the time period it takes to phase out current technology and for new technology to emerge (Lee & Mathews, 2013) . Sectors with shorter cycle times are less reliant on current technologies and present greater opportunities for lagging countries to catch upto and even leapfrog technology leaders, who tend to be risk averse and keep with their current technology. During a technological paradigm shift, barriers to entry tend to be low and the playing field is levelled as each player starts as a beginner.

Despite the challenges that developing countries face such as a shortage of skilled labour and financial resources, these countries do have some competitive advantages that should be leveraged in industries where embedded technologies are either new or mature. Firstly, follower countries can access knowledge that have been generated by the developing world and therefore are not burdened by added expenses of R&D, allowing for low cost based entry into mature technology sectors. Secondly, in contrast to technology leaders, followers are not locked into current technologies and are free to enter emerging industries at an early stage where there are lower barriers to entry and economies of scale can be achieved (Lee & Mathews, 2013).

2.6.1 Strategies for learning and development of technological capabilities

To initiate the process of technological catchup, lagging firms need to have a minimal technological platform from where they can develop capabilities for product and process development, and if amiss, then external assistance is required (Lee & Mathews, 2013). The ability of latecomer firms to develop knowledge are usually severly restricted with limited access to channels through which knowledge can be transferred (Lee, 2009). Lee & Matthews (2013) states that firms need to undergo a three stage learning process through which knowledge are secured and technical capabilities are acquired that will eventually enable firms to conduct R&D and develop knowledge.

During the first stage, learning by doing takes place where latecomer countries tend to focus on sectors with mature technologies and long technological cycle times (for example textiles) or low-end products with shorter cycle times such as to assembly of consumer electronic goods. Typically, Original Equipment Manufacturing (OEM) arrangements are made where firms in leading countries subcontract latecomers to produce parts or assemble goods according to buyer specifications. Low to middle income countries benefit from this through

job creation and access to much needed foreign currency. Sector development through OEM is however not reliable as MNCs can at any point terminate arrangements and change suppliers of goods required as they deem fit (Lee & Mathews, 2013).

To secure long term growth technology latecomers should instead strive to develop capacity for Original Design Manufacturing (ODM), where much of the detailed design are done locally and products are sold to customers who then market it under a different brand name. The final stage of learning would be Original Brand manufacturing (OBM) where products are manufactured and designed, process innovation and R&D of materials takes places, and marketing and sales of completed products are all conducted by lagging firms (Lee & Mathews, 2013).

2.6.2 The Role of Policy

Policy interventions during this progression of learning conventially makes use of tarrifs (vertical/ or sector specific) and local currency devaluation (horizontal/ or general) during the OEM phase to stimulate exports of prioritised technologies. Tarrifs should be applied in a manner that promotes locally produced products and reduces the cost of capital goods required in sectors that are being prioritised (Lee & Mathews, 2013).

Once countries achieve middle income status, sector specific policies are required that support niche development, either targeting low-end products with a cost advantage manufactured for countries that are price sensitive, or high-end products that are quality centred for high income countries. Lee & Matthews (2013) recommends that expansion into industries with shorter technology cycle times, and/or higher value added segments in established industries supported by government policy, presents the most opportunity for niche development and catching up. Import substitution is an ideal approach to develop technical capabilities in high value added segments where products are manufactured that have previously been imported at high cost to follower countries due to an ‘oligopolistic market structure’ (Lee & Mathews, 2013)

A combination of supply and demand policy measures should be utilized to support initial market formation and reduce the risk for local producers related to alternative product choices (Costantini, Crespi, Martini, & Pennacchio, 2015). Policies should also seek to promote physical infrastructure development in particular for transportation and communication (Lee & Mathews, 2013). Examples of supply side measures are incentives such as tax concessions and subsidies that aim to attract capital investment into areas where growth is foreseen to

have social and economic benefits. The risk of misallocation and corruption should be mitigated through a pre-stipulated plan to reduce and withdraw incentives. Financial resources should be managed responsibly and monetary values should be sufficient but not excessive (Lee & Mathews, 2013).

2.6.3 IP Strategies for Developing Countries

Effective regulation of IP is crucial to enable learning of firms in particular those in middle income countries. Lee & Matthews (2013) emphasizes that governments in developing countries should be given leeway to determine their own IPR that would enable local firms to catch-up. There are various strategies that have been shown to benefit developing countries. A patent combination approach can be taken where patent rights are shared across various local industries and technologies. Developing countries in an early developmental stage can adopt in addition to their invention patent system a utility models system (Lee & Mathews, 2013).

In Korea the government provides legal and financial support to local SMEs involved in IPR disputes, and as a preventitive measure even conduct trade and market research for firms who intend to export. A public- private consortium fund has also been created to assist firms in trade and licensing of patents and to protect fund members against possible patent claims (Lee & Mathews, 2013).

2.6.4 The Role of Government and Public Research Institutes

2.6.4.1 *Government Research Institutes*

Government's role is primarily to secure markets for lagging firms, through protection of domestic markets and provision of export subsidies (Lee & Lim, 2001). The market is protected through incentives for early adoption of locally produced products, government procurement to secure demand and locally designed technological standards and tarrifs (Lee & Mathews, 2013). Government research institutes (GRIs) can reduce uncertainty for private firms through joint R&D initiatives that facilitate the learning process as discussed in 2.6.1 (Lee & Lim, 2001). Collaborations with GRIs where technology innovation is frequent (high cumulativeness) or the technological trajectory is fluid (unpredictable) can be of great benefit

to local firms. Creative solutions generated through public research can allow for stage skipping during the catch-up process. The G-P-G model (Lee & Mathews, 2013) illustrates the varying role that government and public research institutes need to play, depending on the technical capabilities that local private firms posess. There are four stages in the GPG model:

GPG0 – This model applies where private firms lack the capabilities required for manufacturing or instances where start-up cost within an industry is extremely high. Here R&D would be conducted by public research institutes and government would be responsible for manufacturing and market initiation and protection (Lee & Mathews, 2013).

GPG1 - Refers to where R&D are performed by government research institutes, manufacturing by private firms and government secures initial demand through implementation of government procurement policies.

GPG2 – Here the risk and cost associated with R&D are shared among government research institutes and private firms. An additional role for GRIs would be to monitor technological and market trends and to coordinate the role of industry actors.

GPG3 – Private firms are capable of conducting R&D and manufacturing with government that are to secure the market for locally produced products (Lee & Mathews, 2013).

Instances where neither government nor private firms are sufficiently capable of knowledge development, access to external foreign knowledge would be critical. Channels through which local firms can access foreign knowledge include licensing agreements, co-development with international research institutions, joint ventures, importation of specialised human capital, OEM, mergers and acquisitions with foreign firms and reverse brain drain initiatives. In this fourth variant of the GPG model abbreviated as FLG (Foreign – Local – Government), the foreign entity are to assist local private firms with R&D and solving of any technical difficulties experienced with production. For knowledge to be transfered successfully and internalised, it is critical that local firms should possess adequate absorbtive capacity (Lee & Lim, 2001). The next phase of development would be where government research institutions or private firms co-conduct research with foreign entities (Lee & Mathews, 2013).

The essence of the GPG model and its variant FLG is to assist private firms so that they should progress through the different stages up to a point where they have developed sufficient capabilities to conduct R&D and for production equivalent to the GPG3 stage of development.

2.6.4.2 *Governmental agencies*

Public agencies have a crucial role to play in capability building of latecomer firms. They coordinate activities of industry actors and compensate for gaps that may exist in prioritised industries through provision of financial resources and ensuring that firms have access to knowledge that are required. In Korea government agencies assisted local firms to overtake local markets that have previously been dominated by big MNC imports. Initiatives driven by various agencies helped local firms to acquire technology, land and finances, with nursing of the local market through R&D subsidies and tax concessions and protection against influence of big MNCs (Lee, 2009)..

2.7 MOLECULAR DIAGNOSTICS

Broadly speaking molecular diagnostic reagents have commercial application in three main areas, namely:

1) Molecular testing that include research as well as DNA testing for legalistic purposes (i.e. parental testing and DNA Forensics)

2) Agriculture including plant genetics as applied to transgenic crops, animal genetics in the form of transgenic animals and animal health diagnostics for the detection of animal related diseases.

3) Clinical diagnostics for the screening, detection and monitoring of human diseases (Walwyn, 2014)

Molecular diagnostics and its application to human healthcare are in the process of changing the clinical diagnostic industry and will be the focus of this discussion. Also referred to as laboratory medicine (Panagiotou, 2013), molecular diagnostics is the fastest growing form of clinical diagnostics (Weile & Knabbe, 2009) and advancements made in the field in recent years are revolutionizing the healthcare sector by causing a paradigm shift from the current focus on diagnosis and treatment to that of preventative care (Jones, Hofmann, & Quinn, 2009). The purpose of Clinical diagnostics within the medical field is to inform health practitioners and patients and enable them to make correct treatment decisions in each

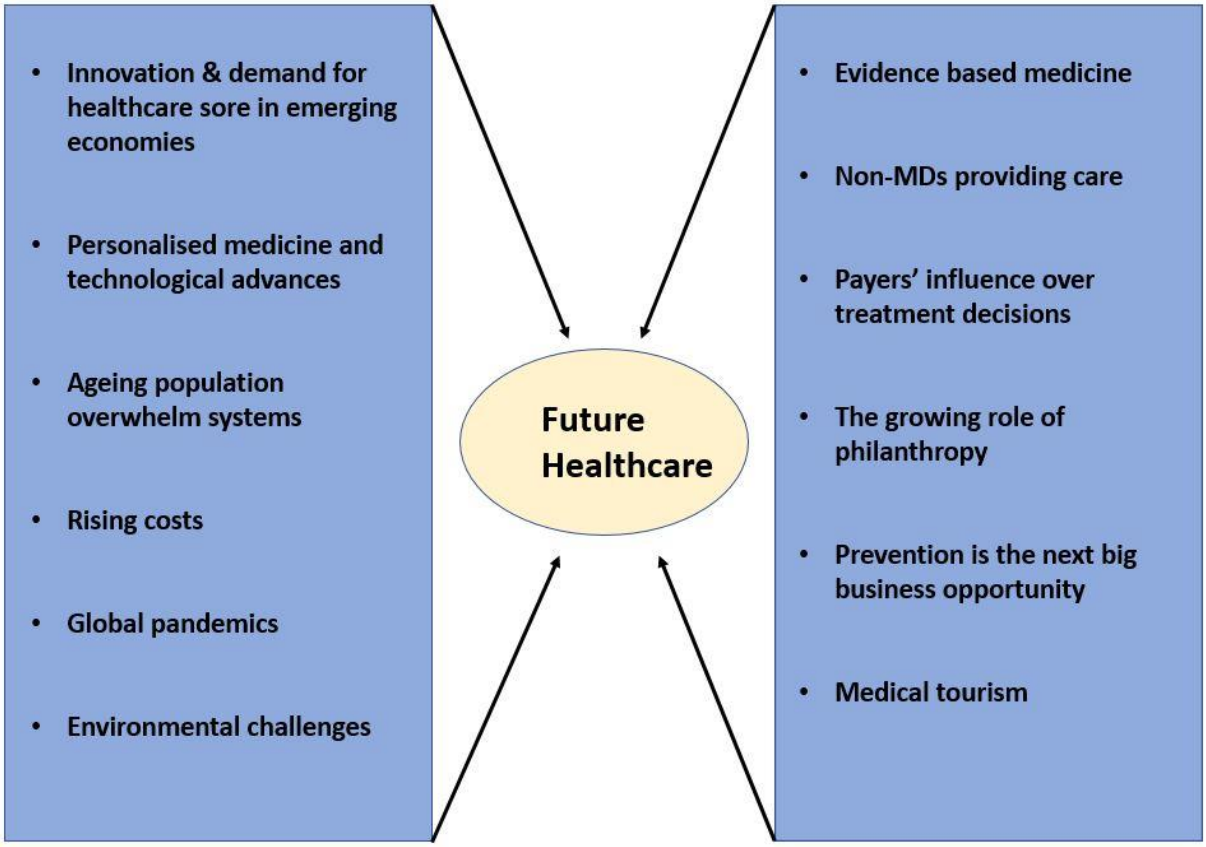
respective stage of the health care process i.e. prevention, detection, diagnosis, treatment and general health management (AdvaMedDX & DXInsights, 2013). Analysis and diagnosis are performed on a bodily fluid sample outside of the body (and are therefore classified as in vitro diagnostics). Reagents for molecular diagnostics are based on PCR (polymerase chain reaction) technology that allows for identification and monitoring of diseases and genetic testing (Walwyn, 2014) that typically use designed biomarkers to bind to protein molecules (the field of proteomics) or specific DNA sequences (genomics) that are associated with a disease and so the presence and the stage of development of the disease can be detected. The technology can also be used to identify other substances in the blood stream such as addictive drugs (Song et al., 2014)

2.7.1 The need for innovation and change in Healthcare

Clinical diagnostics in the future will be characterised by intensified innovation at management and operational level with information technology, genomics and proteomics that will play a central role (Panagiotou, 2013). A number of Mega trends are driving change in healthcare diagnosis and treatment (see Figure 6 for an elaboration on this). Technology for diagnostics have become increasingly complex and requires a highly specialised workforce and instruments to analyse samples which increases the cost and processing time of these tests (Panagiotou, 2013)(Walwyn, 2014). The global aging population that are in need of medical services compounded by the increase in cost are putting immense strain on the medical infrastructure, government healthcare budgets and medical aid funds, thus intensifying the need for more affordable healthcare. Developing countries are low resource settings (Kricka, Polsky, Park, & Fortina, 2015) that in general have underdeveloped and fragmented healthcare systems and diagnostic tests are either not affordable to a large part of the population or not accessible to people that are located in remote areas. The high occurrence of communicable (infectious) diseases and non-communicable diseases such as cancer requires early identification and treatment to prevent further spread of the disease.

Technological developments in biomolecular sciences plus an increase in awareness among the population of the advantages that point of care testing and personalised medicine can offer, are among the factors that are driving change (Panagiotou, 2013). These are two emerging technological trends in healthcare that are aiming to address the challenges that healthcare face globally, in particular in developing countries.

Figure 6: Mega Trends that are driving change in Healthcare



2.7.1.1 *Point of Care testing*

Point of care diagnostics offers an affordable and user-friendly method that does not require skill or expertise to perform the test (Yager, Domingo, & Gerdes, 2008). Testing kits that are in the market covers a variety of diagnostic testing ranging from pregnancy and glucose kits to diagnosis of communicable diseases including sexually transmitted diseases such as HIV, Tuberculosis and Malaria (AdvaMedDX & DXInsights, 2013) Some of these kits are directly accessible to the public and provides a viable alternative to clinical testing in the form of home

testing. Point of care tests are expected to alleviate pressure on healthcare facilities by eliminating the need for initial screening to take place within clinics (Coupland et al., 2010)

The test can be conducted at the point of location of the patient through use of a disposable device or an electronic mobile device/ analyser that contains small amounts of reagent into which a sample is loaded and results are obtained within minutes. The diagnosis can then be communicated to the patient or test data can instantly be sent using mobile phone technology to a remote centre or laboratory where experts can interpret the results and send it back to the tester (Panagiotou, 2013). Point of care tests thus reduces the turnaround time significantly and alleviate the workload pressure on clinical laboratories. This technology is ideal to rapidly identify infectious diseases and tests have been developed for medical first aid respondents also used in the United States military (AdvaMedDX & DXInsights, 2013) to test for biohazardous agents that are released into the environment. Innovation and technological development will in the near future allow for multiple diagnostic tests to be conducted on a tiny silicone chip that further allows for cost reduction known as Lab-on-a-chip (Coupland et al., 2010).

2.7.1.2 *Personalised healthcare*

The concept of personalised healthcare has always been the aim of medical diagnostics. Also known as precision medicine, personalised healthcare is based on the concept of systems biology (focussing on how biological systems interact to influence certain biological functions) integrated with technological development in genomics and DNA sequencing are making this more achievable (Becla et al., 2011). Testing is conducted through sequencing of the patient's genome (genetic makeup) and the data is combined with the analysis of proteins present in the body to obtain a diagnosis of the overall state of health of the individual. This technology not only allow health practitioners to identify diseases that are present, but also genetic diseases that are dormant and that might only be expressed at a later stage in an individual's life, thus making preventative healthcare a reality (Kricka et al., 2015). Technological developments such as Next Generation Sequencing (NGS) that allows for higher throughput of results and a decrease in costs of these applications are expected to make these tests more accessible to populations and it is foreseen that patient genomic profiling will become a common practice in the not too distant future (Kricka et al., 2015).

2.7.2 Regulation of molecular diagnostics

In order to protect the patient's interest and to ensure that results are reliable and of high quality, diagnostic products and laboratories are subjected to a number of regulations and have to undergo rigorous validation testing. Recent years have seen the market become flooded with cheaper products that are predominantly produced in Asian countries but which do not adhere to global standards for diagnostics. Over and above ISO 1400 standards (Panagiotou, 2013) manufacturers also need to adhere by other set out standards. The United States' standard regulatory requirement (Food and Drug Association (FDA)(Becla et al., 2011) and Europe's CE standards have been adopted as the global standard by many countries, especially those in the developing world.

CHAPTER 3

RESEARCH OBJECTIVES

The previous chapter gave an overview of molecular diagnostic reagents and the current industry within South Africa. It focussed on innovation system characteristics and the Technological innovation system's functional approach as a means of analysing system performance (Bergek, Jacobsson, Carlsson, et al., 2008a). The sought after outcome of analysis is to identify barriers to innovation within the system that will inform policy design (Marko P. Hekkert et al., 2011).

The objective of this research is to assess what the likelihood and challenges would be to establish a localised molecular diagnostic reagent manufacturing sector as well as the policy interventions that will be required. With this in mind the following research questions have been identified:

3.1 RESEARCH QUESTION 1

Based on the TIS framework, what are the challenges for the localization of molecular diagnostic reagents?

This will be assessed through performance analysis of the seven functions or processes that have been identified to be critical for TIS to function and develop:

3.1.1 Resource Mobilization

Will assess if there is sufficient financial, physical and human resources (Marko P. Hekkert et al., 2011) to establish a local reagent manufacturing sector, and how policy intervention can assist with mobilization of resources.

3.1.2 Knowledge Development and Diffusion

Is there a sufficient knowledge base (Marko P. Hekkert et al., 2011)and are the knowledge that are being developed currently sufficient in terms of quantity and quality to facilitate a localised reagent industry?

Are sufficient collaboration (Marko P. Hekkert et al., 2011)taking place between industry actors?

3.1.3 Market Formation

- Does the size of the local market (Marko P. Hekkert et al., 2011) form a barrier to localization?
- Are there sufficient supply and demand (Marko P. Hekkert et al., 2011)in the local market that would warrant localisation of a reagent manufacturing industry?

3.1.4 Influence on the Direction of Search

- Are there clear policy goals and aligned vision (Marko P. Hekkert et al., 2011) between the current actors for the localisation of a molecular reagent manufacturing industry?

2.7.3 Entrepreneurial Experimentation and Innovation

- Are experimentation and innovation taking place and do the current actors produce at large scale (Marko P. Hekkert et al., 2011)?
- Are the number of actors sufficient (Marko P. Hekkert et al., 2011) and are there new entrants moving into the sector?

2.7.4 Legitimation

- Are the necessary regulations and institutions (Marko P. Hekkert et al., 2011)that will facilitate localisation of reagents in place?
- Are there coalition groups (Marko P. Hekkert et al., 2011)that are lobbying for the development of a local molecular reagent manufacturing sector?

2.7.5 The Development of Positive Externalities

- What will the spill over effects (Marko P. Hekkert et al., 2011) of localisation of molecular reagent production be?
- How can the skills and knowledge that are acquired through localisation (Marko P. Hekkert et al., 2011) be leveraged for further growth and expansion?

2.8 RESEARCH QUESTION 2

What localization strategy could be pursued to maximize the potential benefits of a strong reagent sub-sector?

Factors that will drive market formation (Bergek, Hekkert, et al., 2008) and possible strengths that exist within the local context which could be leveraged for the localisation of a molecular diagnostic reagent manufacturing industry will be assessed.

2.9 RESEARCH QUESTION 3

What should the role of government be in implementing such a localization strategy?

The role that government should play (Marko P. Hekkert et al., 2011) to ensure innovation system formation and development and to improve performance in terms of the seven TIS functions listed above will be assessed.

4 CHAPTER 4: RESEARCH METHODOLOGY

4.1 METHODOLOGY

In order to reach the objectives of this research a qualitative methodology was adopted in the form of a case study. Collis, Hussey and Hussey (2003) argues for the validity of qualitative research in the business environment by stating that because it is grounded in the natural environment, it provides a strong basis for interpretation and analysis (Thompson & Srivastava, 2009). The aim of qualitative research methods are not to obtain findings that are generalizable and predictive in nature as in the case with quantitative methods, but rather to create an holistic view of the problem or phenomena at hand within its context. Stated differently, qualitative methods are explorative and the scope of its focus is rather on depth than the breadth of a problem or phenomena (Tewksbury, 2009).

Qualitative research is in particular suitable where the concepts under investigation are ‘ambiguous and elastic’ (Saunders, Lewis, & Thornhill, 2009) resulting in data that are less quantifiable. The richness and comprehensiveness of qualitative data that are collected from participants presents an opportunity to explore a subject in greater detail and thereby explain the reasons for a state of being, to evaluate effectiveness of what exist and to generate feedback and suggestions (Ritchie & Lewis, 2014). This project is seen to be exploratory qualitative study that aims to gain a deeper understanding of what the challenges and inducive factors to localisation are and what interventions would be required to establish a local manufacturing reagent subsector. Saunders et al. (2009) confirms that exploratory studies are usefull to gain new insights, to find out what is truly happening and to see a phenomena in a new light. Exploratory qualitative studies are ideal to get a deeper understanding of the current system structures and how system constituents (groups, institutions and indivdiduals) interact and function or their failure to do so (Berkwits & Inui, 1998).

A deductive approach have been taken structured by the Technological innovation systems theoretical framework of analysis that is discussed in greater detail in Chapter 0. This framework uniquely assesses innovation system performance and identifies barriers where performance appear to be weak, to ultimately inform innovation policy design (Reichardt et

al., 2014). The benefit of using a theoretical framework is that it connects research into the existing body of knowledge in the subject area of interest and provides direction during the initial stage of data analysis (Saunders et al., 2009). Thompson & Srivastava (2009) refers to this process as framework analysis and advocates its suitability for applied policy research whilst emphasizing that its main purpose is to interpret and describe what is happening within a particular setting (Thompson & Srivastava, 2009).

Qualitative research in the form of a single case study has been deemed fit for the purpose of this research. Yin (2003) iterates that the use of case studies are appropriate in situations where the contextual conditions of a problem or phenomena under study matters (Baxter & Jack, 2008). Case studies have the ability to generate an holistic and in-depth investigation by drawing on multiple sources of data (including quantitative data where appropriate) and multiple perspectives of participants (Tellis, 1997). Tellis (1997) further states that case studies tend to focus on one or two fundamental issues that are critical to understand the system under investigation better.

Yin (2003) mentions that there are three categories of case studies namely explanatory, descriptive or exploratory. It is foreseen that this research will take on the form of an exploratory study that is known for its ability to provide insight into what is happening in particular in cases where the problem is not clear (Saunders et al., 2009). Exploratory studies are recognizable by the “what” questions (Tellis, 1997) that it attempts to answer, as is illustrated by research question one and two:

1. *Based on the TIS framework, what are the challenges for the localization of molecular diagnostic reagents?*

and

2. *What localization strategy could be pursued to maximize the potential benefits of a strong reagent sub-sector?*

The study also takes on an element of explanatory research that are characterised by “how” questions (Tellis, 1997). This is illustrated in the third research question that essentially asks how the government should assist the process of localization:

3. *What should the role of government be in implementing such a localization strategy?*

Case study methodology follows a process of triangulation where multiple sources of data, interpretation by more than one researcher and multiple theories or methodologies are used to verify the results and so increase confidence in its interpretation. In the context of this project the researcher will aim to verify findings by drawing on multi perspectives of participants through use of a two phase stakeholder comparison process. Semi-structured interviews will be conducted during the first phase with participants that are selected based on their relevance to the molecular diagnostic reagent industry and will include an array of industry stakeholders such as companies, consumers, agencies and research and development experts. During the second phase the findings that were generated in phase one will be verified by presenting it to individuals within governmental departments that are actively involved in matters related to molecular diagnostic reagents such as the Department of Trade and Industry (DTI), Department of Science and Technology (DST), the Technological Innovation Agency (TIA), Trade and Industrial Policy Strategies (TIPS) and the Industrial and Development Corporation (IDC).

4.2 POPULATION & UNIT OF ANALYSIS

Saunders & Lewis defines population as “a complete set of group members”. The population can also be seen as a collection of entities that decisions relate to (Easterby-smith & Jackson, 2015) from which conclusions can be drawn (Cooper & Schindler, 2014). In the context of this study the population are actors within the local biotechnology and related health industry.

The unit of analysis in this project is interpreted to be the molecular diagnostic reagent industry in South Africa. The case is defined by Miles and Huberman (1994) as, “a phenomenon of some sort occurring in a bounded context. The case is, “in effect, your unit of analysis” (p. 25).

4.3 SAMPLE SIZE & SAMPLING METHOD

Non-probability sampling and more specifically purposive sampling were applied during this research project. Non-probability sampling is in particular suitable for case study research where there usually is no sample frame to determine the probability of case inclusion, and where the aim is to gain in-depth understanding of the phenomenon being studied (Saunders et al., 2009). Sample size is in this instant not of real importance but rather that the collected data is content rich and provides insight into the problem being researched.

Purposive sampling is used when a researcher applies judgement to select cases that will best enable him or her to meet the objectives of research, and allows for information rich data to be collected from small sample sizes as with case studies (Saunders et al., 2009) That is true for this research project where cases have been selected based on their knowledge of and experience in the biotechnology and clinical healthcare sectors and familiarity with diagnostic reagents. It was the aim of the researcher to obtain a heterogeneous sample that consists of various stakeholders from the private and public sector, entrepreneurs and academia, users, manufacturers and industry associations. This creates maximum variance within the sample and allows for an holistic perspective on what the major barriers to localisation would be, and what localisation strategies and policy interventions would be required to enable localisation of diagnostic reagents.

Initial searches on the internet revealed potential participants and the organisations that they are employed in, and in some instances their contact details. These individuals were then contacted via electronic mail or a voice call to request their participation and a brief overview of the purpose of the research project were stated. Upon agreement to participate, appointments were scheduled for a time and location that was most convenient for the individual.

In certain instances snowball sampling were used where participants recommended other individuals whom they knew would be able to contribute to the study. As far possible, candidates in Senior management positions were interviewed. This selection criteria was made based on the assumption that individuals in senior management positions are more knowledgable and experienced on the subject matter. Alltogether nineteen participants were interviewed.

4.4 DATA COLLECTION

Primary data was collected through semi-structured interviews to meet the objectives of this study and answer the research questions as set out in Chapter 3. Saunders & Lewis (2009) confirms that semi-structured interviews, though more frequently used with explanatory studies, can be used for exploratory research as is the case with this project. The use of semi-structured interviews and open ended questions create a comfortable setting where an in-depth discussion on the topic can take place. From here the researcher has the flexibility to pick up on questions and guide the conversation to maximize extraction of data that is relevant to the study (Thompson & Srivastava, 2009).

A questionnaire was used as data collection instrument that guided the interview process. The questionnaire (see Appendix 1) contains open ended questions that are guided by the Technological Innnovation Systems framework of analysis. Questions were adopted from the questionnaire stipulated in Hekkert et al. (2011) *Technological Innovation System Analysis – A manual for analysts as a guide* and where necessary amended to suit the purposes of this study. Individual questions were carefully designed and thereafter a few pilot tests were conducted using focus groups to ensure its ability to generate reliable and valid data (Saunders et al., 2009).

As each interview commenced, permission was requested from the participant to digitally record the conversation and all participants gave their consent. Recorded interviews allows the researcher to transcribe, code and analyse the data in a controlled setting (Berkwits & Inui, 1998) and to familiarise him/herself with the data that have been collected. Each participant were also informed that their participation is voluntary and that they reserved the right to withdraw at any moment.

Interviews were then conducted in a semi-structured manner using the questionnaire with open ended questions and where necessary, probing questions were used to further explore interesting responces from participants (Saunders et al., 2009). In certain instances interviews were conducted using Skype for practical reasons, such as where participants were in distant geographical locations (Saunders et al., 2009) not accessable to the researcher, or purely for convenience of participants. For these interviews the same procedure were followed with the difference being that participants were requested to return signed consent forms via electronic mail, and conversations were recorderd with MP3 Skyper recorder software.

4.5 DATA ANALYSIS

Qualitative data analysis is a three stage process during which the data is summarized, then categorised and lastly unitized in order to make better sense of it (Saunders et al., 2009). It is a highly subjective process that rely completely on the interpretation of the researcher. During summarization the researcher becomes familiar with themes that have emerged from interviews and note apparent relationships between them. Categorization (coding) is when categories are developed after which the data is untized and chunks of data assigned are assigned to the appropriate categories.

As far possible the researcher transcribed recordings of interviews himself but due to time constraints, some of the transcription work had to be outsourced to a third party. These transcripts were then reviewed and edited where required by the researcher while listening to the original recordings that have been made. During this process of familiarization while listening to audio recordings, reading transcripts and further studying the field of interest the researcher became immersed in the data. By doing this, the researcher becomes aware of key concepts, reocurring themes and emerging relationships between concepts (Thompson & Srivastava, 2009).

Transcribed documents were imported into MAXQDA 12 Computor Assisted Qualitative Data Analysis Software (QAQDAS) for coding and analysis of data. The use of a deductive approach greatly simplifies the coding process by providing an inititial set of categories that assist the researcher by directing the analysis process (Saunders et al., 2009). The seven critical functions for TIS formation and growth as stipulated in the TIS framework of analysis were used as initial coding categories. Subcategories were generated using factors that influence each system function and where applicable indicators of system function. Entrepreneurial experimentation for example was a primary code, and subcategories were determinant factors such as number of actors, new entrants, large scale production, appetite for risk taking, and key actors in the innovation value chain. Separate code categories titled ‘Barriers’, ‘Localisation strategies’ and ‘Role of Government’ were created to code responses that identified barriers to localisation, suggestions for localisation strategies and the role that government should play respectively. Coding is an iterative process where as it progresses, the researcher discovers new relationships and terms used by interviewees and subsequently modify existing categories or create new categories and sub-categories (Saunders et al., 2009). During the coding process some new codes and subcodes were generated, but in general the feedback of respondents matched the initial code sets particularly well. This is to be expected seeing as the questions that guided data collection were formulated using the TIS framework of analysis.

To answer research question 1 (refer to 0) and indicate the number of respondents that identified a particular TIS function to be a barrier, the Code Relations Browser function in MAXQDA 12 was used. This tool creates a visual presentation of the number of respondents where the primary code ‘Barriers to Localisation’ co-occurs with a particular coded function of interest. The criteria was set to count code co-occurrence for each participant only once to ensure that the data is not scewed by cases where participants mention a particular barrier multiple times. Saunders & Lewis (2009) describes this method of quantification of qualitative data as a “very useful supplement” to the conventional method of qualitative data analysis.

4.6 LIMITATIONS

This project took on an exploratory approach, and therefore drew on the views and personal perceptions of industry experts in order to meet the objectives of this research. Though care was taken to identify and acknowledge response bias accordingly, it is unclear to what extent response bias did influence feedback from participants. The use of a non-random sampling approach implies that findings will not be generalizable to the larger population.

The purpose of this research was to identify the challenges to localisation of a diagnostic reagent manufacturing sector, which is virtually non existing at current. Potential candidates for interviews were chosen based on their perceived knowledge and experience in the health and biotechnology sectors. Inevitably some respondents were more knowledgable than others, and so their views influenced the findings of the research more than the others.

Care was taken during interviews to not influence responces of participants but there is the possibility for interview bias where in some instances the tone of voice or behaviour of the researcher unknowingly did influence response (Saunders et al., 2009). Lastly, this study was conducted during a period where there are negative perceptions of government due to domestic political and economical instability, and it is possible that this could have influenced the perceptions of respondants.

5 CHAPTER 5: RESEARCH FINDINGS

5.1 INTRODUCTION

The previous chapter describes the methodology that have been followed during the process of data collection and analysis. Chapter 5 will report on the key findings that were obtained through semi structured interviews that were conducted with participants. The format of this discussion will be guided by the research questions as stipulated in Chapter 3.

The chapter will start with an overview of the qualitative data that have been collected followed by a description of participant characteristics. The research findings will thereafter be presented.

5.2 QUALITATIVE DATA & SAMPLE CHARACTERISTICS

Semi structured interviews were conducted with nineteen participants that were selected based on their knowledge and experience in diagnostic reagents, the healthcare sector and/ or the biotechnology sector in South Africa. A variety of stakeholders in the public and private sector were interviewed to obtain an holistic view of the local molecular reagent sector. Table 3 provides a summary of the people that were interviewed in their private capacity, with the identity of participants that are withheld to ensure confidentiality. The role of organisations that these participants are employed with indicate their relevance to the topic of discussion. The study aimed to conduct interviews with individuals that are experienced and knowledgable in their field and the role of respondents are meant to indicate this point.

Table 3: An overview of Participants' Profiles

Respondent	Role of organisation	Role of respondent	Public/ or Private
P1	iomanufacturing	Researcher	ıblic

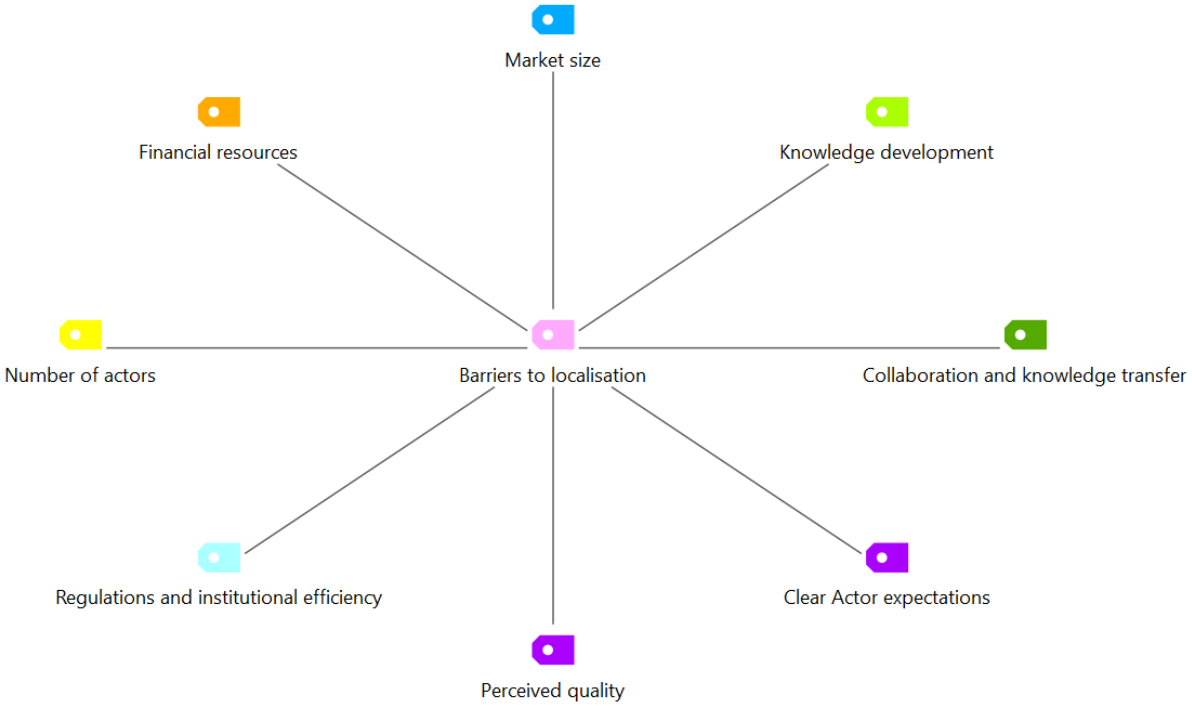
P2	ufacturer of Medical devices	O/ Entrepreneur	vate
P3	University	Researcher/ Entrepreneur	ublic
P4	esearch Institute	Researcher/ Entrepreneur	ublic
P5	Law Firm	specialist in IP for Biotech	vate
P6	holders association	Entrepreneur/ Researcher	ublic
P7	imal Diagnostics	Researcher	ublic
P8	ter and distributor of reagents	searcher/ CEO/ Entrepreneur	vate
P9	holders association	CEO	vate
P10	ters and distributors iagnostic products	Manager	vate
P11	acturer of diagnostic reagents	Director	vate
P12	holder association	Manager	vate
P13	versity technology transfer	Manager	ublic
P14	Biotechnology	preneur/ Academic	vate
P15	science Network	Manager	ublic
P16	nology Laboratory	Manager	vate
P17	acturer of diagnostic reagents	O/ Entrepreneur	vate
P18	ters and distributors iagnostic products	Manager	vate
P19	esearch institute	ctor/Entrepreneur /Researcher	vate

5.3 BARRIERS TO THE LOCALISATION AND POLICY INTERVENTION

1) Based on the TIS framework, what are the challenges for the localization of molecular diagnostic reagents?

The barriers or challenges that were identified by participants are illustrated in Figure 7. Tables in this section are used to illustrate the coding system for a particular function, and the number of participants that have identified it to be to be a barrier to localisation. Further explanation of the analysis process is presented in the section 4.5.

Figure 7: Barriers to localisation of molecular diagnostic reagents



5.3.1 Market formation:

Table 4: Barriers to market formation

Code System	Barriers to localisation	SUM
Market formation		7
TRENDS		0
Drivers		1
Market size		13
Demand		3
Supply		1
Local potential growth		1
International		3
Σ SUM	29	29

Thirteen out of the nineteen respondents (see Table 4) felt that the size of the local market is restricted and is insufficient for sustainable manufacturing of molecular diagnostic reagents when only relying on the local market. Two respondents explained:

"South Africa lacks the critical mass for mass production that will create the industry, because the industry is really relatively very small". "Yes, the local market size is a barrier – I think it will be very difficult to financially sustain a company, depending on your cost structure and your product portfolio, because we are importing most of our molecular diagnostics".

Four participants even went as far as to claim that there is no industry and that the critical value chain that is required does not exist, mainly due to a lack of funding and very few private firms that are entering this space. An entrepreneur had the following to say:

"It is an understatement to say that the size of the local market is restricted, it is absolutely insignificant, and through experience being 20 years in manufacturing of diagnostic tests and using reagents, I can assure you it is not only restricted it is insufficient in size".

Many felt that the user base of these reagents are small and restricted by factors such as access to centralised clinical diagnostic healthcare, medical aid coverage and access to government subsidized healthcare. The market for HIV and Tuberculosis testing however is huge considering the initiatives by government to encourage self testing for HIV using rapid diagnostic technology. Demand for Tuberculosis testing is certainly not small according to calculations made by an entrepreneur/ academic active in that space:

"So the average annual incidence of TB disease in South Africa is around 1% of the population, so call that 500,000 new TB cases a year because we have a population of 50 million right.. and your testing five people to find each one, that's 2.5 million tests each year and that's without looking at active case finding, that is just people who are walking into the clinics right now".

A number of participants envisaged that technological development of point-of-care testing to deliver rapid and reliable quality results, will increase the demand for molecular diagnostic reagents in future.

There was a general consensus among participants that the local market is already saturated in terms of supply, with big companies like Roche that are dominating the market and a few smaller firms that import reagents, and the repackage and distribute these products to local users. One respondent states that centralisation of diagnostics is a problem:

"If Roche signs up the blood bank for a three-year contract with government, you cannot get in there, so it is hard to find small clients to get started. Big companies are dominating the market with imported products. So it will be welcome to see small labs come in and do small bits of work instead of relying on big contracts or do nothing."

Local producers of molecular reagents that focus on the local market will have to compete with low-cost products that are imported from China and other Asian countries. An importer and distributor of diagnostics explains:

"There's access to everything, especially cheaper products that come from markets like China and India at the moment".

Another respondent confirms that to compete on the basis of price presents a great challenge to local firms, and gives an example of his personal experience: "South Africa, we led the consortium to sequence the eucalyptus genome… most of the work was done in collaboration with international laboratories which can do that cheaper than we can".

Interviewees were quick to point out that, even though the local market is small, it should not prohibit the country from developing manufacturing capabilities for molecular diagnostics. Most (if not all) respondents mentioned that opportunities exist in Africa for human and animal diagnostic reagents and in the global market that is "massive", as referred to by one respondent.

A need was expressed for more support for entrepreneurs in this field. An entrepreneur voiced his frustration with the fact that there was no incubators when he started out his business, and others mentioned that there now are a few incubators, but not enough. The need for an accelerator, which would assist entrepreneurs in drawing up a marketing strategy in order to get products quicker into market, was also mentioned. A solution was given by one respondent on how to create more incubators:

"Well, I mean the option that we may have in the area would be to look at the universities' space and adopt the model of less researchers, and use the facilities as incubators to develop capabilities for the production of molecular diagnostics."

5.3.2 Influence on the direction of search

Table 5: Barriers to influence the direction of search

Code System	Barriers to localisation	SUM
Influence on the direction of search		1
Government/ Philanthropic subsidies		1
Infrastructural investment in current technological regime		1
Projects and initiatives		8
Public health cost burden		0
Perceived quality		10
Local Distributors		0
Global competitiveness		2
Market potential		0
Clear Actor expectations		10
Policy goals		8
Implementation plan		1
Customer expectations		2
Σ SUM	44	44

The majority of respondents have pointed out that there are no clear goals or expectations among industry actors. One respondent elaborates further on why she thinks that the industry lacks coordinated drive:

"I think the pipeline is interesting and rich at an early stage there are one or two, I mean Jonathan Blackburn is one of the key entrepreneurs, there is a molecular diagnostic initiative also at the University of the north west …but I don't think there is a clear vision, I don't think there's critical mass to drive that sector forward… There is a need for leadership to drive the industry forward… I don't think it's strategically being driven".

Two other respondents suggested that there should be a coordinated drive between government and industry to develop products that address the needs of the country and the

SADEC region, either being driven by government or by industry. Another entrepreneur shares the vision for the African market:

"The vision is that we can make more appropriate products that can survive in Africa, and you have to take Africa off that import treadmill cycle, because these components are the most expensive."

It was suggested by a number of participants that to produce generic products and so compete with importers based on price would just not be sustainable in the long run. Local producers should instead aim to develop diagnostic products with unique value propositions. A researcher states his view on how South Africa should leverage its competitive advantage within the African market:

"South Africa has a very rich and endemic biodiversity… that could give you new genes to make various things like your polymerase enzymes, your ligases. We are finding very special things… including genome editing, endonucleases from Meta genomes … in South Africa and Africa as a whole as a market, the competitive advantage might actually be a growing sick population.. HIV ..increasingly prevalent lifestyle diseases like your diabetes … we would be geographically placed to feed that market"

Producers of reagents that want to compete within the local market would have to overcome numerous challenges. In addition to the fact that the market is small and saturated with imported products as previously mentioned, some respondents warned that there will be a reluctance from users of molecular reagents to switch from their familiar suppliers to local products that are of unknown quality. Respondents explain:

"When a lab has its SOP in place, the lab does not want to change, importers are not going to change, so it does take an industrial effort and a concerted will to do this as a country". "If you do make a significant change in the reagents that you use you have to go through whole validation again and that can cost you millions in time and lost revenue".

A further challenge exist to discplace the instrumentation that have been developed and validated by suppliers for use with the current reagents as a respondent explains:

"Government has already put its cards on the table by investing heavily in instrumentation and tests that are imported… You have to introduce your new test but you also have to displace an established capital equipment base as well."

The respondent goes on to say that local reagent producers can overcome this challenge by waiting for the instruments to reach the end of their natural life cycle (on average a five year period). As users are then looking to replace their equipment it presents an opportunity for user adoption of the new product. A number of participants indicated that due to the high cost burden on the public health sector, government and philanthropic agencies are through subsidies putting pressure on suppliers to keep the prices of these reagents low. An entrepreneur explains:

"The HIV and TB space are heavily subsidised by people like the Gates foundation, so the costs of tests are run up in this country, it's not the true economic cost of producing…So the pressure to keep the prices down is not only from government, it is also from the philanthropic agencies that is providing subsidies. That makes it very difficult for a new start-up company needing to make money to get an entry into that field".

To overcome this obstacle of local price pressures manufacturers of medical devices are striving to produce high value products to ultimately compete in the international market. Manufacturers of reagents that aim to compete in the international market would have to overcome the challenge of being geographically far removed from the world market by having sales and distribution forces within the international market, or through sales and marketing agreements with international suppliers as explained by an entrepreneur.

Mixed responses were received from respondents on wether there are clear policy goals for the development of a local diagnostic manufacturing industry. The Bioeconomy strategy and

IPAP (Industrial Participation Action Plan) were mentioned by the majority of participants but some felt that it lacked in detail and setting out of clear goals. Others stated that there are clear policy goals but it is with the implementation of these that government falls short as a researcher explains:

"I think that the DTI's, your DST and bio economy strategies and your IPAPS and the rest would for me say that actually in terms of policy there is clear policy goals that support localisation in these technologies, but I think perhaps it falls apart on the implementation and actually putting money and investing proper funds and support towards those initiatives".

IPAP in particular places more emphasis on creating local capacity for biopharmaceutical manufacturing but a respondent felt that the manufacturing of diagnostic reagents should be included. Government seems to support and prioritize development of Life Sciences in the country as a respondent explains:

"I think there is a very strong drive, both from department of trade and Industry, department of health and department Science Technology to apply our knowledge base, medical devices, the pipeline that is being developed there is SHIP and the MRC to create local capacity. There is an enormous drive and a high priority is being set for life sciences kind of manufacturing.. our Life Science potential for manufacturing is strong and for development of the knowledge economy that is an essential part. I think the time is ripe, there is and I think there's enormous incentives and support from the key government departments to established local capacity, even in the IDC"

There are few tales of success that could attract other Bio-entrepreneurs to manufacture molecular reagents locally. Kapa Biosystems, a company that has been acquired by Roche in 2015 and the only large-scale manufacturer of molecular reagents in the country was

mentioned by almost all participants as an example of success that can be achieved in the country. An entrepreneur gives his take on the situation:

"But I think there is very little success stories here to give people a good feeling and they back off, it is like a vicious circle because there is no good feelings and good success stories nobody is willing to be the first success story."

5.3.3 Entrepreneurial experimentation

Table 6: Barriers to entrepreneurial experimentation

Code System	Barriers to localisation	SUM
Entrepreneurial experimentation		6
Appetite for risk taking		3
Consumerism mindset		0
New Entrants		0
Large scale production		9
Number of actors		14
Key role players		0
Σ SUM	32	32

The key roleplayers that were identified in the industry by participants are the private pathology labs (Ampath and Lancet), the public National Health Laboratory Services, the Department of Science and Technology (DST), the Department of Trade and Industry (DTI), the Technology and Innovation Agency (TIA), the Industrial Development Corporation (IDC) for funding, public research institutions such as universities, private research institutions, the Council for Scientific and Industrial Research (CSIR) Bioscience department for process and development, the Medical Research Council (MRC) and their Strategic Health Innovation program (SHIP) initiative to promote innovation in health sciences, amongst others to develop

a localised precision medicine ecosystem. There are international NGOs PATH and FIND that collaborate with the MRC to provide access to affordable diagnostic products for lower income groups. The Southern Africa Network for Biosciences (SAN-BIO) is a formalised network that collaborates with the CSIR to promote innovation in biosciences in the SADC region. Coallition groups that were identified relevant to molecular diagnostic reagents are Africa Bio a non profit association that represents the interests of stakeholders in the Biotech industry, The Medical Device Manufacturers Association of South Africa (MDMSA) and the South African Medical Device Industry Association (SAMED) that promotes manufacturing and innovation of medical devices.

It was confirmed by the majority of participants that there are very few actors that are currently producing molecular diagnostic reagents, the only companies that could be identified are Kapa Biosystems and Biotech Africa. These companies are actively experimenting and innovating but otherwise very little experimentation and innovation are taking place in industry.

In the South African context there are very few new entrepreneurs moving into biomanufacturing of reagents and a few participants ascribe this to a lacking culture of risk taking and innovation and even a consumerism mindset that is prevelant under researchers and in the South African population as a whole. It was also mentioned that there is a global tendancy where pharmaceutical companies are diversifying into the biomanufacturing space:

“There is a cross over between diagnostics and genetic therapy, there is no big pharma company that does not have a program to develop biological drugs.. alongside that, comes all the products that you need … enzymes for diagnostics or just for process diagnostic… There is more diversification than new entrepreneur work going on in SA”

Kapa Biosystems was identified to be the only actor that are currently producing on a large scale. A few participants stated that these reagents in general do not need to be produced at large scale but a researcher explains otherwise:

"Again depends on the area. Where we talk about TB diagnostics that is not true. When I worked in the Gates foundation consortium, we spent considerable time looking at paths to scale for local manufacturing issues, because the number of testing you want to produce is large. In other areas outside TB and HIV that may well be true yes"

5.3.4 Legitimation

Table 7: Barriers to legitimation

Code System	Barriers to localisation	SUM
Legitimation	1	1
Validation testing	0	0
Resistance from global suppliers	4	4
Advocacy coalitions & lobbying	7	7
Market research	0	0
Regulations and institutional efficiency	16	16
Standardization	5	5
Σ SUM	33	33

The need for legitimation and to create awareness of diagnostic reagents were expressed by quite a number of participants. There are no formal coalition groups that are specifically focussing on diagnostic reagents per se and current producers of reagents are incorporated under the wing of SAMED and the MDMSA who are focussed on promoting innovation of medical devices. One manufacturer expresses his frustration with the current situation:

"We definitely need a biotech industry organisation, and grouping and lobbyists. It's like there is an untapped industry, there's nothing. We are holding onto the co-tales of SAMED who is the medical device, manufacturing body, importer. Inside SAMED, there is a local manufacturing group, and in a meeting you have people that are making and selling tubing sitting with people talking about DNA and genetic engineering, it can get very confusing at times. They lump everyone together, saying you are medical there you go".

The majority of participants do not foresee that there would be resistance from big multinational companies to the development of a localised molecular reagent manufacturing industry and it was therefore not identified as a barrier to localisation.

A number of participants voiced the need for stricter regulation of imported products to prevent low quality tests from flooding the local market and so protect local manufacturers. An entrepreneur expresses his view on the matter:

"..customs regulations and duties…should be changed to protect products that are produced locally. That is not the case, it is an open market system that we are following so in other words, there is no protection for inferior products that are flooding in from China, there is no protection laws or duty that is put on imported products and so border control is a problem"

Varying responses were received in terms of standardization of diagnostic reagents and wether it posed a challenge to localised manufacturing. The globally accepted standard for diagnostics and healthcare products in general are complience with either EC (European committee for standardization) or FDA certification (Food and Drug Administration) which is the standardization authority of the United States of America. A researcher explains that among South African consumers of reagents the NHLS require products to carry either mark but the rest do not. For local manufacturers of diagnostics, in particular those that want to export their products this complicates matters as there are no EC notification board within South African borders as explained by an importer of diagnostic products:

"Our biggest limiting factor in SA is ..we don't even have a CE officer in SA to approve anything for CE. If you need to export anything into Europe, you'll need to get an officer from that side to approve it, which create a lot of problem, I found that it will cost about R150000 for a single CE inspection, you will need such inspection about twice three times a year".

An employee of the MRC confirmed that this problem is currently being attended to in an effort to reduce the high cost associated with CE certification. The South African regulatory environment has recently changed on 23 August 2017 where the MCC (Medicines Control Council) now require all healthcare products, manufacturers and importers thereof to be registered. A producer of medical devices and an importer of diagnostic products explain the implications that this will have for local industry:

"at least it would keep some of the inferior quality competitors from Asia out of the market and it is absolutely there to support local manufacturing". "you will see a lot of smaller companies dying out, there is huge cost involved .. it will cost you per product. So entrepreneurs will be shut out almost immediately".

A researcher/ entrepreneur states his view on how FDA and CE certification do not prevent low quality products from entering the market:

"They tell you that you can make the test reproducibly and that you can manufacture reproducibly, it doesn't tell you anything about the technical performance of the test. There are FDA approved tests for TB that have a clinical sensitivity of 13%, so that means that 87% of people with TB tested will get a negative result, it is still FDA approved .. So the problem is that if EC and FDA marks doesn't distinguish between a good test and a bad test in terms of clinical utility, then it provides an additional barrier for people trying to develop new good tests to get in, because the market is potentially just swamped with rubbish tests, and people can't differentiate".

Institutional inefficiencies have been identified by the majority of participants to be a barrier to localisation of diagnostic reagents. General complaints in particular from entrepreneurs were that processing times for finance applications take too long and that there are too many levels of bureaucracy to deal with. One entrepreneur tells the story of how he had applied for seed funding at TIA and received a reply three years later that stated his application had been turned down. TIA was pointed out by most participants to be a highly inefficient organisation and two entrepreneurs share their thoughts on what the reasons are:

"The one is the IDC then the other is TIA, they are exceptionally inefficient so these are the reasons why the industry's in the mess that it is…I also think the people that are involved in those institutions are not necessarily skilled to understand what the applications are about". "there are no people with MBAs, the are no people that have run businesses before they are just kind of guessing what it might take to make a business."

Similare reasons were given for inefficiencies at Tech transfer offices at universities that were mentioned by some with an entrepreneur that expresses his frustration with the current situation:

"Universities are having spinoff companies, but those companies are not doing anything; they are not linked to the industry. I mean, if we can go to the CSIR, for example, it has a portfolio of ready-to-use commercial products packaged well, but there's no uptake."

Respondents warned that these inefficiencies are bound to deter prospective entrepreneurs from entering this sector, and that it has put off big companies from investing in the country.

5.3.5 Resource Mobilization

Table 8: Barriers to resource mobilisation

Code System	Barriers to localisation	SUM
Resource Mobilization		2
Human resources		7
Networks		0
Physical Resources		4
Financial resources		15
Σ SUM	28	28

5.3.5.1 Financial resources

Access to financial resources was identified by fifteen out of nineteen respondents (see Table 8) to be the biggest stumbling block to development of a local molecular reagent

manufacturing sector. The remaining four felt that funding could be accessed if a firm had a good business model and unique value proposition. Government was identified to be the dominant funder, with very little funding coming from private investors and venture capitalists (VCs). It was said that thus far there had only been one venture capital firm in South Africa that invests in Biotech, namely Bioventures who has a very small and restricted fund. Two respondents express their thoughts on what the reasons are for lack of private funding:

"There is definitely a higher barrier in these type of industries because you have a higher capital investment, there is slightly higher technical risk, your market is not that certain". "… investment landscape in South Africa is still very fearful of this – of the space of biotechnical landscape; they don't understand it… sometimes we have to cross the oceans and go to countries that have investors that know this space and ask them to come and invest in South Africa."

An entrepreneur explains how VC firms in the early 2000s have globally backed out of investment in Biotechnology due to a shortfall on expected returns on investment, but that the tide has changed and in recent years where there again has been an increase in VC firm investment. In his view the high inflation rate are deterring to private investment in Biotechnology:

"inflation rates has historical been much higher than around the rest of the world and so if you can get 10% just by putting your money in the bank, why would you take the risk of creating venture capital investment where 9/10 investments probably won't make you anything, and where the local IPO market is nothing like the size of an IPO anywhere else?"

The bulk of government funding is allocated through TIA, with SHIP and the IDC that are providing some funding and the MRC that is said to assist with funding in the near future. Numerous examples were given by entrepreneurs of the inefficiencies that exist in TIA, where the processing of funding applications took in excess of a year to be completed. Respondents mentioned a South African-Finnish collaboration BIOFISA that aim to assist entrepreneurs with funding on a small scale. The Governmental body CHIETA (Chemical Industries Education & Training Authority) assist entrepreneurs with funds to train employees. An entrepreneur explains the funding landscape in South Africa:

"…funding instrument for the resources in South Africa is related to the business cycle … angel funding comes in at an early and later stage – some of your venture capital would come in early, but the South African venture capital market is very small, except for section 12J, which is now being created and being streamlined. There's lots of government funding at the early stage. There is obviously the IDC funding for the later stage, for the commercialisation of operating capital. There's a lot of trade and industry. There's a lot of IDC funding available… TIA funds late stage, they do seed funding. The majority of their funding goes into developing proof of concept and development up to commercialisation, then they bring in other partners like the IDC and other organisations and agencies."

Entrepreneurs in general pointed out that they require more financial support from government. A number of respondents mentioned that there are "gaps" in funding within the innovation pipeline as highlighted in these comments:

"There is not enough in my mind seed funding going in to prime the system to create new diagnostics". "Government have to make seed fund available and co-invest to lower the risk for entrepreneurs to support them to get into the market". "I think the barrier is set in the translation, the funding to translation". "…there is that missing initial gap where … they (VC firms) won't get involved until you reach a certain point, and we can't get to that point because we don't have a robust industry. Government needs to come and fund the high risk portion". "support in terms of hard cash to these initiatives is very difficult, from an R&D stage right through, more so and more prevalently when you reach commercialisation".

A researcher/ entrepreneur felt that the government only funding model for the biotechnology sector within South African were not working. Government agencies tend to invest in the wrong projects due to their lack of industry knowledge and expertise. Instead he proposes a different approach:

"The right thing is that there should be some sort of public-private partnership here where … government partners with people from the private sector who have direct and relevant experience to guide investments that they are going to make…there is no experience either side of the bench, not the investors nor the people who are being vested in to make an success of those investments".

5.3.5.2 Human resources

The majority of respondents were of the view that there are sufficient access to skilled workers that would be required for manufacturing of diagnostic reagents in South Africa. Concerns were however raised over the inability of the industry to retain and nurture these skills. Employment opportunities are few and far between for graduates and postgraduates in biosciences who then tend to seek employment abroad or in other sectors. An academic explains the nature of the problem:

"We train enough people, but we lose them to overseas institutions and to government departments (even PhD graduates), as employment opportunities are not there and remuneration is not commensurate with experience."

Graduates and postgraduates in biosciences lack industry experience and entrepreneurs should budget for additional inhouse training that will be required as explained by an entrepreneur:

"So, your collateral fundamental is that you will have to train the skills. So take that into account in your business model; it will be one of your key success factors. The bankability factor will be: can you manage the cost of training?"

Some participants felt that the quality of school education and lowered entry-level requirements at tertiary institutions are bound to produce graduates that are less skilled and qualified to do the work. An entrepreneur/ academic expresses her concern:

"I would say that the quality of human resource has been and is increasingly deteriorating, because of the lowering of standards at the universities. The quantity is not the issue, because there are more graduates that can actually be absorbed… it is all about quality. So the notion that we have is just churn out thousands of PHD or whatever other degree if that certification or that degree lacks in substance".

A suggestion was made that capabilities and talents should be identified in children at a young age, and further cultivated. For bioscience in particular, this would result in having researchers that are of high standard.

5.3.5.3 Physical resources

Biomanufacturing in general requires high initial CAPEx which makes it difficult for an entrepreneur to attain. Tech transfer offices, incubators and accelerators assist entrepreneurs by providing access to instrumentation, required skills and knowledge. The majority of respondents felt that physical resources is not a barrier to the localised production of molecular reagents.

It was mentioned by one person that there is no GMP (Good Manufacturing Practice) facility for diagnostics in South Africa, and that investment of a multinational company in local research infrastructure can address this problem. Another respondent had the same idea when he said:

"What we need in this country is multinational companies that operate in South Africa, like Johnson and Johnson, for example. What they need to be doing is, in addition to setting up their offices in South Africa, we should then be encouraging them to set up research infrastructure. That will attract scientists to work for them or attract SMEs so that you create that value chain."

Two other respondents suggested that government could incorporate this idea into the offset obligations that MNCs are required to fulfil, but they also mentioned that the DTI are not effectively enforcing these obligations currently. The requirement for cold chain management in order to preserve reagents restricts access to certain markets, as one respondent explains:

"… in other African countries, the electricity source is not reliable…They rely on generators, so if you don't have a constant supply of electricity, you can't run this industry. Reagents perish, they have a shelf life."

Technological development provides solutions to this challenge as highlighted by an entrepreneur when he talks about how his company is currently looking at incorporating freeze-dry technology into some of their reagents.

5.3.6 Knowledge development

Table 9: Barriers to knowledge development

Code System	Barriers to localisation	SUM
Knowledge Development		3
IP		2
R&D		7
Knowledge development		11
Knowledge base		9
Σ SUM	32	32

5.3.6.1 *The knowledge base*

The general sentiment was that the knowledge base, in terms of scientific knowledge required, does not form a barrier. Numerous respondents mentioned that the shortage of entrepreneurs in biosciences can be attributed to the fact that graduates and postgraduates are academically skilled, but lack the knowledge that is required to translate their research into a product and to start-up and run a business, as explained by two participants:

"Our education system focus only on the academic part; it does not enable those who want to start a business. There is a gap in process development." "I think generally there is a lack of knowledge about what it means to translate application workflow processes from a university environment into an industrial environment… post graduates have relatively little experience, for example, with process marketing, process management…"

A laboratory manager suggested that business-related subjects should be incorporated into the curriculums of science courses at tertiary level to enable graduates to become entrepreneurs, and that this could address the shortage of employment that many graduates in biosciences face. Other participants reacted to this suggestion by stating that entrepreneurship is an inherent personality characteristic that cannot be taught. They all agreed that incorporation of business courses into the curriculum of science degrees could equip potential entrepreneurs with the necessary skills that are required.

5.3.6.2 *Knowledge development*

The quantity of knowledge development was not mentioned to be a restrictive factor to localisation, but the majority of participants felt that the quality thereof is an issue. There was a general perception that research programmes conducted at universities are not commercially driven, and that researchers generally only aim to get their work published, as explained by an entrepreneur:

"Researchers don't look at the commercial end of their research– they are just chasing the academia applications, and there's no drive to say - Let's do research on this antibody or biomarker, whatever, and then take it down to the market and produce it."

The funding of research at universities by government thus assists in knowledge development, but there is very little benefit to industry.

An entrepreneur expresses his frustration with industry-university collaborations that is funded by government, where the success of the company's research project depends on the quality of researchers that are allocated by the university to that project. He further goes on to suggest that this problem can be addressed by government by creating "industrial post-doc" programmes, in addition to what is currently run at universities, where companies can have input into the selection of researchers that work on their project and where researchers then work on projects that are commercially orientated and meet the needs of industry.

An international entrepreneur/ researcher describes his personal experience at a South African university:

"When I look around at my colleagues at health sciences there are almost no people who have companies sitting on the outside, there are very few people who are doing work where you can perceive the commercial value to industry… So generally yes it feels to me a bit like…University did in the mid-90s, where academics still thought that their job was to drive your pure academic enquiry, when … commercial and entrepreneurial activity has been somehow frowned upon".

He continues to explain how the perception of academics at a world renowned university changed from being academically focussed to become more commercially minded and gives suggestions on what should change in South African universities:

"The two things that drove that in my mind were partly having a series of role models, examples of people who formed companies and derived benefit from the sales of doing, but also what happened was the government started to put much greater emphasis on the value of commercialisation…every time you submitted a grant application you had to fill in a box at the end of the grant application to say… how is what you are doing going to do be of value to the country later? …it seeded in everybody's mind that actually the government was expecting some kind of return from investment in their research. So I think this idea about the academic focus needs to be led by the funding agencies…Universities need to have some way to recognise that when people go for promotions in the University system, that entrepreneurial activity and output are counted alongside and equally with academic outputs and currently they aren't".

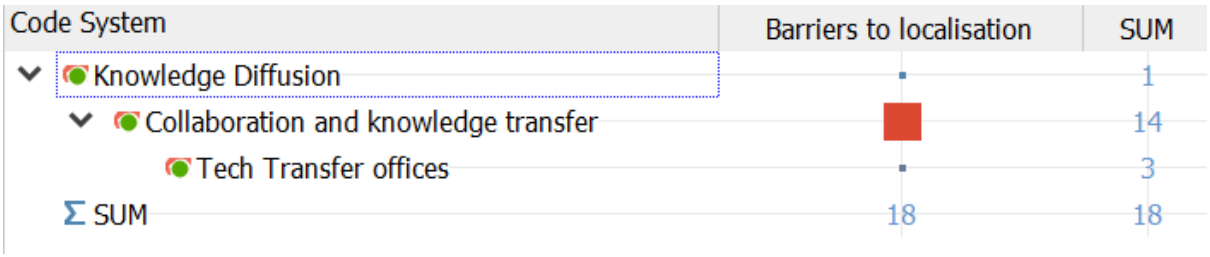
IP regulations were not identified to be a barrier to localisation by the majority of participants, but a few entrepreneurs expressed their frustration with how Tech transfer offices at universities handle the legalities around IP allocation and registration as explained in the following statement:

"The University of … doesn't have policy around whether we should be paid in our companies or try and keep the IP inside the University and licence it elsewhere , so it's getting bogged down in the regulations surrounding the national IPR act , constantly worrying about what we can and cannot do with intellectual property".

It was said that until recently the focus of academia were more on development of new therapeutics than on diagnostics, with most of the discovery work that are done offshore and South Africa that serves as a clinical trial site. The MRC and SHIP have initiated research projects to develop next generation TB point of care diagnostics and HIV diagnostics, but most of these were still early stage projects.

5.3.7 Knowledge diffusion

Table 10: Barriers to knowledge diffusion



The lack of collaboration was identified as the second most restrictive barrier to localised manufacturing of diagnostic reagents (refer to **Error! Reference source not found.** and

Table 9). In terms of the local diagnostic industry, collaboration is said to be good in some areas whilst in other areas it poses a challenge. There seems to be a division between private and public organisations as well as industry and the academic sector. A participant sums up the current situation:

"… my personal experience in the field is that there's an enormous degree of hesitation, or a lack in willingness to work together, it is amongst academics – it's amongst companies and also amongst companies and academics. I think there is a huge amount of mistrust and suspicion not least I think it's also fuelled by the government's own stance toward industry and business in the biotech sector. So, for example, they have got all kinds of suspicions about the price policies and strategies on behalf of molecular diagnostic laboratories in the country, and because of the high cost or the perceived high cost of healthcare, you have also got mistrust about activities and actions by pharma companies. This is a blanket statement. There will always be collaborations, but I think that is not as good as it should be."

The lack of trust among industry actors were confirmed by two other respondents, with one stating:

"You sit in meetings where people don't say much. They cannot talk because of conflict of interest, confidentiality and IP-protection reasons. The universities are trying to do tech transfer and trying to help by teaching researchers how to research their work, but there is a gap between what the industry and universities want. The biggest gap is in the development process".

A prominent government role player however indicated that the situation is changing with initiatives such as the Innovation Bridge that is aimed at improving private-public relations and interaction among industry actors and THRIP, an initiative by the DTI to facilitate interaction and knowledge diffusion between industry and academia.

Some respondents felt that there is good collaboration between industry and academia through the facilitation of tech transfer initiatives, but that it could still be improved. A suggestion was made that standard contracts should be drawn up by a professional third party in order to speed up the technology transfer process.

There were a need expressed by some for industry forums and government or industry driven health initiatives that would coordinate actions of industry actors:

"There needs to be access to conversations… interaction with high governmental players…and you get together to discuss the next possible threat of diseases and plan how you will go about to prevent it. There should be health initiatives, where big players get together, like what is done e.g. in the US, and create a big push to get it going. We should sit together and work together, we need reagents from you, we need enzymes, we'll buy plastics from this one, and we put a test together and go for it together. There is no action like this; there is too much silence. There should be forum so that people are just even being aware of one another."

An entrepreneur express his view on what the spillover effect would be of increased collaboration between industry actors:

"Government ought to try to provide incentives for people working in these spaces to work together and not in isolation, and I think the outcome would be in providing more centralised access to clinical trial resources for example and sample collections so people that are developing different styles of tests, for the same disease using coordinated sample collections. There would be an economy of scale to gain…"

The importance of collaboration between industry and users of these products during the development phase was emphasised by a participant. Collaboration with international actors have also been identified as a challenge because of the cost involved, and it seems to be driven mostly by industry. It was mentioned that there used to be an initiative called Bio Bizz that connected actors in biotechnology with others on the continent and internationally, but this has been terminated. An entrepreneur suggested that big multinational firms like Roche should be incentivised to participate in collaborative research programmes with local universities, as is currently being done in Switzerland.

5.4 LOCALISATION STRATEGY

2) What localization strategy could be pursued to maximize the potential benefits of a strong reagent sub-sector?

A number of suggestions were made by participants on how a local manufacturing sector for diagnostic reagents should be established. The general feedback was that as a starting point, a feasibility study would have to be conducted to assess the viability of localisation of these reagents. An entrepreneur explains what the important considerations would be for a localisation effort:

"One should use the value chain approach and understand exactly which components of this value chain can be sourced locally. After this, one would have to look if we have the diagnostic portfolio that is very competitive, whether it be based on cost, accuracy or the point-of-care route. One would need to understand what is the job creation prospective, the skills development prospective, the pathways that need to be created to achieve success, and communicated! … the strategy should be to really understand how to maximise the socio-economic impact. You need to do that using a rational modelling process, and you need a champion; somebody that wants to communicate from the top to the bottom – private sector, public sector, academic sector – to leverage enough momentum to get support. SHIP is doing a great role to build a pipeline, but you need two or three critical players."

Participants gave a few ideas on how to develop a local diagnostic reagent industry. An entrepreneur explains that the first step would be to do a five to ten year technological forecast, followed by rapid experimentation ultimately to gain a solution that would be scaled up in production. To reduce the dominance of big companies locally and the cost of transport and import duties to importers, a distribution hub should be created that import reagents in bulk, repackage and then distribute locally, whereafter capital gains can be used to set up manufacturing capacity and to fund R&D.

Partnerships with big multinational companies can also stimulate development of the industry through investment in physical infrastructure and transfer of skills, and potentially stimulate SME growth when MNCs source services, raw materials and intermediary products from local SMEs. A respondent explains what factors would be important in such a partnership:

"I would partner with MERC, but you can only partner with a value proposition. What is your value proposition? Do you have a molecular diagnostic reagent portfolio that has a competitive advantage either based on cost or on accuracy and precision compared to what MERC has? Otherwise you will struggle and remain a cottage industry."

A successful localisation initiative would require that support are provided to entrepreneurs in the form of incubators and accelerators. The Biomedical Translational Research Initiative (BTRI) programme, a collaboration between UCT and the CSIR is given as an example and aims to serve this purpose.The advantages that this would have to entrepreneurs are explained by two researchers:

"Have various facilities in the country that make that possible by providing capital equipment of course with some skills associated… new companies also don't have to invest immediately in capex, and usually capex is a big barrier to entry. "…to enable people that got good ideas and something that looks like proof of principle coming out of an academic environment, to be able to pursue those and develop those concepts and products rapidly without having to set up a company… and it is that access to business skills that is the biggest issue here, because having access to facilities is not such a big deal".

Suggestions to companies or entrepreneurs were to not only consider diagnostic reagents for human purposes, but to look at the ecosystem as a whole (plants, animals) and at applications in agriculture and research. One approach would be to develop one product that is of high quality, use it to gain recognition in the market and financial resources and so develop the second product until eventually an entire product portfolio is established.

Local firms would have to consider whether to compete in the local or international market. There is potential for high earnings in the international market as an entrepreneur explains:

"The growth rate on the global market has climbed with 16% compound aggregated growth rate that is in developing markets. And if you look that the rest of the world is actually growing faster than that, there is a market of about $78 billion. There is a huge demand, but you would have to be competitive and have a differentiated value proposition."

Local manufacturers would have to overcome the disadvantage of being geographically far removed from the global market that is predominantly in the northern hemisphere. This implies that a company would have to develop or gain access to existing sales, marketing and distribution channels to these markets. Firms that choose to compete locally would have to decide on whether to compete on price or quality. Consumers in the private sector are not as price sensitive and are willing to pay for quality products in contrast to the public healthcare

system where government is the dominant funder and exerts pressure on providers of healthcare products to keep prices low. Some participants articulated the potential that exist in the African market and in particular the SADEC region. South African reagent manufacturers would have a geographical advantage over their international counterparts to supply these markets. Two participants expresses their view on potential within the African market:

"As South Africa we come from a relatively advanced competitive position in relation to the African markets, … you want to look at the African market as an extension, and in that case actually there is a huge market for these things." "One such niche strategy exists to create products that provide solutions for indigenous diseases in South Africa and the SADEC region that global suppliers do not find to be lucrative."

Numerous entrepreneurs felt that local manufacturers would not be able to compete on price with the low cost products that are being imported from Asian markets. The competitive advantage for local producers of diagnostic reagents would be to have an unique value proposition where access to a genetically diverse population and a high communicable disease burden places the country in a unique position. Thus far South Africa has served the purpose as a clinical trial testing site for global companies with very little product development that take place. A researcher explains the change that need to take place:

"The value proposition in South Africa should be that we actually have unique products that nobody else can make, because we have intellectual property protecting this products. What underpins a good diagnostic test that would gain market segments in that space, would be a new set of bio-markers that underpin the new test and outperform what was available already on the market… In order to find new bio-markers you have to have access to patients, to very well characterised patient populations which we almost uniquely do in this country… so I think the capacity issue to produce innovative diagnostic products relates directly in my mind to the local burdens of disease and the uniqueness of local burdens of disease".

A number of factors were mentioned by participants that is foreseen to drive the demand for diagnostic reagents locally. Firstly, South Africa has an ageing population that is expected to result in an increased demand for health services. Secondly, the country's disease burden, in particular communicable diseases such as HIV and TB and lifestyle diseases for example diabetes are on the increase. Thirdly it was mentioned that the Discovery Health medical scheme are encouraging their members to make use of the precision medicine services that will be accessible in the near future. Fourthly, technological development in point of care diagnostics, medical devices and next generation sequencing used for precision medicine

and an increased awareness of the benefits of these technologies will translate into more reagents that will be used in the near future. An entrepreneur expresses a need for screening tests that would increase reagent consumption even further:

"There's a critical need for advanced metabolic kind of early screening diagnostics for prevention. So not just disease confirmation, but also early screening, which is a new fact that will drive the market."

It was mentioned that the MRC and SHIP are currently working on a number of big projects with the focus on precision medicine, point of care diagnostics for TB and HIV and medical devices that would require more reagents once completed:

"…we are looking at setting up an initiative with the Beijing Genomics Institute, where they would set up a lab here to do whole genome sequencing…the deal is that they will actually supply the reagents from China and that is what they get out of the deal. They are putting a whole lot of equipment in here at their cost, we are paying the research cost around sequencing 20,000 genomes … Whether there is scope to in future look at local manufacturing of those reagents, I'm not sure. It would be ideal when one is going to do sequencing on such a large scale so there is that. On the rest of the precision medicine side we are investing in a few projects at the moment around cancer and precision medicine and genetic screening…I think there is going to be a growing need for diagnostic reagents. We are supporting a few projects around developing point of care devices for diagnostics… if we are serious about setting up local manufacturing, those reagents would have to come from somewhere…so if we could source those kind of reagents locally, it would be of huge benefit."

5.5 THE ROLE OF GOVERNMENT

3) What should the role of government be in implementing such a localisation strategy?

There was general consensus among participants that most importantly, government need to provide support to entrepreneurs. Many participants felt that government's role is first and foremost to provide sustainable funding, in particular for R&D to reduce the risk to entrepreneurs that is associated with innovation as is explained in the following statement:

"… there is that missing initial gap where the funders want to get involved but they won't get involved until you reach a certain point, and we can't get to that point because we don't have a robust industry. Government needs to come and fund the high risk portion".

Government institutions tasked with providing support and funds to industry such as TIA are highly inefficient, and participants were in general agreement that government need to rectify this as a matter of urgency. A need for more support in the form of more accelerators and incubators were expressed, where entrepreneurs would have access to instrumentation, knowledge and business skills to translate their ideas into marketable products. To increase investment in local infrastructural development and transfer of skills, it was said that government should form partnerships with big MNC's and use their offset agreements to enforce it. Government can further alleviate risk and uncertainty for local producers through preferential public procurement of localised products as explained by an entrepreneur:

"I think DTI and Department of Health should bring localisation into their tender processes; they are, but it is not being enforced. The localisation policies that drives tender decisions, because the size of the public market here is key".

Some participants felt that government should provide incentives to companies and entrepreneurs to move into this space. A suggestion was made for government to incentivise local actors to produce innovative and low cost diagnostic products through tender contracts that are awarded to those that succeed. One participant gives his opinion on tax breaks as a form of incentive:

"…if there is really support from government to say look, if you want to get involved in developing and researching and producing innovation in terms of molecular diagnostics, we will give you a tax break for five years, you will find a string of companies that start to take this on. You'll find international companies who will come here and kick-start the local industry".

Government should initiate and encourage collaboration and knowledge diffusion between industry actors, either by means of incentives or through coordinated health initiatives aimed at addressing local disease burdens as explained by an entrepreneur:

"…you get together to discuss the next possible threat of diseases and plan how you will go about to prevent it. There should be health initiatives where big players get together like what is done e.g. in the US and create a big push to get it going".

Participants felt that government has a role to play in creating awareness of industry, especially in the global market. An entrepreneur explains:

"What we need is for government to book a stand in every major tradeshow for the next five years and take us with them…That is how we generate exports…It is too much to expect from industry players to do that alone".

It was mentioned by some that local consumers of reagents should be incentivised to use localised reagents. Examples that were given of what these incentives should be are conditional subsidies offered to consumers of local products, or the alternative would be to increase the duties and taxes on imported products. There is a need for better regulation of imported products that enter the market as explained by an entrepreneur:

"… customs regulations and duties - what should happen is that they should be changed to protect products that are produced locally. That is not the case…there is no protection for inferior products that are flooding in from China, there is no protection laws or duty that is put on imported products…"

Government policies need to be better aligned – a statement confirmed to be true by the majority participants. A prominent point that was raised by the majority of participants was that the bioeconomy strategy lacks a clear implementation plan. Government needs to provide a clear plan on how to develop and grow the industry going forward. One point in

particular that the bioeconomy strategy needs to address is the retention of skilled labor as explained by a researcher/ entrepreneur:

"the demand for such jobs far exceeds the supply, and so the bio economy strategy really needs to look at that issue.. as the diagnostic industry grows and is more profitable, it will be able to afford to pay more competitive salaries and then people won't leave".

A number of proposals were given with regard to science education and skills development. Suggestions for universities are included here as they are generally state owned within the South African context. Firstly government has to better the standard of school education that was mentioned to not adequately equip students with the basic knowledge that is required for a career in science. Internship programmes for undergraduates and postgraduates in science are foreseen to develop product and process development skills that was said to be sorely lacking in the industry. Industrial Post-doctoral programmes will ensure that research is conducted that have relevance to industry and are of commercial value. Lastly business subjects should be included in the curriculum of science courses to equip potential entrepreneurs with the necessary skills.

5.6 CONCLUSION

The results presented in this section mentions the challenges to build-up of a local diagnostic reagent TIS as foreseen by the majority of research participants, followed by their suggestions for localisation strategy and policy intervention, and lastly the role that government should play. The TIS functional framework as described in section 2.3 was used to structurise the feedback given regarding challenges, as per the objective stated in research question 1 (section 0).

Results show that there are challenges to each one of the seven functions required for system formation and development. Unconducive regulations to localisation, such as high cost registration that are imposed on local manufacturers, and the inefficiencies of governmental organisations, in particular TIA have been mentioned to negatively influence the legitimation of technology. In terms resource mobilization, the inaccessibility to financial resources are considered to be a major stumbling block. Private funding options are virtually abscent, and applications for government funding takes and extremely long time to process.

Insufficient collaboration between industry actors will pose a challenge to any efforts of transfer knowledge between various actors within a future TIS. There are currently only two private firms that are manufacturing diagnostic reagents in South Africa, and therefore very little experimentation that is taking place. Research at universities prioritise academic achievements with neglegable commercial value to industry, and so negatively influence the knowledge development process that is critical for innovation. There are no common goals or expectations among industry actors for system development, with very little drive from government to coordinate action. It was said that local users of reagents will be reluctant to change suppliers of reagents, changover would require downtime and result in lost revenue. The lack of actor expectations and reluctance to change will deter potential SMEs and entrepreneurs from entering into this space.

With regards to strategies for localisation, it was proposed that a value chain approach should be taken to assess the strengths, competitive advantage, skills and capabilities within the local context that will enable manufacturing of reagents. Technological foresight should be used to determine the development pathway that not only maximises economic benefit, but also social spillovers. System development would require capable leadership to coordinate actions of all actors in industry. Local firms would need to develop a niche strategy where they foresee opportunities within different markets to compete, either through cost advantage or based on quality. Feedback suggested that opportunities exist within the African market and SADEC region to produce unique diagnostics that meet the region's specific needs. Other respondents felt that an approach should be taken where the country utilizes its access to a genetically diverse population to develop unique products for the international export market. Drivers of demand, such as an increasing local disease burden, aging population, technological trends e.g. point-of-care, medical devices, precision medicine and DNA population sequencing should also be considered for opportunities.

Government's role in localisation was said to provide support, in particular financial support for R&D that is associated with high risk for SMEs. The inefficiency of government organisations should be addressed and improved by government as a matter of urgency. Support in the form of more accelerators and incubators are needed, to provide entrepreneurs with access to the capital equipment, resources and skills that are required for innovation. Government should secure demand for local diagnostic products through public procurement and incentives for users to change to local suppliers, and improve regulation of the local market by implementing import tarrifs. To encourage entrepreneurs and SMEs to move into local diagnostics manufacturing, government need to provide incentives such as tax breaks, that will influence direction of search and as entrants increase, stimulate

experimentation. An approach of competitive tendering was suggested where government coordinate actions of local innovators to produce products specific for needs in the country, and this would also facilitate collaboration. As a leader, government should provide an implementation plan for the development of industry. Partnerships should be formed with MNCs to assist with skills development and infrastructural investment, and potentially create opportunities for local SMEs through subcontracting. It was suggested that government should create awareness of local industry by promoting local companies at international trade shows. Lastly, government should improve the quality of secondary and tertiary education and facilitate skills and knowledge development through internship programmes and industry post-doctoral programmes.

6 CHAPTER 6: DISCUSSION

6.1 INTRODUCTION

The previous chapter presented the results that were collected using a qualitative approach. The discussion in chapter 6 will be structured according to the research questions that were stipulated in chapter 3. They are:

Research question 1: Based on the TIS framework, what are the challenges for the localization of molecular diagnostic reagents?

Research question 2: What localization strategy could be pursued to maximize the potential benefits of a strong reagent sub-sector?

Research question 3: What should the role of government be in implementing such a localization strategy?

This chapter will start-off with a discussion of the TIS framework and its perceived appropriatness for this study, followed by a discussion and interpretation of results.

6.2 TIS AS A FRAMEWORK OF ANALYSIS

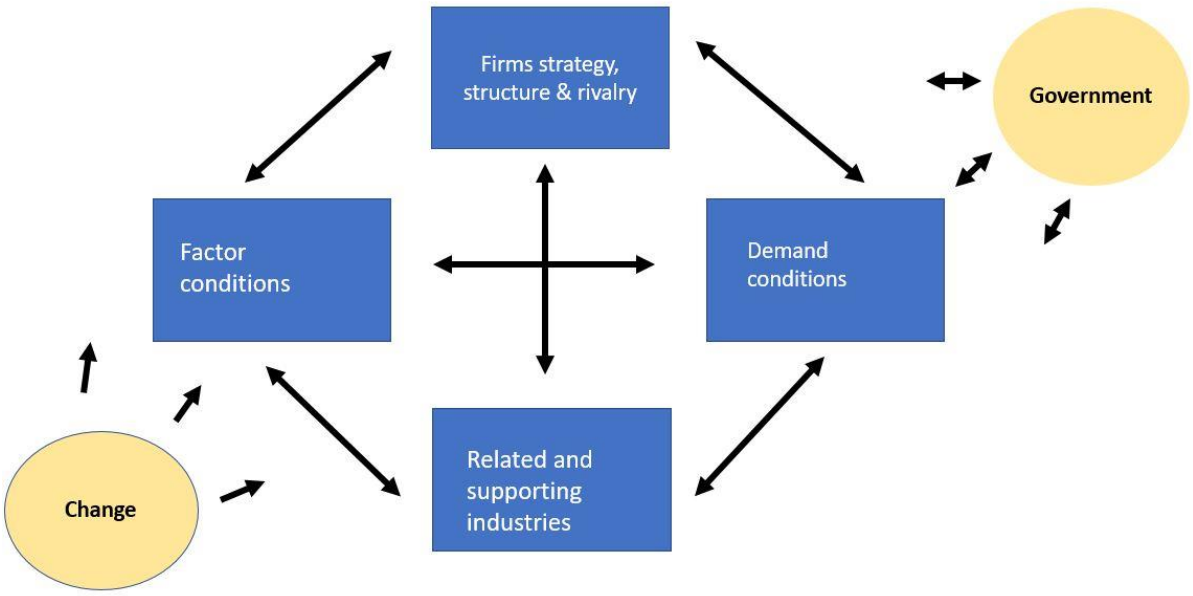
This study looked at the current nature of the diagnostic reagent industry in South Africa with the sole purpose to assess the interventions that would be required to create manufacturing capacity, and the role that government would need to play to ensure system formation and sustainable growth. The lense through which this was achieved - the TIS framework, proved to be highly effective, in particular with the assessment of current challenges to localisation of diagnostic reagents. It provided a structured approach to the data collection and analysis processes, and the qualitative data overall aligned with the initial code sets that were created based on the functional framework of TIS theory.

A point worth mentioning is that some respondents needed further clarification on certain technical terms that were taken from TIS theory and included in the questionnaire. This did not have any implications in terms of data validity, but could complicate matters when other data collection methods such as surveys are used. Discussions with participants on system function performance successfully evoked suggestions for localisation strategies, needed policy interventions and what the role of government should be. Above all, what made the TIS

framework truly useful and suitable is its emphasis on technology, knowledge development and transfer of knowledge. Biotechnology is evolving at a rapid pace and bio-entrepreneurship/ biomanufacturing are knowledge intensive undertakings. The TIS framework was therefore perfectly suited for this research topic.

Porter's Diamond framework of competive advantage is an alternative framework that could be used to assess system weaknesses and strengths for competitive advantage (Porter, 1990). In this framework he describes four different determinants of competitive advantage for firms within a particular industry or region, namely factor conditions (quality and cost of production factors), demand conditions, strength of supporting and related industries, and lastly firm structure, strategy and rivalry. Government and chance (conditions that cause change over which firms have no control), are seen as external influences.

Figure 8: Porter's Diamond framework



There are numerous similarities between the diamond and TIS frameworks. Porter does acknowledge that government has a role to play, though its influence is seen as more indirect. The influence of industry actors and interactions that take place between them are seen as primary contributing factors to attain competitive advantage. Similar to TIS system dynamics explained by functional interactions and feedback, Porter also describes the diamond as a dynamic system in which all elements interact and reinforce each other (Oz, 2002).

In certain areas the two frameworks are also distinctly different. Parameters of the diamond model are defined by location (region) versus technology that defines a TIS. Porter's framework do not acknowledge formal institutions (laws and regulations) and informal institutions (norms, values, culture) as major determinants of competitive advantage. Cultural influence is acknowledged but not seen as separate from other economic factors.

The diamond seems to downplay the influence of macroeconomic policies, multinational firms and foreign direct investment (FDI), and the role that technology plays in system development. It can be said that with the diamond model, the firm is the centre of focus, with interactions between actors that are explained through neo-classical economic principles such as market competition, supply and demand. In contrast the TIS framework takes on a more a holistic and systemic approach where access to knowledge and development of technical capabilities within the system are the primary source of system competitiveness. The underlying objective of this study was to inform policy design, and considering certain limitations inherent to the diamond model as described here, the TIS framework was therefore the logical choice to go by.

Despite the fact that the TIS framework was initially designed with developed countries in mind, recent studies conducted in developing countries have indicated that it can indeed be applied in the context of emerging economies. One such a study conducted by Kebede & Mitsufuji indicates through use of historical event analysis how development of system functions have positively influenced diffusion of PV technology and formation of the local PV industry (Kebede & Mitsufuji, 2017). They argue that while the capacity to innovate is underdeveloped or even absent in many latecomer countries, the TIS framework can still be applied as an analytical framework to understand system formation within this context (Kebede & Mitsufuji, 2017). The TIS functional framework indicators are modified in their study to distinguish between the knowledge generating international TIS that possess R&D capabilities, and the local diffusion-based TIS. The focus in latecomer countries, using a diffusion-based TIS, is on adoption and diffusion of established technology through which knowledge can be accumulated and capabilities for innovation can be developed.

For the purpose of this research project it was not necessary to distinguish between a local and international TIS, seeing as the local diagnostics and biotechnology innovation systems are R&D based, and there is very little knowledge transfer that is taking place between local and international TISs. The approach taken by Kebede & Mitsufuji is however worthy of consideration for future TIS analysis in developing countries where the capacity to generate knowledge is underdeveloped.

6.3 RESEARCH QUESTION 1: BASED ON THE TIS FRAMEWORK, WHAT ARE THE CHALLENGES FOR THE LOCALIZATION OF MOLECULAR DIAGNOSTIC REAGENTS?

6.3.1 Introduction

The feedback received from the majority of participants has identified a number of challenges to localisation of diagnostic reagents. Table 11 presents a summary of system function barriers arranged in the order of most to least (deduced from the number of participants that have flagged it as a challenge to localisation, indicated in brackets). Firstly these will be discussed through use of the TIS functional framework as a guide, after which contradicting evidence will be highlighted.

Table 11: Summary of Barriers identified by respondents

TIS Function	Barrier
timation	ducive regulations and institutional encies (16)
ource mobilization	cient financial resources (15)
wledge diffusion	cient collaboration between actors (14)
epreneurial experimentation	number of actors (14)
ket formation	ctive size of the local market (13)
wledge development	sity research not commercially ated (11)
ence on the direction of search	f clear actor expectations (10) ance of users to switch suppliers (10) y perception).

6.3.2 Barriers to Localisation of molecular diagnostic reagents

6.3.2.1 *Legitimation*

Regulation

Stricter regulation is required of imported products that go through import customs and enforcement of import duties on these products, to ensure that low cost and quality products do not flood the local market. Recent legislation changes that aim to regulate the local market were implemented, that require manufacturers, importers and healthcare products to be registered, and the foreseen result is that though this should be effective in keeping out low quality products from Asian markets, smaller local companies would not be able to carry the "huge cost involved" (P18).

Standardization

Currently there are no CE standardization officer in the country, thus local firms have to request an inspection from an international officer at high added cost. The MRC seem to be aware of this challenge and are currently looking at ways to address this issue. Some respondents were of the view that SA should have its own standardization board and regulations, while others felt that this is not feasible and would unnecessarily add to the cost burden of firms who supply products to the local and international market.

Institutional inefficiencies

Certain government institutions and agencies that have been designated to support innovation are inefficient. One such organisation, the Technological Innovation Agency (TIA) was specifically mentioned and numerous entrepreneurs testified that their applications for finance took in excess of a year to be processed. Employees at these institutions, including incubators and those at university technology transfer offices, do not have adequate business experience and lack the knowledge, skills, and networks with industry that is necessary to successfully guide products through the commercialisation phase and uptake in the local market. Due to lack of knowledge, government agencies then tend to make uninformed investment decisions and invest in projects that do not generate expected returns.

6.3.2.2 *Resource Mobilisation*

Financial resources

Government is the dominant funder with little or no private or VC funding available. Private investors are reluctant to invest in biotechnology start-ups for reasons highlighted by an entrepreneur:

"you have a higher capital investment, there is slightly higher technical risk, your market is not that certain" (P6).

TIA provides the bulk of funding and as explained in the previous discussion under legitimation, they are seen to be inefficient and this limits their ability to fulfil their mandate as a supporter and enabler of innovation in South Africa. SHIP and the IDC provides some funding and the MRC plan to assist with financing in the near future.

6.3.2.3 *Knowledge diffusion*

Collaboration - There are little collaboration between industry actors and in some cases it was expressed that a divide exist within industry, between industry and government, and between industry and academia. An entrepreneur/ academic ascribe it to a "huge amount of mistrust and suspicion" that exist between industry actors. Collaboration with international entities and forums also pose a challenge with little assistance from government. Newly implemented initiatives such the Innovation Bridge driven by the MRC and THRIP, a DTI initiative to encourage collaboration and knowledge transfer between industry and academia seems to be promising changes that could improve collaboration in future.

6.3.2.4 *Entrepreneurial experimentation*

Number of actors - There are currently very few industry actors, with only Kapa Biosystems and Africa Biotech that have been identified to manufacture molecular diagnostic reagents, and only Kapa Biosystems that produce at large scale. Other than these two firms, there is very little experimentation taking place. Some participants were of the opinion that considering the limited demand in the local market and small quantities of reagents that are required per test, it does not warrant large scale production of these reagents.

6.3.2.5 *Market Formation*

Size of the local market

The overall response was that the size of the local market is restrictive and too small if only relied upon by local manufacturers of reagents. One respondent and local entrepreneur, goes as far as to say that the size of the local market is "absolutely insignificant". The market lacks the critical mass that is required for mass production and local manufacturers would have to diversify into the African and International markets to achieve sustainable growth. Firms that aim to export their products would need access to well-developed channels for sales, marketing and distribution within the global market, either through agreements with international entities or by developing their own, in order to overcome the disadvantage of being geographically far removed from the international market. Local demand for these reagents is said to be limited to the part of the population that have access to centralised healthcare and government subsidised healthcare or those who have health insurance cover.

Market saturation

Imported products from big MNCs and low cost products from Asian markets dominate supply in the local market. To compete within the market local firms would need sufficient market penetration and would have to compete with generic low cost imported products based on cost, which is "not sustainable in the long run" (P3).

6.3.2.6 *Knowledge development*

The quantity of knowledge development does not pose a challenge to efforts of localisation, but the quality of knowledge development does present a challenge. Research conducted at universities is not commercially driven; the majority of this work is blue-sky research with the aim to get it published in academic journals. Health science research for industry is conducted internationally, with South Africa purely serving as a clinical trial destination. Industry – university collaborations thus far have not delivered the expected results due to the fact that industry has no input on selection of researchers and minimal influence during the research process (P8).

6.3.2.7 *Influence on the Direction of Search*

Generally it was observed that actor expectations are unclear. There are no common goals or vision among industry actors, explained by the absence of leadership that is necessary to coordinate and strategically drive industry development (P6, P17, P19). The general

consensus was that the bio economy strategy was a good starting point but an implementation plan is lacking, as illustrated by comments such as “I think perhaps it falls apart on the implementation” (P1). The DTI raise the IPAP document as a strategy for localisation, but it does not prioritise local manufacturing of diagnostic reagents. Currently there does not seem to be any coordinated drive through industry forums or driven by government to address disease burdens in the country (P17).

6.3.3 Contradictions in Data

Responses from participants varied in some instances on what the challenges to localisation are and the underlying reasons for these challenges. One should keep in mind that this is an exploratory study that seeks to gain a rich understanding of the problem within its context, therefore the varying explanations that were received is seen as testimony to the strength and thoroughness of the data that were collected. The different occupations of individuals, their roles (government or private) and experiences within the local biotechnology and healthcare sectors are influential factors that could possibly explain the variation in responses that have been observed in certain cases.

Feedback on whether there is sufficient support from government somewhat varied. Some respondents felt that there is sufficient financial support and incentives for manufacturing in place for local firms with a unique value proposition and marketable idea (P2, P4, P6, P9, P11). Government has renewed its focus on Life science development as part of its Bio economy strategy to develop the Knowledge Economy as a bio entrepreneur highlights:

“There is an enormous drive and a high priority is being set for life sciences kind of manufacturing” (P6).

Others felt that there is not enough financial support from government and that little is being done to protect local suppliers from the influence of imported products that are flooding the local market as explained by an entrepreneur (P2):

“…customs regulations and duties…should be changed to protect products that are produced locally. That is not the case, it is an open market system … there is no protection for inferior products that are flooding in from China.”

In terms of local market demand and large scale production, the majority of respondents felt that demand for diagnostic reagents in the local market is small and these reagents are used in small quantities, and as a consequence it does not require large scale local manufacturing.

A somewhat contradicting view was expressed by a researcher and entrepreneur actively involved in TB healthcare. According to his calculations over 2.5 million TB tests are conducted each year nationally (P3). This estimate is based on tests performed in centralised laboratories and does not include active case finding (referring to mobile screening of target populations, who have been identified to be at risk of contracting a disease). Considering government initiatives to promote HIV screening in recent years, the number of HIV diagnostic tests conducted yearly is expected to be in the same region or higher. The researcher confirmed that as part of a consortium they did look at ways to scale up production for TB diagnostics, and that there is the need for large scale production.

In terms of the science knowledge base, there was disagreement on whether the local science knowledge base is adequate for localisation of reagents. Deteriorating standards of science and maths education at school level and universities were given as explanations by those who felt it is insufficient. An entrepreneur explains:

“if you discount the ones that we can actually use then maybe it’s not about quantity it is all about quality. So the notion that we have is just churn out thousands of PHD or whatever other degree if that certification or that degree lacks in substance” (P19).

In terms of collaboration – The overall sentiment is that there is little collaboration among industry actors. Some differed with this view by stating in some areas collaboration is sufficient, and in other areas it can be improved (P1-4, P11, P13)

6.3.4 Interpretation of Data

What follows is a discussion of what is interpreted to be the major challenges to localisation of reagents and how they influence system functions.

6.3.4.1 Access to funding

Inadequate access to financial resources was indicated to be the most prominent challenge to localisation of diagnostic reagents and negatively influence entrepreneurial experimentation and the direction of search for potential entrants. Due to the lack of funding, few entrepreneurs and firms are entering into biomanufacturing and therefore little experimentation is taking place.

Access to private and VC funding is limited, and government act as the prominent funder. It was stated that there are gaps in funding within the innovation value chain. VC firms are

reluctant to get involved in early stage funding, and government is not providing sufficient seed funding for R&D as explained by these comments:

"There is that missing initial gap where… they (VC firms) won't get involved until you reach a certain point, and we can't get to that point because we don't have a robust industry"…" "There is not enough in my mind seed funding going in to prime the system"…" "Government have to make seed fund available and co-invest to lower the risk for entrepreneurs to support them to get into the market"

Allocation of funds are administered by a government agency that are described as inefficient, illustrated by numerous examples where they were said to delay processing of financial applications for periods in excess of a year. Local firms who very often cannot afford time delays due to the risk of losing their first mover and competitive advantage, then have to search for sources of private funding internationally. As a result many entrepreneurs or small firms who are unsuccessful in their search for funding do not follow through and opportunities are lost.

6.3.4.2 *Government institutional inefficiencies:*

As mentioned in 6.3.4.1 the inefficiency of government agencies negatively influences that availability of financial resources, and also the knowledge diffusion process. Government institutions such as TIA, innovation hubs, incubators and university technology transfer offices lack business experience and knowledge and this severely hinder their ability to assist local technology entrepreneurs with the commercialisation and adoption of their product in the local market. According to the feedback obtained, university technology transfer offices are not connected to industry. Government is also not facilitating interaction between local firms and international entities for knowledge transfer to take place, and any such initiatives are left up to industry to implement. It is quite clear that efforts to provide support for local tech entrepreneurs and SMEs are hindered by inefficiencies within supportive institutions.

6.3.4.3 *Formal networks and industry associations:*

There are currently no formal industry associations that are specifically lobbying for the development of a localised reagent industry. Instead current reagent manufacturers are "lumped together" (P 17) in SAMED and MDMSA who are more focussed on local manufacturing of medical devices. Challenges that relate to insufficient collaborations and knowledge transfer is seen to be directly related to the fact that there are no formal networks or associations that specifically prioritise development of a local manufacturing diagnostic sector. Industry associations fulfil the role of industry leaders that facilitate collaborations

locally and with international players, coordinate knowledge flows and resource allocation, and have the ability to overcome institutional gaps (Szogs, Cummings, & Chaminade, 2011). Industry associations thus have the ability to mobilize financial resources, overcome inefficiencies in government institutions and influence policy and regulatory design to favour development of a local diagnostic reagent manufacturing industry.

6.3.4.4 *Size of the local market and local firm support*

The overall consensus was that the size of the local market is restrictive and that it lacks the criticial mass for sustainable manufacturing of reagents. Contradictory evidence were however presented that indicate there is a lot of market potential in particular areas, specifically for the manufacturing of TB and HIV diagnostics.

Current innitiatives to develop TB and HIV point-of-care diagnostics, development of medical device technology and the creation of a precision medicine healthcare systems is foreseen to increase the demand for diagnostic reagents drastically in future. Unfortunately it appears that diagnostic reagents are not being prioritized for localisation currently. A MRC official confirmed that for the precision healthcare initiative, the agreement with the BGI is that they will provide the initial capital investment for infrastructure development and in return the MRC will procure diagnostic reagents from China for the foreseeable future. Reagents are currently being imported to develop a medical device prototype and recent price increases of reagents are delaying the development process (P4). Going forward it could be benefitial to the country if reagents are manufactured locally:

"if we are serious about setting up local manufacturing, those reagents would have to come from somewhere…so if we could source those kind of reagents locally, it would be of huge benefit." (P4)

If localisation of these reagents thus were to be prioritised in future, it is foreseen that demand for these products would not be the major restricting factor within the local market, on the condition that the necessary measures for market protection are in place. Currently that does not seem to be the case. The local market is saturated with imported products, of which many are low cost/ quality products imported from the Asian markets. That makes it difficult for local firms to compete based on cost and to achieve sufficient market penetration that is required for sustainable manufacturing. Furthermore, government procurement does currently not prioritise localisation of diagnostics, evident in the following comment:

"I think DTI and Department of Health should bring localisation into their tender processes; they are, but it is not being enforced" (P6).

Pressure on suppliers of health products to keep prices low from government and philanthropic organisations such as the Bill & Melinda Gates foundation, serves as a barrier to entry for new start-up companies who desperately require capital gains to develop their business and be competitive (P3). Long term contracts that government have with big MNCs to supply reagent kits and captical equipment, also complicate matters for local SMEs:

"…if Roche signs up the blood bank for a 3 year contract with government, you cannot get in there" (P17).

A prominent challenge to local manufacturing of reagents thus seems to be the fact that local firms are not protected within the local market, and are exposed to compete head on with imported products. The consequence of lacking support in the form of protectionist measures is foreseen to affect every system function required for development negatively.

6.3.4.5 *Regulation of the local market*

Until recently there has been little regulation of foreign diagnostic products that enter the market. Legislation has now changed to make it compulsory for importers and local producers and all health products to be registered, apparently at huge cost. Though this approach will help to regulate imported products, it is foreseen to have devastating consequences for local firms:

"you will see a lot of smaller companies dying out, there is huge cost involved .. it will cost you per product. So entrepreneurs will be shut out almost immediately" (P2).

At current import tarrifs are not strictly enforced and there is room for border control to improve.

6.3.4.6 *Few stories of success*

An interesting comment was made by a participant that is worth mentioning here. There are few success stories in the local reagent manufacturing industry, and this has a negative impact on the guidance of search. Kapa Biosystems is the only example of success that could be achieved by manufacturers in the domestic market, and it was voiced that this was mainly due to the fact that they had financial backing from Roche. The result is a never ending circle of cause and effect - entrepreneurs and firms are reluctanct to enter into this space (direction of search), and because of their reluctance no success stories are generated. (P2)

6.3.4.7 *Displacement of current technology*

Consumers of these reagents would be reluctant to switch from international suppliers to use local products that are of unknown quality. Adoption of a new product would mean that downtime would be required to conduct internal validations that would result in revenue loss. A statement by P 17 summarizes the situation:

"When a lab has its SOP in place, the lab does not want to change, importers are not going to change, so it does take an industrial effort and a concerted will to do this as a country".

The matter is further complicated by the fact that government has up to now made a substantial investment in the instrumentation that is used to conduct these tests. Local producers would have to overcome the challenge of not only replacing imported reagents, but also the accompanying capital equipment base (P3).

6.3.4.8 Research is not commercially driven

Research at universities have little commercial application, and is motivated more by academic achievements for researchers to get their work published. The underlying for this is that the internal promotional systems of universities do not count commercial contributions as equal to academic contributions, and thus incentivise blue sky research (P3).

6.4 RESEARCH QUESTION 2: WHAT LOCALIZATION STRATEGY COULD BE PURSUED TO MAXIMIZE THE POTENTIAL BENEFITS OF A STRONG REAGENT SUB-SECTOR?

6.4.1 Introduction

This section starts off with an explanation of the rationale behind government intervention, followed by a discussion on policy interventions that will address the challenges to localisation mentioned in the previous section. The discussion will draw on feedback obtained from respondents and strategic interventions suggested in industrial policy and IS literature.

6.4.2 Government intervention in developing countries

The development of local capacity for technological innovation presents unique opportunities for emerging and middle-income countries to grow their economy, become more competitive and possibly achieve technological catch-up, or even leapfrog their developed counterparts (Lee, 2009). Market failures, asymmetrical access to information (Szczygielski et al., 2017)(Stiglitz, Lin, & Monga, 2013) and coordination and collaboration failures (Ahn, 2017) are among the challenges that innovation systems (IS) within catching-up countries alone cannot overcome, and as a result require government intervention and support to develop the necessary skills and capabilities, gain access to the relevant markets and be competitive.

Government intervenes through policy that aims to change institutional and industrial structures that will favour development of a new technology and IS. More specifically, intervention aims to mobilize and coordinate resources, secure access to markets and to provide market protection (Binz, Gosens, Hansen, & Elmer, 2017).

In areas of science, technology and innovation, STI policies are best suited to achieve the necessary change. Science policy influence the actions of universities and other researchs institutes, technology policy influence interaction between industry and science and innovation policy places an emphasis on industrial policy to influence the process of innovation (Ahn, 2017). Policy instruments are applied in a manner that influence supply or demand for technology and can be horizontal (general) or specific, direct or indirect. Examples of supply-side policies are domestic R&D policies and technology transfer policies, and demand-side policies include government procurement, export promotion and import tarrifs that secure demand for domestic products.

6.4.3 Factors for consideration

Resources within developing countries are restricted and in the case of South Africa this is no exception. Technologies and sectors that present the greatest likelihood of generating growth should be prioritized for development. Among the factors to consider for localisation of diagnostic reagents would be the availability of adequate financial, human and physical resources (Stuart & Sorenson, 2003), accessibility of external knowledge and the existing knowledge base and absorptive capacity of local firms (Lee & Mathews, 2013). The cumaltiveness of technical advances and the predictability of technology's trajectory should also be considered, where high cumulativeness imply frequent innovation and would require

more R&D for firms to catch-up. A fluid trajectory makes it difficult to predict the direction that technological development would take (Lee & Lim, 2001).

Technological cycle time, that refers to the time period it takes to phase out current technology and for new technology to emerge is of importance, in particular within the local diagnostic sector where not only imported reagents would have to be displaced by local suppliers, but also the capital equipment base that accompanies it. During technological paradigm shifts barriers to entry are low and it presents an ideal opportunity for catch-up firms to enter (Lee & Malerba, 2017). The local reagent capital equipment base has a technological cycle time of five years after which it requires replacement. This presents and ideal opportunity for local suppliers to displace imported reagents and equipment.

An important factor for consideration is the contribution of technological innovation, with spillover effects that should not only be economical, but also hold social benefits (Aiginger, 2014). There are numerous advantages that local manufacturing of diagnostic reagents hold for the country. Firstly, it has the potential to reduce the cost burden of healthcare on government and as a result make diagnostics more accessable to a wider section of population that currently cannot afford it. Secondly, it could spur on innovation in the reagent sector and complementary technologies such as point-of-care and medical devices, to provide solutions to health problems more specific to the SADEC region. Exports of reagents presents the opportunity to earn foreign currency for the local reagent sector to further develop and gain economies of scale (Lee & Lim, 2001).

Thought should be given to what the competitive advantages are that could be leveraged by a local reagent sector. Feedback from respondents suggest to leverage the country's unique access to a genetically diverse population and the opportunities that a growing disease burden presents in order to design new biomarkers and diagnostic reagents with a unique value proposition. Competitive advantage is obtained when sectors efficiently utilize factors that are abundant within their local environment (Lin & Chang, 2009) in order to lower production cost or produce products that are of a superior quality.

Lastly, local firms would have to identify niche markets where they will be able to compete, either through low-end products with a cost advantage for countries that are price sensitive, or by producing high-end products that are quality centred for high income countries. Feedback that have been obtained indicate that the African market holds potential for local firms to manufacture diagnostics that meet the specific needs of that market. Lee & Matthews (2013) recommend that expansion into industries with shorter technology cycle times, and/or higher value added segments in established industries supported by government policy,

present the most opportunity for niche development and catching up. Import substitution is an ideal approach to develop technical capabilities in high value added segments, where products are manufactured that have previously been imported at high cost to follower countries due to an 'oligopolistic market structure'.

6.4.3.1 *Technological Forecasting to inform decision making*

Feedback from respondents suggested that as a starting point, a value chain approach and technological foresight should be used to assess the feasability of localisation of diagnostic reagents. Technological Forecasting (TF) is recognised in literature as an informative systematic process used to evaluate innovation plans and direct the development pathway of technological change (Pietrobelli & Puppato, 2016). The process involves a collaboration between public and private entities and civil society to best inform decision making. Science and academia experts and those in industry have deeper technological insights that can reduce uncertainty, improve TF coherence with industrial strategy and increase the probability of positive gains (Pietrobelli & Puppato, 2016). When TF is integrated into regular decision making processes as a rule, it can improve public-private collaboration and network building, legitimize the technology in focus, and improve transparency and accountability of all parties involved. TF however provides limited monetized information for investment decisions and should be used in conjunction with a value chain logic model to increase its discriminatory power (Ahn, 2017). The value chain logic model considers the inputs (resources), activities, outputs (products and services), and short, medium term and long term impact of technological change.

The feedback that was obtained highlighted that government has made bad investment decisions in the past, mostly due to a lack of information and understanding. In the local diagnostic reagent context the implementation of TF into regular decision making processes have the potential to improve choices of investment, facilitate accountability and transparency of public and private actors and improve collaboration and strategic coordination. Warwick (2013) refers to it as the concept of embeddedness that emphasises the importance of strategic co-operation between government and the private sector to better inform policy design and investment decisions. Governments often have limited understanding of investment potential and of where market constraints exist that require support through policy intervention (Warwick, 2013)

6.4.4 Steps Towards Knowledge Development – Industrial Strategies for Developing Countries

Sections 6.4.2 and 6.4.3 explained the rationale for government intervention and shed light on important factors for consideration. This section will propose specific actions and requirements to increase the probability of successful localisation of diagnostic reagents.

6.4.4.1 *Support business to start and grow*

Access to financial resources

Government has a key role to play in providing finance for the pre-competitive phase of technology innovation (Farla et al., 2012). Respondents felt that there are funding gaps that exist in the innovation pipeline for biotechnology, in particular availability of funds for R&D. The R&D phase is characterised by uncertainty, risk and a lack of information in many cases, due to fear that ideas might be 'stolen' by private investors for personal gain (Stiglitz et al., 2013). Private and VC funding is therefore reluctant to get involved during the R&D phase. It is crucial that government then steps in to fill this gap in funding, in particular with technologies that require high capital investment. In cases where technological breakthrough are achieved, it is only appropriate that government should then benefit and extract small royalties (Mazzucato, 2015).

A process of competitive tendering allocation (Warwick, 2013) can help to alleviate the funding challenges that SMEs face. The foreseen benefits of this approach is threefold: It will stimulate entrepreneurial experimentation, and provide cost effective diagnostic reagents that will reduce the cost burden on the public health system. Actions of innovators can be coordinated so that it provides solutions that address the local disease burden. As a further incentive, innovaters should be awarded with ownership of IPRs that they can competitively leverage within the private market.

A similar approach was taken in the United States of America (USA). The Small Business Innovation Research (SBIR) programme, a funding network that facilitate collaboration between industry, academia and government, has been shown to improve industry development and create employment, while successfully attracting VC funding in some cases (Warwick, 2013).

Market protection and domestic support

Government agencies have a key role to play in overcoming the dominance of imported products within the South African diagnostic reagent market. In Korea, government agencies drove various initiatives to help firms in the domestic switch industry to overtake local markets that have previously been dominated by imports from big MNCs. These initiatives included nursing of the local market through R&D subsidies and tax concessions, and protection against influence of big MNCs (Lee, 2009).

Some responses suggested that more incubators and accelerators should be created that provide start-ups with access to capital equipment, knowledge and the necessary business skills. Through this approach the barriers to entry are lowered and firms are not exposed to risks that are associated with high capital investment. Literature support the use of nursing markets that facilitate further learning and technological development. These markets provide a safe haven and protects start-up firms from direct competition with MNCs. Demand for domestic products are secured through preferencial government procurement, consumption quotas for SOEs and public research institutions (PRI), incentives for consumption, subsidies and import tarrifs (Gosens et al., 2014). The argument for preferencial public procurement carries even more weight where social spillovers are created, as in the case with innovation in healtch sciences. There is a real risk that protectionist measures may encourage rentseeking behaviour, and to avoid this deadlines for gradual phase out should be predetermined, to expose firms to market forces and encourage competitive behaviour that stimulates innovation.

Regulatory support

The approach taken by government to regulate the local market for diagnostic reagents through company and product registration is not conducive to potential efforts of localisation in this sector. Respondents warned that entrepreneurs will be reluctant to enter into this space, and it presents a cost burden that is not sustainable for SMEs. Instead government should improve its border control of imported products and exempt domestic companies from registration obligations while subjecting them to strict quality standard requirements.

6.4.4.2 *Development of skills and technological capabilities*

Developing countries are mostly adopters and users of technology that are imported from the developed world, and generally lack the capacity for knowledge development as a

prerequisite for innovation (Pietrobelli & Puppato, 2016). In order to develop the skills and capabilities for knowledge development, domestic firms require a minimum knowledge base that serves as a platform for learning, access to technology and external sources of knowledge, and sufficient absorptive capacity to learn and apply the knowledge that is gained (Lee, 2009). Sources of learning include informal learning, licensing, strategic alliances and FDI amongst others (Lee & Lim, 2001).

Historically the approaches to learning of developing countries and the role of FDI have been different. The South Korean government's approach was to develop learning capacity whilst prioritizing technological change, and Korean firms gained skills and capabilities through a gradual process of learning. Firstly through OEM agreements with big multinational firms to supply them with basic goods or services, where technical knowledge is gained through learning by doing. During the next stage firms actively seeked systemic learning through technological licensing, and the importance of absorptive capacity as a determinant for learning increases. In the third phase, local firms develop R&D inhouse capabilities with a clear focus of what should be done. In the fourth phase the value of learning gained through partnerships with international firms are limited, and local firms engage in research collaborations with public and international research institutions, or technology specialists. Firms thus slowly progress from being technology imitators to innovators, while increasing capacity for design during each stage (Lee, 2009)

In comparison, Brazil relied on multinational subsidiaries to invest in local infrastructural development by setting up turn-key plants (Lee, 2009). Hong Kong and Singapore used their global networks to pursaude MNCs to engange in more complex processes of learning (Pietrobelli & Puppato, 2016).

Korea's integration within the global value chain (GVC) has been most fruitful but not without effort from the Korean government and local firms. Big MNCs would seek to gain through interactions of knowledge transfer, either from knowledge that is generated during the learning process, or through access to resources and infrastructure. Government has an active role to play by directing the interest of lead firms to high value services and products that can be sourced locally, or to support upgrades of local processes and infrastructure. This will require government to invest in complementary assets and provide incentives for technological development and to address challenges of coordination failure that will deter foreign firm investment (Tang & Hussler, 2011)(Pietrobelli & Puppato, 2016).

6.4.4.3 *Facilitate Coordination & Collaboration*

The focus of industrial policy intervention has evolved from a tradionalist approach of market intervention and addressing market failures, to a soft approach where government becomes a coordinator and facilitator. In this role government assists with alignment of strategic objectives, system and network building and institutional development (Warwick, 2013). Industrial policy should work coherently with innovation policy to influence the creation and development of institutions that facilitate and promote networking and collaboration

NIS consists of formal and informal network connections between industry actors. Formal networks such as industry associations or forums strategically create and coordinate system resources to achieve collective goals and visions, and can facilitate collaborations that mobilize resources for system building (Jörg Musiolik et al., 2012). Industry associations also have the ability to overcome institutional gaps and government agency inefficiencies. Thus in the South African diagnostic reagent TIS where government agencies fall short due to inefficiencies, industry associations have the potential to bridge that gap.

6.4.4.4 *Encourage exports*

Developing countries generally speaking find it difficult to access foreign currency. A strategic focus of promoting exports of selective technologies or products that have high growth potential, provides an opportunity to earn much needed foreign currency to pay for investment goods that are mostly imported (Lee & Mathews, 2013). Additionally, export promotion incentivise industry actors to further invest and upgrade their technological capacity, as was the case with Korean industries where exporters overinvested in capacity upgrades. This in turn accelerated technological learning of actors in an attempt to utilize the added capacity (Ahn, 2017). In the Korean context, local firms gained economies of scale through access to foreign markets that were made possible by export promotion (Lee & Lim, 2001).

6.5 RESEARCH QUESTION 3: WHAT SHOULD THE ROLE OF GOVERNMENT BE IN IMPLEMENTING SUCH A LOCALIZATION STRATEGY?

Broadly speaking, the role of government is to provide local firms with access to markets, market protection and necessary support to start up and develop (Lee & Mathews, 2013). Government intervenes The previous discussion on localisation strategy highlighted some of

the roles that government need to fulfil. This section will summarize some of the main points that have been mentioned and elaborate on other roles that mentioned in literature and by research participants.

6.5.1 Government is a funder

As previously mentioned, government should finance the pre-competitive phase, in particular RnD that is characterised by high risk and uncertainty (Farla et al., 2012). Government should also provide credit in the form of incentives to ensure that liquidity problems do not stifle efforts of development (Asongu, 2014), and to influence the direction of search into sectors that require high capital investment.

6.5.2 Government is a protector and supporter

In the context of developing countries, government needs to intervene to compensate for deficiencies of local firms and to enable learning and capability development (Lee, 2009). Government can achieve this through use of a niche or nursing strategy, where local firms are provided with a safe haven that promotes experimentation and innovation. Subsidies and tax concessions will incentivise firms and entrepreneurs to invest in domestic manufacturing of diagnostics, while preferential government procurement and import tarrifs protect local firms from direct competition with big MNCs and importers (Farla et al., 2012).

6.5.3 Government is a researcher

Government and public research institutions (GRI/PRI) can alleviate some of the risk for SMEs within sectors that require high capital investment, by assisting with knowledge development through RnD collaborations. GRIs can also help generate knowledge at stages where the knowledge gained through production is no longer sufficient (Lee, 2009). Another approach is to create accelerators and incubators, where local firms can have access to skills, knowledge and equipment that they are lacking.

6.5.4 Government is a leader and facilitator

Government has a leading role to play in network and system building, and achieves this through institutional change that promote and facilitate collaboration (Warwick, 2013). Government is also to align strategic objectives and provide strategic goals and an implementation plan for system building of the local diagnostics and biotechnology sectors.

6.5.5 Government is a promotor

Government needs to encourage exports of promising technologies and products by actively promoting local firms at international tradeshows (P17). By means of this approach, local firms will be encouraged to invest in capacity upgrading and system development. Lee (2009) emphatically states that *" the ability of latecomer economies to promote vibrant private companies is the most important fundamental criterion that determines the success or failure of economic development or growth"*

6.5.6 Government is an educator

Government needs to ensure that quality education is provided at secondary and tertiary levels that creates a solid scientific knowledge base for further learning and technological development. Furthermore, government should provide or subsidise vocational and technical training that will equip graduates with the necessary skills for the workplace, and encourage training at work places through internship programs (Asongu, 2014).

6.6 CONCLUSION

The objective of this study was to assess what the barriers would be to establish a local diagnostic reagent manufacturing sector in South Africa and what policy and strategic interventions would be required to maximise the benefit a local reagent industry to the country. A qualitative approach using semi structured interviews was used in order to answer the three research questions as formulated in chapter 3, and the TIS analytical framework was used to guide the data collection process and data analysis.

The findings of research question one indicate that the size of the local market are restrictive and forms a barrier to market formation. Evidence have been presented indicate that local demand for certain diagnostic reagents, especially TB and HIV is high, and current

technological development in health diagnostics locally is foreseen to increase local demand for reagents significantly. Instead the saturation of the local market with imported products and insufficient regulation of the market makes it difficult for local manufacturers to gain critical mass. Pressure from government to keep prices low and new legislation to enforce company and product registration limits the ability of local firms to compete. Current under regulation thus far of imports and the inefficiencies of government agencies will negatively influence legitimation of the local TIS. The availability of funding is a challenge, seeing as there are very little private funding available, and application for funding is delayed due the inefficiencies of government agencies and organisations. These inefficiencies affect the ability of agencies to provide the necessary support for innovation and facilitate collaboration, thus negatively influencing knowledge diffusion. There are few local manufacturers of reagents currently, thus little experimentation and knowledge development taking place. The reason for this was said to be the lack of access to funding. The fact that universities are academically focussed and research are of little commercial value hinders the ability of government to assist firms with knowledge development. A lack of clear goals and an implementation plan to develop industry, and the reluctance of users to adopt locally produced diagnostics negatively influence the guidance of search.

The findings of research question 2 have indicated that there are a number of localisation strategies that can be pursued for localisation. Considering that opportunities are limited within the local market and the market is small in size, it was suggested that there are opportunities for high earnings within the international market, provided that firms have a unique value proposition. Access to a genetically diverse population and an increasing local disease burden should be leveraged by local firms to develop new diagnostic products for the export market. A strategy that promote exports will encourage local firms to invest in local capacity upgrades and contribute towards job creation and economic growth through access to foreign currency. To develop the capacity for knowledge development required for innovation and exports, partnerships facilitated by government between international and local firms will open up channels for knowledge transfer. It was mentioned that opportunities exist within the African, but it was unclear on how lucrative and sustainable this would be to support local manufacturing. A note worthy strategy is the concept of competitive tendering, where local firms are incentivised by government to develop innovative diagnostics that provide solutions in the local context. This will encourage collaboration, provide firms with access to funding and have the potential to reduce the cost burden of healthcare to government.

The role of government would be to facilitate interaction and collaboration among local actors and with international firms or entities, allign strategic goals, provide support in the form of funding and by creating incubators and accelerators. Government need to provide access to markets, either through export promotion or market protectionary measures such as government procurement, import tarrifs and subsidies. Lastly and most importantly government should assist with funding of R&D to reduce the risk to local SMEs and entrepreneurs. Table 12 highlights the government interventions that were suggested by participants.

Table 12: Barriers to localisation and suggested policy interventions

TIS Function	Barrier	vernment Intervention
1. Legitimation	nducive regulations and (16)	arket protection: Public urement and import tarrifs
1. Legitimation	ernmnet agencies efficiencies (16)	nological forecasting (TF)
esource mobilization	ufficient financial esources (15)	overnment to provide sustainable funding. tnership with MNCs and er international entities Competitive tendering processes ate stock trade fund for SMEs/ entrepreneurs Create incubators and accelerators
Knowledge diffusion	icient collaboration ween actors (14)	nological forecasting (TF)

		ompetitive tendering te partnership with MNCs ther international entities
4. Entrepreneurial experimentation	l number of actors (14)	ide incentives for market y, such as tax breaks or exemptions
. Market formation	trictive size of the cal market (13)	<u>Secure market:</u> mote exports, access to niche markets <u>cal market protection:</u> lic procurement, import tarrifs
owledge development	ersity research not nercially orientated (11)	ndustry post-doctoral programmes
Guidance to search	ck of clear actor pectations (10)	chnological forecasting ernment should lead and ide implementation plan
Guidance to search	ctance of users to ch suppliers (10) ality perception).	de incentives for users to dopt locally produced ucts, raise import tarrifs.

7 CHAPTER 7: CONCLUSION

7.1 INTRODUCTION

Through use of a qualitative study that is exploratory in nature, this reseach assessed the current state of the local diagnostic reagent market to determine what the barriers would be to establishing a localised manufacturing reagent sector. The study further looked at strategic approaches and policy interventions that will facilitate localisation and maximise the socio-economic benefit of a localised reagent manufacturing.

Efforts of innovation within catch-up countries can greatly contribute to socio-economic development and growth, provided that supportive structures and instutions are in place to facilitate learning and mobilization of resources (Lee & Mathews, 2013). Collaboration and market failures, and assymetrical access to information limits the opportunities for learning and thus development of technical capabilities that are required for innovation (Szczygielski et al., 2017)(Stiglitz et al., 2013)(Ahn, 2017). Domestic firms within follower regions are often unable to compete with imported products from big MNCs, and in the case of the domestic diagnostic reagent sector in South Africa it is no different. For this reason government policy intervention is essential to facilitate learning, provide access to local and foreign markets and provide protection for SMEs and entrepreneurs in the local market until such time that they have the capacity to compete directly with big MNCs. The role that policy intervention play has evolved from merely correcting market failures to a systemic approach where government influence collaboration through institutional change to enable strategic alignment of actors and system building (Warwick, 2013).

The TIS framework of analysis takes on a systems approach by analysing interaction between actors through a performance assessment of seven critical functions that is crucial for system formation and growth. By means of functional analysis, barriers to system development are then identified and used to inform policy design and intervention. The TIS was particulary suitable for the purpose of this study because of its technological focus, which in this study is molecular diagnostics.

7.2 PRINCIPLE FINDINGS

7.2.1 Research Question 1 – Barriers to Localisation

Resource Mobilization: The most prominent barrier to localisation of reagents is the lack of access to financial support. Biotechnology startups require high capital investment and VC firms are reluctant to invest due to the risk that is associated with R&D. Government agencies that provide funding take extremely long to process applications which is counterintuitive to the process of innovation where timing is of the essence. The lack of funding for local firms is interpreted to also affect the guidance of search and thus entrepreneurial experimentation negatively.

Market Formation: The size of the local market is small and lacks the critical mass for setting up a local manufacturing industry for diagnostic reagents. Contradictary evidence was presented that indicate that local consumption of diagnostic reagents for TB and HIV are significantly high. It was also established that the market is saturated with imported products and that big MNCs dominate the local market. Considering these facts, it is interpreted (and feedback suggests) that there are opportunities within the local market for local firms to enter, but they are unable to compete with big firms and importers based on cost. Pressure by government and philanthropist organisations to keep prices low further complicates matters.

Knowledge diffusion: Insufficient collaboration among industry actors restricts the potential for knowledge transfer and learning. The results have indicated that there are fragmented pockets of collaboration within local industry, but also that there is a degree of mistrust among actors that restricts collaboration.

Legitimation: Current legislation are not condusive to localisation of reagents. Results have shown that import tarrifs are not being enforced to regulate the influx of low cost/ quality products into the market . Recent legislational changes that makes it compulsory for health related firms and products to be registered will improve regulation, but present a cost burden to local firms that will stifle industry growth. Government institutions have been said to be inefficient with lack of business skills and experience, and this limit their ability to provide the necessary support that domestic firms require for innovation.

Entrepreneurial experimentation: There are currently very few manufacturers of diagnostic reagents, and as a result very little experimentation that is taking place. Among the explanations provided for this, suggested that it is due to a lack of access to funding, and lacking success stories of success achieved by local manufacturers of reagents.

Knowledge development: The quality of knowledge development poses a challenge. Research by universities are not commercially driven and internal promotional structures incentivise academic research.

Guidance of search: There are no clear common goals for development among actors. The Bioeconomy strategy prioritizes biomanufacturing as part of building the knowledge economy (KE), but a clear implementation plan is lacking that will coordinate action. Another barrier to localisation is the reluctance of local firms to switch suppliers of reagents. Such change would require downtime for internal validations that need to be conducted and will likely result in lost revenue. Internal standard operating procedures (SOPs) would also have to be amended.

7.2.2 Research Question 2 – Localisation Strategies

Technological Forecasting (TF), a process that emphasizes public-private collaboration and inclusion of stakeholders in the decision making to better inform investments, strategy and policy design should be applied. Based on value chain logic, an assessment should be made of what the strengths, competitive advantage, capabilities and skills within the local context are. Access to a genetically diverse population and a high disease burden within the country and SADEC region presents opportunities for local firms to develop and manufacture unique products that meet the needs of the region and/ or international market. There are opportunities for high earnings in the export market, provided that firms have a unique value proposition and if so, this could also be used to facilitate knowledge transfer through collaboration with international firms. A strategy of promoting exports will encourage local firms to invest in capacity upgrades and system development, and present an opportunity to access foreign currency that can further stimulate growth. A note worthy strategy is the concept of competitive tendering, where local firms are incentivised by government to develop innovative diagnostics that provide solutions in the local context. This will encourage collaboration, provide firms with access to funding and have the potential to reduce the cost burden of healthcare to government.

7.2.3 Research Question 3 – The Role of Government

First and foremost the role of government is to provide support, in particular financial support for R&D that is characterised by uncertainty and poses high risk for entrepreneurs and SMEs. More accelerators and incubators should be created to provide entrepreneurs with access to capital equipment, resources and skills that are required for innovation. There is a need for government to support localisation of reagents through preferential government procurement,

and to better regulate the local market by implementing imported tarrifs. Incentives for example tax breaks should be used to attract prospective firms and entrepreneurs for manufacturing of diagnostics, and on the demand side local users should be incentivised to adopt local products.

Inefficiencies of government organisations should be addressed and improved through private-public collaborations. This will improve accountability and transparency, and provide government with access to information that will result in better decision making. Government should form partnerships with MNCs to encourage infrastructural investment and skills development that will potentially create opportunities for local SMEs through subcontracting. It was suggested that government should create awareness of local industry by promoting local companies at international trade shows. Lastly, government should improve the quality of secondary and tertiary education and facilitate skills and knowledge development through internship programmes and industry post-doctoral programmes.

7.3 IMPLICATIONS FOR STAKEHOLDERS

7.3.1 Government

Localisation of reagents could be beneficial to the country socially and economically, and government should take this into consideration. Then, government should fulfil its role as a coordinator to align strategy and goals for development. There is a need for government to actively lead and drive development, to facilitate and improve private-public collaboration and to provide a clear implementation plan and goals to build the local bioeconomy. The concept of competitive tendering holds much promise for industry but it would require government to lead and drive it. Further, government need to provide the necessary domestic market protection and support for local firms that will foster learning and skills development, including funding for R&D. Government has a key role to play in promoting local firms and exports and in facilitating knowledge transfer through partnerships with big MNC.

7.3.2 Managers in Industry

The study has indicated that support for local firms are improving, but inefficiencies of government organisations hinder their ability to provide effective support for local development, and it is unclear wether this will change in short to medium term. Local

competitors would have to stand together and collectively drive the change that they seek. One way to pursue this is by creating an industry association that lobbies for the development of a local reagent industry, actively seeking collaborations with government.

7.4 LIMITATIONS OF RESEARCH

This project took on an exploratory and deductive approach with two implications: Firstly, the findings are not generalisable. Secondly, the study therefore drew on the views and personal perceptions of industry experts in order to meet the objectives of this research. Though care was taken to identify and acknowledge response bias accordingly, it is unclear to what extent response bias did influence feedback from participants. It has to be noted that currently, there is no TIS for molecular diagnostic reagents in South Africa. The sampling method was to interview candidates that are knowledgeable and active in the local health diagnostics and biotechnology sectors, two related sectors that will constitute a potential future diagnostic reagent TIS (Stephan et al., 2017). Inevitably some respondents were more knowledgable than others, and so their views influenced the findings of this research to a greater extent than others.

Care was taken during interviews to not influence responces of participants but there is the possibility for interview bias where in some instances the tone of voice or behaviour of the researcher unknowingly did influence response (Saunders et al., 2009). Lastly, this study was conducted during a period where there are negative perceptions of government due to domestic political and economical instability, and it is possible that this could have influenced the perceptions of respondants.

7.5 SUGGESTIONS FOR FUTURE RESEARCH

During this study it was revealed that the current government funding model in South Africa does not support scientific innovation as it should, due to internal inefficiencies and lack of business experience. The KOSDAQ trade board funding model that have been implemented by the Korean government to fund start-ups of SMEs, could hold potential for R&D funding in

developing countries and should be further explored, particularly in the context of the African continent.

7.6 CONCLUSION

The objectives of this project was to determine what the challenges to localisation of diagnostic reagents would be, what strategy should be pursued that will maximise spillovers for the country and the government interventions that would be required to support this. The study achieved this goal by applying the TIS framework to identify system weaknesses and inform further policy design.

8 REFERENCES:

AdvaMedDX & DXInsights. (2013). Introduction to Molecular Diagnostics: The Essential of Diagnostic Series, 1–19.

Ahn, S. J. (2017). Institutional basis for research boom: From catch-up development to advanced economy. *Technological Forecasting and Social Change*, *119*, 237–245. https://doi.org/10.1016/j.techfore.2016.05.022

Aiginger, K. (2014). Industrial Policy for a Sustainable Growth Path. *WIFO Working Papers*, (13). https://doi.org/10.1093/acprof:oso/9780198706205.003.0019

Asongu, S. A. (2014). www.econstor.eu.

Baker, L., Rotolo, D., Kern, F., Nightingale, P., Martin, B., Tidd, J., & Savona, M. (2016). Technology Development in South Africa : The Case of Wind and Solar PV, *5*.

Baxter, P., & Jack, S. (2008). Qualitative Case Study Methodology : Study Design and Implementation for Novice Researchers Qualitative Case Study Methodology : Study Design and Implementation, *13*(4), 544–559.

Becla, L., Lunshof, J. E., Gurwitz, D., Schulte In den Bäumen, T., Westerhoff, H. V, Lange, B. M. H., & Brand, A. (2011). Health technology assessment in the era of personalized health care. *International Journal of Technology Assessment in Health Care*, *27*(2), 118–126. https://doi.org/10.1017/S026646231100002X

Bento, N., & Fontes, M. (2015). Technological Forecasting & Social Change The construction of a new technological innovation system in a follower country : Wind energy in Portugal. *Technological Forecasting & Social Change*, *99*, 197–210. https://doi.org/10.1016/j.techfore.2015.06.037

Bergek, A., Hekkert, M., & Jacobsson, S. (2008). Functions in innovation systems : and identifying goals for system-building activities by entrepreneurs and policy makers RIDE / IMIT Working Paper No . 84426-008 Functions in innovation systems : A framework for analysing energy system dynamics and ident, (84426).

Bergek, A., Jacobsson, S., Carlsson, B., Lindmark, S., & Rickne, A. (2008a). Analyzing the

functional dynamics of technological innovation systems : A scheme of analysis, *37*, 407–429. https://doi.org/10.1016/j.respol.2007.12.003

Bergek, A., Jacobsson, S., Carlsson, B., Lindmark, S., & Rickne, A. (2008b). Analyzing the functional dynamics of technological innovation systems : A scheme of analysis Analyzing the Functional Dynamics of Technological Innovation Systems : A Scheme of Analysis **.

Bergek, A., Jacobsson, S., & Sandén, B. a. (2008). “Legitimation” and “development of positive externalities”: two key processes in the formation phase of technological innovation systems. *Technology Analysis & Strategic Management*, *20*(5), 575–592. https://doi.org/10.1080/09537320802292768

Berkwits, M., & Inui, T. S. (1998). Making use of qualitative research techniques. *Journal of General Internal Medicine*, *13*(3), 195–199. https://doi.org/10.1046/j.1525-1497.1998.00054.x

Binz, C., Gosens, J., Hansen, T., & Elmer, U. (2017). Toward Technology-Sensitive Catching-Up Policies : Insights from Renewable Energy in China. *World Development*, *96*(2015), 418–437. https://doi.org/10.1016/j.worlddev.2017.03.027

Binz, C., Truffer, B., & Coenen, L. (2014). Why space matters in technological innovation systems—Mapping global knowledge dynamics of membrane bioreactor technology. *Research Policy*, *43*(1), 138–155. https://doi.org/10.1016/j.respol.2013.07.002

Cooper, D., & Schindler, P. (2014). Business Research Methods.

Costantini, V., Crespi, F., Martini, C., & Pennacchio, L. (2015). Demand-pull and technology-push public support for eco-innovation : The case of the biofuels sector ☆, *44*, 577–595. https://doi.org/10.1016/j.respol.2014.12.011

Coupland, P., Batchelor, M., Convine, N., Davies, K., Farrington, K., Howes, L., … Wilson, E. (2010). Lab on a Chip Lab on a Chip. *Lab on a Chip*, (207890), 531–540. https://doi.org/10.1039/C5LC00716J

Easterby-smith, M., & Jackson, P. R. (2015). Management and Business Designing Management and.

Edsand, H. E. (2016). *Technological Innovation Systems and the wider context: A framework for developing countries*.

Farla, J., Markard, J., Raven, R., & Coenen, L. (2012). Sustainability transitions in the making: A closer look at actors, strategies and resources. *Technological Forecasting and*

Social Change, *79*(6), 991–998. https://doi.org/10.1016/j.techfore.2012.02.001

Figueiredo, N. I. O., & Almeida, A. (2011). From Concept to Policy : Building Regional Innovation Systems in Follower Regions, *19*(7). https://doi.org/10.1080/09654313.2011.573140

Foxon, T., & Pearson, P. (2008). Overcoming barriers to innovation and diffusion of cleaner technologies : some features of a sustainable innovation policy regime, *1*, 148–161. https://doi.org/10.1016/j.jclepro.2007.10.011

Gosens, J., & Lu, Y. (2013). Clean - tech Innovation in Emerging Economies: Transnational Dimensions in Technological Innovation System Formation, 44. Retrieved from http://www.circle.lu.se/upload/CIRCLE/workingpapers/201310_Coenen_Gosens_Lu.pdf

Gosens, J., Lu, Y., & Coenen, L. (2014). The role of transnational dimensions in emerging economy Technological Innovation Systems for clean-tech. *Journal of Cleaner Production*, 1–11. https://doi.org/10.1016/j.jclepro.2014.08.029

Hekkert, M. P., Negro, S. O., Heimeriks, G., & Harmsen, R. (2011). Technological Innovation System Analysis: a manual for analysts. *Utrecht University*, (November), 15.

Hekkert, M. P., Suurs, R. A. A., Negro, S. O., Kuhlmann, S., & Smits, R. E. H. M. (2007). Functions of innovation systems: A new approach for analysing technological change. *Technological Forecasting and Social Change*, *74*(4), 413–432. https://doi.org/10.1016/j.techfore.2006.03.002

Hohberger, J. (2016). Diffusion of science-based inventions. *Technological Forecasting and Social Change*, *104*, 66–77. https://doi.org/10.1016/j.techfore.2015.11.019

Hohberger, J., Almeida, P., & Parada, P. (2015). The direction of firm innovation: The contrasting roles of strategic alliances and individual scientific collaborations. *Research Policy*, *44*(8), 1473–1487. https://doi.org/10.1016/j.respol.2015.04.009

Jacobsson, S., & Bergek, A. (2006). A framework for guiding policy makers intervening in emerging innovation systems in " catching up " countries RIDE / IMIT Working Paper No . 84426-013, (84426).

Jacobsson, S., & Bergek, A. (2011). Innovation system analyses and sustainability transitions: Contributions and suggestions for research. *Environmental Innovation and Societal Transitions*, *1*(1), 41–57. https://doi.org/10.1016/j.eist.2011.04.006

Jones, D., Hofmann, L., & Quinn, S. (2009). 21st century medicine: A new model for medical education and practice. *… Institute for Functional Medicine: Gig Harbor, WA*. Retrieved from http://scholar.google.com/scholar?hl=en&btnG=Search&q=intitle:21st+Century+Medicine:+A+New+Model+for+Medical+Education+and+Practice#8

Kebede, K. Y., & Mitsufuji, T. (2017). Technological Forecasting & Social Change Technological innovation system building for diffusion of renewable energy technology : A case of solar PV systems in Ethiopia. *Technological Forecasting & Social Change*, *114*, 242–253. https://doi.org/10.1016/j.techfore.2016.08.018

Kern, F. (2015). Environmental Innovation and Societal Transitions Engaging with the politics , agency and structures in the technological innovation systems approach &, *16*, 67–69. https://doi.org/10.1016/j.eist.2015.07.001

Kivimaa, P., & Kern, F. (2016). Creative destruction or mere niche support ? Innovation policy mixes for sustainability transitions, *45*, 205–217.

Klein, M., & Sauer, A. (2016). *Celebrating 30 years of innovation system research: What you need to know about innovation systems*.

Kricka, L. J., Polsky, T. G., Park, J. Y., & Fortina, P. (2015). Clinica Chimica Acta The future of laboratory medicine — A 2014 perspective. *Clinica Chimica Acta*, *438*, 284–303. https://doi.org/10.1016/j.cca.2014.09.005

Kukk, P., Moors, E. H. M., & Hekkert, M. P. (2016). Institutional power play in innovation systems : The case. *Research Policy*, *45*(8), 1558–1569. https://doi.org/10.1016/j.respol.2016.01.016

Laranja, M., Uyarra, E., & Flanagan, K. (2008). Policies for science , technology and innovation : Translating rationales into regional policies in a multi-level setting, *37*, 823–835. https://doi.org/10.1016/j.respol.2008.03.006

Lee, K. (2009). How Can Korea be a Role Model for Catch-up Development ? Keun Lee *.

Lee, K., & Lim, C. (2001). Technological regimes , catching-up and leapfrogging : findings from the Korean industries q.

Lee, K., & Malerba, F. (2017). Catch-up cycles and changes in industrial leadership : Windows of opportunity and responses of firms and countries in the evolution of sectoral systems &. *Research Policy*, *46*(2), 338–351. https://doi.org/10.1016/j.respol.2016.09.006

Lee, K., & Mathews, J. (2013). S o c i a l A f f a i r s Science , technology and innovation for sustainable development, (16).

Lin, J., & Chang, H.-J. (2009). Introduction: growth and industrial upgrading. *Development Policy Review*, *27*(5), 483–502. https://doi.org/10.1111/j.1467-7679.2009.00456.x

Manessah, A., Teresa, C., & Kerrin, M. (2015). Dynamics of biotechnology entrepreneurship in South Africa and Brazil. *African Journal of Business Management*, *7*(18), 641–660. https://doi.org/10.5897/AJBM2015.7917

Markard, J., Hekkert, M., & Jacobsson, S. (2015). Environmental Innovation and Societal Transitions The technological innovation systems framework : Response to six criticisms ☆. *Environmental Innovation and Societal Transitions*, *16*, 76–86. https://doi.org/10.1016/j.eist.2015.07.006

Markard, J., & Truffer, B. (2008). Technological innovation systems and the multi-level perspective: Towards an integrated framework. *Research Policy*, *37*(4), 596–615. https://doi.org/10.1016/j.respol.2008.01.004

Marketsandmarkets.com. (2015). *Molecular Diagnostics Market by Application (Infectious Disease (HIV, HPV, TB), Oncology, Genetics, Microbiology), Technology (PCR, Microarray, DNA Sequencing), End User (Hospital, Laboratories), Product (Instruments, Reagent, Software) - Forecast to 2020*. Retrieved from http://www.marketsandmarkets.com/Market-Reports/molecular-diagnostic-market-833.html

Mazzucato, M. (2015). *The Green Entrepreneurial State*. *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.2744602

Mia, R. (2015). *The South African Precision Medicine Program (SHIP)*. *South African Swedish Collaboration on Research and Innovation*.

Musiolik, J., & Markard, J. (2011). Creating and shaping innovation systems: Formal networks in the innovation system for stationary fuel cells in Germany. *Energy Policy*, *39*(4), 1909–1922. https://doi.org/10.1016/j.enpol.2010.12.052

Musiolik, J., Markard, J., & Hekkert, M. (2012). Technological Forecasting & Social Change Networks and network resources in technological innovation systems : Towards a conceptual framework for system building. *Technological Forecasting & Social Change*, *79*(6), 1032–1048. https://doi.org/10.1016/j.techfore.2012.01.003

OECD Annual Report. (2005).

Ou, J. (2010). AN ANALYTICAL MODEL FOR INNOVATING LOCALIZATION POLICY, *8*(2), 110–119.

Oz, O. (2002). Assessing Porter ' s framework for national advantage : the case of Turkey, *55*, 509–515.

Panagiotou, N. (2013). Clinica Chimica Acta Forces driving change in medical diagnostics. *Clinica Chimica Acta*, *415*, 31–34. https://doi.org/10.1016/j.cca.2012.09.005

Park, S., & Isaksen, A. (2002). Regional Innovation Systems : The Integration of Local " Sticky " and Global " Ubiquitous " Knowledge, 1–14.

Pietrobelli, C. (2010). Technology and Indigenous Innovation in Emerging Economies : Technological Change The Role of Foreign Technology and Indigenous Innovation in Emerging Economies : Technological Change and Catching Up, (September).

Pietrobelli, C., & Puppato, F. (2016). Technological Forecasting & Social Change Technology foresight and industrial strategy. *Technological Forecasting & Social Change*, *110*, 117–125. https://doi.org/10.1016/j.techfore.2015.10.021

Porter, M. E. (1990). Determinants of National Competitive Advantage. *Competitive Advantage of Nations*.

Randelli, F., & Rocchi, B. (2015). Analysing the role of consumers within Technological Innovation Systems towards sustainability: the case of Alternative Food Networks. *IDEAS Working Paper Series from RePEc*. Retrieved from http://ez.sun.ac.za/login?url=http://search.proquest.com/docview/1698101754?accountid=14049%5Cnhttp://sunsfx.hosted.exlibrisgroup.com/sun?url%7B_%7Dver=Z39.88-2004%7B&%7Drft%7B_%7Dval%7B_%7Dfmt=info:ofi/fmt:kev:mtx:journal%7B&%7Dgenre=preprint%7B&%7Dsid=ProQ:ProQ:abiglobal%7B&%7Datitl

Reichardt, K., Negro, S. O., Rogge, K. S., & Hekkert, M. P. (2014). A N A LY Z I N G P O L I C Y M I X - T I S The case of offshore wind in Germany B a c k g ro u n d a n d m o t i v a t i o n, (August).

Ritchie, J., & Lewis, J. (2014). *Qualitative Research Practice: A Guide for Social Science Students and Researchers*. *Qualitative Research*. https://doi.org/10.4135/9781452230108

Saunders, M., Lewis, P., & Thornhill, A. (2009). *for business students fi fth edition* (fifth).

Pearson Higher education.

Song, Y., Huang, Y., Liu, X., Zhang, X., Ferrari, M., & Qin, L. (2014). Point-of-care technologies for molecular diagnostics using a drop of blood. *Trends in Biotechnology*, *32*(3), 132–139. https://doi.org/10.1016/j.tibtech.2014.01.003

Stephan, A., Schmidt, T. S., Bening, C. R., & Hoffmann, V. H. (2017). The sectoral configuration of technological innovation systems : Patterns of knowledge development and diffusion in the lithium-ion battery technology in Japan. *Research Policy*, *46*(4), 709–723. https://doi.org/10.1016/j.respol.2017.01.009

Stiglitz, J., Lin, J., & Monga, C. (2013). *The Rejuvenation of Industrial Policy*.

Stuart, T., & Sorenson, O. (2003). The geography of opportunity : spatial heterogeneity in founding rates and the performance of biotechnology firms, *32*, 229–253.

Szczygielski, K., Grabowski, W., Teoman, M., & Sinan, V. (2017). Does government support for private innovation matter ? Firm-level evidence from two catching-up countries. *Research Policy*, *46*(1), 219–237. https://doi.org/10.1016/j.respol.2016.10.009

Tang, M., & Hussler, C. (2011). Technology in Society Betting on indigenous innovation or relying on FDI : The Chinese strategy for catching-up. *Technology in Society*, *33*(1–2), 23–35. https://doi.org/10.1016/j.techsoc.2011.03.001

Tellis, W. M. (1997). Application of a Case Study Methodology Application of a Case Study Methodology, *3*(3), 1–19.

Tewksbury, R. (2009). Qualitative versus Quantitative Methods: Understanding Why Qualitative Methods are Superior for Criminology and Criminal Justice. *Journal of Theoretical and Philosophical Criminology*, *1*(1), 38–58. https://doi.org/10.1017/CBO9781107415324.004

Thompson, S. B., & Srivastava, A. (2009). Framework Analysis : Research Note, *4*(2), 72–79.

van Mierlo, B., Leeuwis, C., Smits, R., & Woolthuis, R. K. (2010). Is the Creation and Development of Biotech SMEs Localised ? Conclusions Drawn from the French Case. *Technological Forecasting and Social Change*, *77*(2), 318–334. https://doi.org/10.1016/j.techfore.2009.08.004

Varblane, U. (2012). *www.econstor.eu*. Retrieved from http://hdl.handle.net/10419/67496

Walwyn, D. (2014). *Protein-Based Laboratory Reagents*.

Wang, Y., Vanhaverbeke, W., & Roijakkers, N. (2012). Exploring the impact of open innovation on national systems of innovation - A theoretical analysis. *Technological Forecasting and Social Change*, *79*(3), 419–428. https://doi.org/10.1016/j.techfore.2011.08.009

Warwick, K. (2013). Emerging Issues and New Trends. *OECD Science, Technology and Industry Policy Papers*, (2), 57. https://doi.org/http://dx.doi.org/10.1787/5k4869clw0xp-en OECD

Watkins, A., Papaioannou, T., Mugwagwa, J., & Kale, D. (2015). National innovation systems and the intermediary role of industry associations in building institutional capacities for innovation in developing countries: A critical review of the literature. *Research Policy*, *44*(8), 1407–1418. https://doi.org/10.1016/j.respol.2015.05.004

Weile, J., & Knabbe, C. (2009). Current applications and future trends of molecular diagnostics in clinical bacteriology. *Analytical and Bioanalytical Chemistry*, *394*(3), 731–742. https://doi.org/10.1007/s00216-009-2779-8

Yager, P., Domingo, G. J., & Gerdes, J. (2008). Point-of-care diagnostics for global health. *Annual Review of Biomedical Engineering*, *10*, 107–44. https://doi.org/10.1146/annurev.bioeng.10.061807.160524

APPENDIX 1 Research Questionnaire

Background

Name of organization:

Role of organization (government, agency, firm etc.):

Proportion of activities/time/revenue that can be ascribed to molecular diagnostics and related matters:

Terms: Reagents – Reagents used for molecular diagnostics

Resource mobilization

1. Are there sufficient access to financial resources? If not, how could funding be made more accessible to entrepreneurs in this space in a way that minimizes risk?

2. Do you consider human resources to be a limiting factor to the local production of molecular reagents? If yes, how could this problem be addressed?

3. Are there sufficient physical resources, such as materials and infrastructure that will enable diffusion of locally produced reagents?

Knowledge development and diffusion

4. Do you consider the knowledge base to be a limiting factor to the local production of reagents for molecular diagnostics? If yes, what could be done to improve it?

5. Is there sufficient collaboration and knowledge exchange between industry and universities or public research institutions? If not, how can this be improved?

6. Does the quality and/or quantity of knowledge development form a barrier for localised production of reagents?

7. Does your company fund research on reagents for molecular diagnostics? If so, is it done internally or is it done at a university?

Market formation

8. How well developed is the local market with regards to demand and supply of molecular diagnostics?

9. What in your opinion are the drivers of market formation and growth within the local molecular diagnostics industry?

10. Does market size form a barrier to the development of a local molecular reagent manufacturing industry?

Influence on the direction of search

11. What are the expectations and vision for local manufacturing of molecular reagents within South Africa?

12. Are there clear policy goals with regards to developing a local manufacturing industry of these reagents? Are these goals regarded as reliable?

13. Do the actors involved have sufficiently clear and aligned visions and expectations of how a locally produced reagent industry should develop in order to reduce uncertainties?

Entrepreneurial experimentation

14. With reference to the structural components of a Technological Innovation System i.e. actors, networks, institutions (**Error! Reference source not found.**), who in your view are the prominent role-players within this particular innovation system?

15. In your opinion are the number of industrial actors sufficient to generate a strong and competitive local manufacturing industry?

16. Are the current actors producing at large scale? If not, what are the reasons?

17. Are current actors innovating and experimenting sufficiently? How can this be improved or further encouraged?

18. To your knowledge, are there firms that are diversifying into this space or do new entrants mostly consist of entrepreneurs?

Legitimation

19. Are the regulations and institutions that are necessary to facilitate development of a local reagent manufacturing industry in place? If so is it effective? How can it be improved?

20. To your knowledge, are there any advocacy coalitions or interest groups that are lobbying for the development of a local molecular reagents industry and policy support?

21. Are there resistance from current global suppliers to the local production and diffusion of reagents for molecular diagnostics? Does this form a barrier to local manufacturing of reagents? If so, how can this barrier be addressed?

Development of positive externalities

22. What do you foresee will be the 'spill over' effects of a developed local molecular reagents manufacturing sector?

23. How can the skills and networks that are generated through the development of a local manufacturing industry of molecular reagents be leveraged in the export market to position South Africa within the competitive global market?

The role of Government

24. What are the challenges and possible policy interventions that will address these challenges in the localization of reagents used for molecular diagnostics?

25. What localization strategy should be pursued to maximize the potential benefits to the local socio-economic context from a strong reagent sub-sector?

26. Based on the functions that are stipulated in the theoretical framework of Technological Innovation Systems (**Error! Reference source not found.**), what should the role of government be in implementing such a localization strategy?

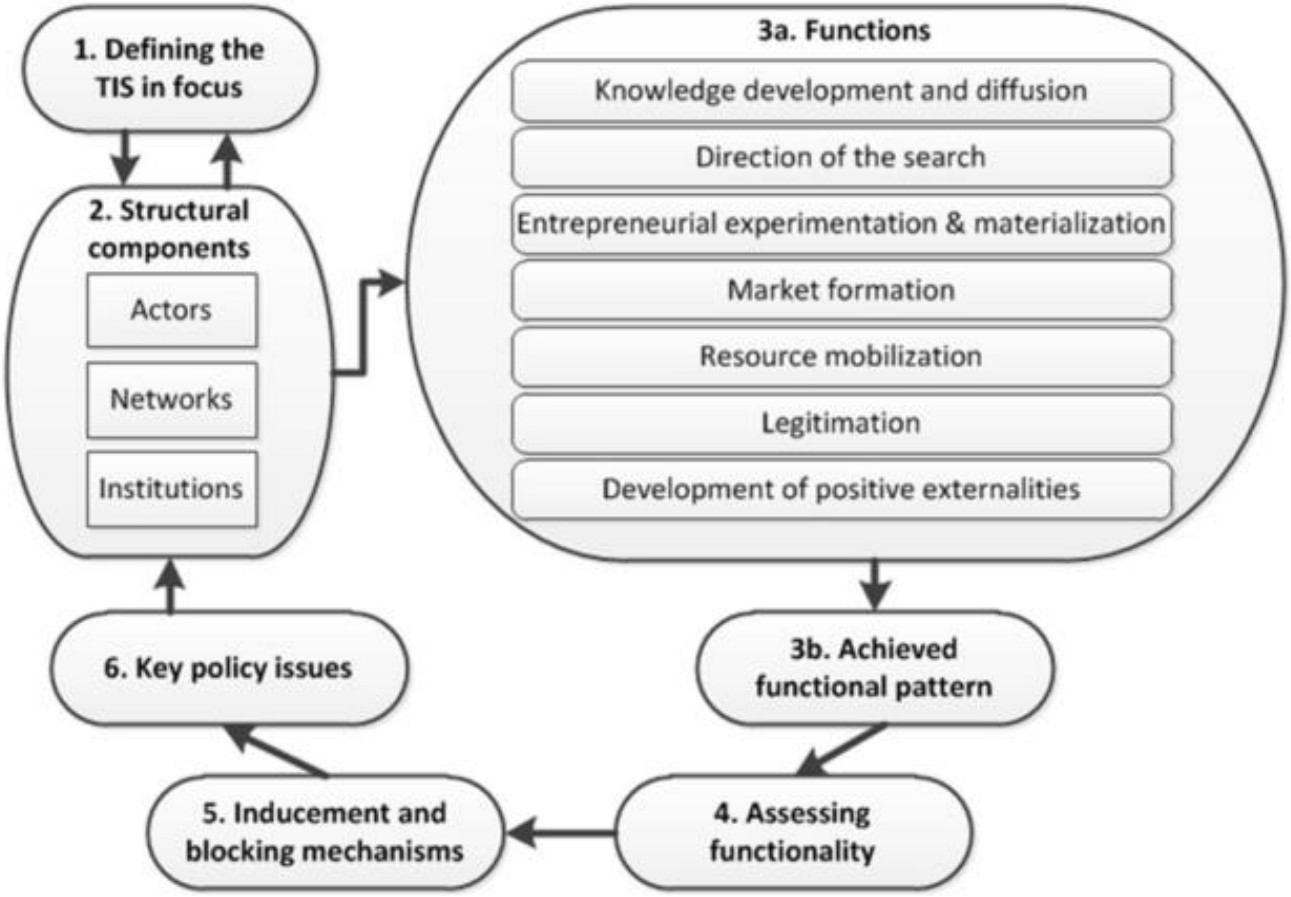


Figure 10: The Technological Innovation System framework of analysis

APPENDIX 2 Copyright Declaration Form

Student details			
Surname:		Initials:	
Student number:			
Email:			
Cell :		Landline:	
Course details			
Degree:	MBA	Year completed:	
Department:	GIBS		
Supervisor:			
Supervisor email:			
Confidentiality / Embargo			
Do you need to have your report embargoed? If so, attach a motivation letter. Without a letter this will not be granted.			
Yes		No	
If yes, please indicate period requested			
Two years		**Permanent	
If permanent, please attach a copy of the letter of permission from the Vice-Principal: Research and Postgraduate Studies. Without a letter this will not be granted.			
Access			
A copy of your research report will be uploaded to UPSpace Can the Information Centre add your email address to the UPSpace web site?			
Yes		No	
If no, please motivate (ignore if report is to be embargoed)			

Copyright declaration	
I hereby certify that, where appropriate, I have obtained and attached hereto a written permission statement from the owner(s) of each third-party copyrighted matter to be included in my research report ("the work"), allowing distribution as specified below. I certify that the version of the work I submitted is the same as that, which was approved by my examiners and that all the changes to the document, as requested by the examiners, have been included. I understand that all rights with regard to intellectual property in the work vest in the University who has the right to reproduce, distribute and/or publish the work in any manner it may deem fit. I agree that, a hardcopy of the abovementioned work be placed in the Gordon Institute of Business Science Information Centre and worldwide electronic access be given to the softcopy on UPSpace.	
Signature:	**Date:**

APPENDIX 3 CODING SYSTEM

- Code System
  - Innovation Pipeline
  - Innovation value chain blockage
  - YELLOW
  - Role of Organization
    - Law expert - IP
    - Consumer
    - Firm
    - Research institution
    - Distributor
    - Government
    - Intermediary
  - Capacity % dedicated to Molecular diagnostics
  - Factors to consider with local production
    - Logisitics
  - Market formation
    - TRENDS
    - Drivers
    - Market size
    - Demand
    - Supply
      - Local potential growth
      - International
  - Collaboration with MNC's
  - The Role of Government
    - Entrepreneurial support
    - Cost reduction
    - Localisation strategy
      - Coordination of projects
    - Needed policy interventions
  - Barriers to localisation
  - Development of Positive externalities
    - Skills and networks for global competitiveness
    - Spillover effects
  - Entrepreneurial experimentation
    - Appetite for risk taking
      - Consumerism mindset
    - New Entrants
    - Large scale production

Number of actors
Key role players
Legitimation
Validation testing
Resistance from global suppliers
Advocacy coalitions & lobbying
Market research
Regulations and institutional efficiency
Standardization
Influence on the direction of search
Government/ Philanthropic subsidies
Infrastructural investment in current technological regime
Projects and initiatives
Public health cost burden
Perceived quality
Local Distributors
Global competitiveness
Market potential
Clear Actor expectations
Policy goals
Implementation plan
Customer expectations
Knowledge Development
IP
R&D
Knowledge development
Knowledge base
Knowledge Diffusion
Collaboration and knowledge transfer
Tech Transfer offices
Resource Mobilization
Human resources
Networks
Physical Resources
Financial resources