Emerging technologies and technological catch-up in the pharmaceuticals sector in South Africa

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ABSTRACT

This study investigates the establishment and evolution of innovation capabilities in synthetic biology, an emerging technology used as a mechanism for technological catch-up in latecomer countries, for application in the South African pharmaceuticals sector which aims to make innovative health treatments more accessible to patients, especially those in developing countries. There is a crucial need for developing countries to obtain endogenous technological and innovation capabilities as these are vital for achieving progress with regards to a countries desire to catch-up to leading nations.

The qualitative research design used a longitudinal case study approach to determine how the development of capabilities in synthetic biology has evolved in South Africa since its inception at a dedicated research centre established in 2007 by The South African Council for Scientific and Industrial Research (CSIR). Two innovation capability frameworks were applied to assess these capabilities to determine the current level of innovation capability in relation to its technology development, operations, management, and transactions capabilities which ultimately inform its innovation performance. The study utilized data from interviews with individuals directly involved with the centre's research and management activities; a categorical questionnaire seeking data on technology development activities; as well as data extracted from organizational operational reports and strategic plans.

The key findings showed that South Africa has a shortage of skilled human capital in synthetic biology coupled with insufficient financial resources to enable the area to realise its full potential. Therefore the innovation capability ranking of the centre has stagnated at an incremental/ intermediate level. The resulting effect is that, despite the national goals it has set out to achieve, the area has yet to create real impact for the pharmaceutical sector. The recommendations provided at the end of the study will advise the centre on possible pathways it could take to improve its overall innovation capability. At this present level, technological catch-up by means of leapfrogging, remains out of reach, and will hinder the countries progress in closing the gap between itself and leading countries in terms of the rates of technical change with respect to synthetic biology.

KEY WORDS

Innovation capability, Emerging technologies, Technological catch-up, Sectoral Systems of Innovation, National Systems of Innovation, Synthetic Biology, Pharmaceuticals

DECLARATION

I, **Vyasha Singh**, declare that this dissertation is my own unaided work except as indicated in the references and acknowledgements. It is submitted in partial fulfilment of the requirements for the degree of Master of Management in the field of Innovation Studies at the Wits Business School in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination in this or any other University.

Signature: ………………………………………………..

On this …………10………… day of …………March…………………2023

-----Vyasha Singh---------------------------------

Name

DEDICATION

Dedicated to my parents for their continued motivation, encouragement, and faith in me throughout my life.

ACKNOWLEDGEMENTS

I wish to express my gratitude, first and foremost, to my immediate family whose support during this journey was unparalleled. This has been, by far, one if my life's most challenging experiences. I had struggled extensively with prolonged illness during the completion of this research which caused many unforeseen delays. To this end, I would like to give my deepest and sincerest thanks to my supervisor, Prof. Thembela Hillie, for his patience, understanding, and continuous guidance as I undertook this process.

CONTENTS

LIST OF ABBREVIATIONS & ACRONYMS

API: Active pharmaceutical ingredient

CSIR: Council for Scientific and Industrial Research

DoH: Department of Health

DSI: Department of Science and Innovation

DUI: Doing, Using, and Interacting

EHT: Emerging Health technologies

ERA: Emerging Research Area

GDP: Gross Domestic Product

KPI: Key Performance Indicator

NIE: Newly Industrialized Economy

NSI: National System of Innovation

PHS: Pioneering Health Sciences

RGL: Research Group Leader

SSI: Sectoral System of Innovation

STI: Science, Technology, and Innovation

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1 CHAPTER 1: INTRODUCTION

1.1 PURPOSE OF THE STUDY

This study aims to investigate the evolution and establishment of innovation capabilities in emerging technologies in South Africa. Focus is primarily given to the specific role played by technologies that have been developed in the area of synthetic biology and their applications in alleviating global health challenges faced by the pharmaceuticals sector, both locally and abroad.

1.2 CONTEXT OF THE STUDY

Medical technologies, pharmaceuticals, and biotechnology has been identified as an active field in innovation in 2020 following the onset of the global COVID-19 pandemic (World Intellectial Property Organization, 2021). While the global healthcare sector has seen an upward trend in the commercialization of new innovations, particularly with regards to the speed of the development and manufacture of COVID-19 vaccines as well as an increased approval rate in new drugs developed (World Intellectial Property Organization, 2021), the aim of sector to make such innovative health treatments accessible to patients worldwide still remains (EFPIA, 2021).

Statistically, in 2020 it was reported that North America accounted for 49% of the sale of pharmaceutical products worldwide, Europe held 23.9% of the share of sales, with the emerging markets of Brazil, China, and India experiencing respective market growth rates of 11.3%, 4.8%, and 10% (EFPIA, 2021). However, as is the case for the majority of developing countries, the creation of effective healthcare systems and strong domestic pharmaceutical industries continue to elude these latecomers that lack industrial competence and access to reliable medicine (Ramani & Guennif, 2012).

1.3 RESEARCH PROBLEM STATEMENT

There is a crucial need for developing countries to obtain endogenous technological and innovation capabilities as these are vital for achieving progress with regards to a countries desire to catch-up with leading nations (Freeman, 1995; Lee, 2013). However, the global south faces challenges related to weak absorptive capacity as well innovation policies that are narrowly focused on STI modes of innovation (Lundvall, 2007). They also lack the significant financial means required to invest in the same, older technologies of leading nations (Lee & Lim, 2001). Developing countries are also faced with the additional challenge of learning to develop multiple, non-existent, capabilities simultaneously (Bell & Figueiredo, 2012). To overcome these limitations, the use of emerging technologies has been identified as a key strategy for developing countries to achieve rapid technological catch-up through leapfrogging (Lee, 2005) and public research organisations have been acknowledged as a key enabler in the provision of domestic training and the acquisition of related technological capabilities (Mazzoleni & Nelson, 2007). The South Africa government, by way of the Department of Science and Innovation (DSI) and its entity, the CSIR, has made significant efforts over the years in the establishment of dedicated research centres that are geared towards building national capabilities in emerging technologies. A research centre for Synthetic Biology was established in in the early 2000's but an assessment is required to understand how innovation capabilities have evolved over the period. The study will explore the use of two frameworks that, while contradictory in the elements of innovation capability being analysed by each, will be integrated in a new way to provide a holistic evaluation of the overall innovation capability of the CSIR centre. The results obtained through the study will then be used to recommend future potential pathways that the Centre can take in support of ensuring technological catch-up in the pharmaceutical sector both at national and global levels.

1.4 SIGNIFICANCE OF THE STUDY

South Africa's R&D intensity was reported as 0.62% of Gross Domestic Product (GPD) in 2019/20 demonstrating a steady decline from previous years (Human Sciences Research Council, 2022). As governments all over the world attempted to counteract the effects of the financial impact brought on by COVID-19, the South African government was not exempted as many of its departments had to brace for impending budget cuts. The department of Science and Innovation saw their annual budget reduced from R8.7 billion to R7.3 billion in 2021 (Department of Science and Innovation, 2021) and this had a subsequent knock-on effect on all its funded entities including the CSIR whose budget was also reduced (CSIR, 2021). Considering the limited finances, and competition for resources, it is vital that investments in R&D lead to tangible outcomes that will create significant growth and impact for relevant economic sectors. The assessment of the state of innovation capabilities at the Synthetic Biology research centre can serve as a steppingstone towards determining whether the investments made towards the establishment of these capabilities are indeed resulting in the desired technological success and can also inform whether a strategic shift might be necessary to implement based on learnings from global practices. This study will also be beneficial to the broader research community as it provides a way of understanding how innovation capabilities can be developed and exploited to achieve technological catch-up success. Additionally, the methodology could be replicated for investigating of role of other emerging technologies in sectors where they intend to create similar growth and impact.

1.5 DELIMITATIONS OF THE STUDY

- Limited to the establishment of capabilities in synthetic biology, as an emerging technology, within a government funded research program at the CSIR in South Africa.
- The study of the role of synthetic biology for achieving technological catch-up is limited to its applications in the South African Pharmaceuticals sector.
- The ethical concerns that relate to the use of synthetic biology do not fall within the scope of this study.

1.6 ASSUMPTIONS

- Public institutions are appropriate for building indigenous capabilities because they serve as enablers of learning through doing, using, and interacting, (Mazzoleni & Nelson, 2007).
- There is a linear relationship between increasing innovation capability and the ability of a latecomer to close the gap between itself and a frontrunner in terms of their rates of technological change.

1.7 DEFINITIONS OF KEY TERMS

- **Economic catch-up:** "The process of closing the gap in global market shares between firms in leading countries and firms in latecomer countries." (Lee & Malerba, 2017).

- **Emerging technologies:** "Emerging technologies are the core technologies, which have not yet demonstrated potential for changing the basis of competition." (Hung and Chu, 2006).

- **Innovation capability**: "…an overall capability encompassing the ability to absorb, to adapt and to transform a given technology into specific management, operations and transactions routines that can lead one firm to Schumpeterian profits, i.e., innovation." (Zawislak et al., 2012).

- **Synthetic biology:** "The field of synthetic biology centers on design, construction, and characterization of improved or novel biological systems using engineering design principles." (Zhao, 2013).

- **Technological catch-up**: "The generating of more rapid technological innovations than advanced countries." (Lee, 2013).

1.8 RESEARCH QUESTIONS

A. How has South Africa developed innovation capabilities in Synthetic Biology for the pharmaceuticals sector?

   A.1. How has the development of capabilities in synthetic biology evolved in South Africa?

   A.2. What is its current level of innovation capability i.e., basic, intermediate, advanced, or world leading?

   A.3. What are the future potential pathways that South Africa can take to improve its catch-up efforts in the sector using synthetic biology?

1.9 OUTLINE AND STRUCTURE OF THE REPORT

Chapter 1: Introduction – Gives the overall background and context to the study by providing an overview of the aims of the study and presents the research questions to be investigated.

Chapter 2: Literature Review – Highlights the theories that underpin the research study. Two main frameworks were identified i.e. innovation capability framework and technological catch-up pathways.

Chapter 3: Research Strategy and Methodology – Outlines the research methodology followed as it pertains to the study.

Chapter 4: Presentation of Data and Findings – Presents the data and findings of the study.

Chapter 5: Analysis and Discussion of Research Findings – Provides an overview and discusses the findings.

Chapter 6: Conclusion and Recommendations –Concludes the study by offering recommendations on the potential future pathways to enhance efforts in achieving innovation capability.

1.10 CONCLUSION

This chapter provides insights into background and context that informed the study. It illustrates the nature and some of the challenges which developing countries are facing with regards to innovating in the pharmaceuticals sector which include limited financing, lack of industrial competence, inefficient healthcare systems, etc. Following an articulation of the specific research problem, the resulting research questions pertaining to the study are presented.

2 CHAPTER 2: LITERATURE REVIEW

2.1 INTRODUCTION

This section aims to contextualize how building innovation capability can be used as a tool to enable technological catching-up in the pharmaceutical sector. A selection of peer-reviewed journal articles and book chapters were used to illustrate the significance of technology, innovation systems and practices of countries in the Global North versus the Global South. **Section 2.2.** broadly describes the nature of National Innovation Systems and its role as an enabler of developing innovation practices for countries in the Global North versus those situated in the Global South while also highlighting the need for sound policies that can ensure the effective implementation of these innovation practices. **Section 2.3.** distils innovation down to its specific applications in a sectoral context that is underpinned by aspects of knowledge generation and different modes of learning. Specific attention is paid to the pharmaceuticals sector, a key component of this study, in which the current challenges facing the sector are indicated and current global developments and technological activities are highlighted. The section also makes mention of Synthetic Biology as an innovative emerging technology that can be used to enable the sector in overcoming several of the world's current health challenges. **Section 2.4.** discusses the importance of innovation capability and its associated frameworks that will be used to assess the evolution and progress that has been made to date in the establishment of capabilities in Synthetic Biology at the CSIR in South Africa for its application in the South African pharmaceutical sector. Technological catch-up is then introduced in **section 2.5.** to denote the various mechanisms through which a developing country can build its capabilities in technology and innovation to essentially catch-up to countries that are leading in a particular sector. Public research organisations' and their role is particularly emphasized in this regard.

2.2 NATIONAL SYSTEMS OF INNOVATION

The National Systems of Innovation (NSI) concept was originally brought to the fore in 1841 by economist Fredrich List following his conceptualisation of the "National System of Political Economy" whereby he was primarily concerned with how an under-developed country, such as Germany, could over-take front-runner England in terms of economic growth (Freeman, 1995). Research carried out by Swedish economics Professor Bengt-Ake Lundvall, and British economist, Christopher Freeman, has solidified the term "National Systems of Innovation" in evolutionary economics and social sciences, and positioned it as a focusing device for economic analysis that can enable comparisons of the economic wealth and growth of nations (Lundvall et al., 2011; Lundvall, 2007). Freeman's focus at the time was on how a country could advance its economic development and international competitiveness at the national level through knowledge accumulation (Lundvall et al., 2011).

While the concept of the NSI has been adopted in the fields of economics and the social sciences, several definitions have been proposed by scholars over the years (Freeman, 1995; Lundvall, 1992; Metcalfe, 1995; Nelson, 1993). A common thread identified among these scholars' definitions is that a National Innovation System will always require interactions between networks of institutions for new products/ processes/ technologies/ innovations to successfully diffuse through an economy. It was suggested by Freeman (1995), however, that countries differ in the ways in which they are organized in enabling them to develop, introduce, improve, and diffuse new products and processes within their economies and that these differences could be explained by the varying features of an individual country's National System of Innovation such as its education and training institutions, science and technology institutions, interactions between users and producers, adaptation of imported technology, as well as its knowledge accumulation processes, among others.

Innovation systems research has taken on two differing perspectives over the years. Earlier science and technology systems performance indicators had led to the NSI being viewed from a narrowly defined perspective, termed the science, technology and innovation (STI) mode, which focuses on innovation that is based solely on research and development efforts informed by experimentation, formalisation, and codification of the identified knowledge (Jensen et al., 2007; Lundvall et al., 2011). In contrast, a broader perspective, termed the doing-using-interacting (DUI) mode, has been introduced that recognises social institutions, financial systems, education systems, and macroeconomic regulations as additional contributors to innovation processes, (Jensen et al., 2007; Lundvall et al., 2011).

2.2.1. National Systems of Innovation in the Global South

The adoption of innovation systems has proven successful in the analysis of innovation activities of countries, such as those in the Global North, that are characteristic of having well-developed infrastructure and institutions, however, innovation activities in the Global South are less advanced and relate instead to the stimulation, development, and promotion of effective innovation systems (Lundvall, 2007). The minimal advancement in developing countries can be ascribed to the fact that such countries do not have a fully functioning innovation system that can be fairly compared to other, more established countries, thus leading them to a more immediate task of developing strategies to create an effective system (Arocena & Sutz, 1999).

Lundvall (2007) further suggests that the innovation systems approach for less developed countries should not mirror that of the Global North and should rather be adapted to suit its own domestic conditions for system building while simultaneously avoiding endeavours that focus solely on the STI mode. Lundvall et al. (2011) argues further that narrow definitions of the NSI have limited bearing in helping to understand the challenges of less developed economies.

2.2.2. Innovation policies

Successful innovation depends on the state of a country's economic conditions, infrastructure, education systems, and governance and it is only through efficient innovation policies that a country's overall innovation climate can be addressed (World Bank, 2010). Therefore, innovation policies are viewed as a conscious activity that stimulates the development of an innovation system (Freeman, 1995). However, the numerous challenges facing the Global South in relation to its political, societal, and institutional contexts make the efficient implementation of innovation policies a difficult feat.

South Africa, in particular, first introduced an innovation policy in 1996 which was driven by the NSI concept (Mouton, 2006). This White Paper was subsequently revised in 2018 with the intention of replacing the 1996 policy as well as the Ten-Year Innovation plan developed in 2008. The current White Paper is geared towards alleviating poverty in South Africa and improving the overall quality of life of its people through the attainment of 26 policy intents (Mouton, 2006; Walwyn & Cloete, 2018). Following a review of the 2018 Draft White Paper, Walwyn and Cloete (2018) are of the view that the NSI approach may not be radical enough to achieve the ambitious goals of the current policy (Walwyn & Cloete, 2018). This is in agreement with the view that the NSI framework is inappropriate for dealing with processes of technical change occurring in developing countries (Viotti, 2002). Regardless, the most immediate concerns of developing nations to ensure that research and innovation activities are supported and are aimed at serving the needs of the poor, the illiterate, and the marginalized groups in societies still remain (Mouton, 2006). The World Bank (2010) affirmed that the priority of developing countries is to acquire existing global knowledge, in favour of creating new knowledge, and adapt it to its local conditions. Policies that facilitate access to global knowledge are therefore critical.

Lundvall (2011) has argued that the characterisation of innovation systems in a national context can be misleading as the dissemination of knowledge really takes place through global value chains where the differences between regions or sectors are more dramatic as compared to national systems. Malerba (2005) also advocated that a sectoral systems of innovation (SSI) approach may prove more useful in policy development as systemic failures can be identified more easily.

2.3 SECTORAL SYSTEMS OF INNOVATION

The SSI concept had emerged from the intersection of evolutionary theory and innovation systems whereby evolutionary theory promotes learning and knowledge as being the key to economic systems, whereas innovation systems regard innovation as a collaborative process that takes place between many different actors (Malerba, 2005). A conceptual framework was subsequently developed to determine the rate, type, and organization of innovation activities within sectors and it also proposed that a sectoral system is comprised of basic elements such as technologies, products, learning, and agents (Malerba, 2002). The theory further states that it is the combination, or changes, between and among these elements that determine the state of innovation within a particular sector. It has since been argued however that the SSI approach is too strongly focused on knowledge development and fails to account for how these elements are linked neither does it consider the diffusion and use of technologies or the impact that it creates (Geels, 2004). Although, it was agreed that the framework could still, in fact, prove useful for the comparisons of countries performance in specific sectors and industries (Geels, 2004; Li et al., 2021).

2.3.1. Learning in sectoral systems

Sectors differentiate based on the knowledge they encompass and the technologies that they produce and innovation within sectors therefore results from the capabilities possessed by the systems actors and positions knowledge, systems, and institutions at the heart of any sector based innovation analysis (Malerba & Niosi, 2018). The two modes that characterize a country's innovation process suggests that, in the STI mode, knowledge is gained through basic research and development activities whereas in the DUI mode, (i) learning-by-doing involves knowledge gained in design and engineering capabilities, (ii) learning-by-using refers to knowledge obtained through the adoption and use of an innovation, and (iii) learning-by-interacting states that it is the continuous interaction between users and produces that stimulates the creation of knowledge (Lundvall, 2007).

Learning refers to the ability of a developing country to absorb and improve new innovations developed in industrialised countries for the purpose of gaining knowledge and achieving technical change within its own economies (Viotti, 2002). However, many developing countries are facing numerous challenges in being able to benefit from global advancements in knowledge due to the fact that most poor countries are largely involved in activities that lack a potential for learning thus indicating an inherent absence in the overall demand for knowledge (Arocena & Sutz, 2010). It was asserted by Malerba and Nelson (2011) that learning processes are key for the development of technological capabilities and several elements common to sectors were identified in relation to the learning capabilities of firms, the accessibility of foreign knowledge, skilled human capital, as well as the effectiveness of government policies. Mazzoleni and Nelson (2007) also stated that the ability of countries to modify existing foreign technologies will depend on the presence of its own endogenous scientific capability. Their studies had also found that accessing foreign knowledge occurred through individuals in developing countries being given the opportunity to study abroad as well as through the transfer of skills directly from foreign advisors (Mazzoleni and Nelson, 2007).

Using evidence from the studies of six different sectors, Malerba and Nelson (2011) also showed that, despite the common elements highlighted above, each sector will still require different approaches with regards to technological development as success in some sectors such as pharmaceuticals are mostly dependent on science-based research whereas application-based technologies in the form of processes and tools are more applicable to sectors such as manufacturing.

2.3.2. Innovation in the Pharmaceuticals Sector

The pharmaceutical sector has been classified by many as a research-intensive sector that depends on innovation for its growth (Coombs & Metcalfe, 2002; Lakdawalla, 2018; Schuhmacher et al., 2021). Gassmann et al. (2008) have highlighted that the dependence on innovation for growth within the sector creates risks that are associated with the high costs of R&D infrastructure, and product complexity. In addition, Lakdawalla (2018) stated that the total R&D costs per employee in the sector is twice that of other industries such as computers or electronics which have almost triple the number of employees.

Wang et al. (2021) argues that pharmaceutical innovation evolves from advancements in scientific understanding of new technologies and techniques e.g., vaccines, diagnostics reagents, or genetically engineered drugs, etc. for the purpose of improving and saving the lives of patients. Innovation in pharmaceuticals is, therefore, largely driven by medical progress and the resultant rising costs of healthcare (Lakdawalla, 2018). Gassmann & Reepmeyer (2005) have implored that the most immediate task of the sector is to close the R&D productivity gap, but Wang et al. (2021) have cautioned that while innovation in pharmaceuticals is an important policy intent for countries, it also poses a financial burden due to the high levels of investment required with returns expected only in the long-term.

The path followed in the development of pharmaceutical drugs, as illustrated in figure 2.1. below, begins with basic science to discover leading compounds, which are then developed further using a range of chemical manufacturing techniques, and ends with testing, clinical trials, and, market approval (Wang et al., 2021b). However, it is the revenue from 3 in 10 drugs that cover the costs of R&D, and approximately only 1 in 10 000 substances result in a marketable product (Gassmann et al., 2008). Furthermore, it can take up to 13 years for a pharmaceutical formulation to eventually reach the market (Akkari et al., 2016; Gassmann & Reepmeyer, 2005).

Figure 2.1. Drug research and development process. Source: Adapted and modified from (Wang et al., 2021a)

Over the years, drug therapies have been positively impacted by novel life science and genetic technologies (Coombs & Metcalfe, 2002). Gassmann & Reepmeyer (2005) identified numerous emergent technologies such as high-throughput screening, proteomics, and genomics, to name a few, as new prospects for the pharmaceutical industry particularly in relation to the treatment of smaller patient populations with specific genetic constitutions.

The knowledge intensiveness of the pharmaceuticals value chain, when categorized from lowest to highest value-added products, is depicted in figure 2.2. below.

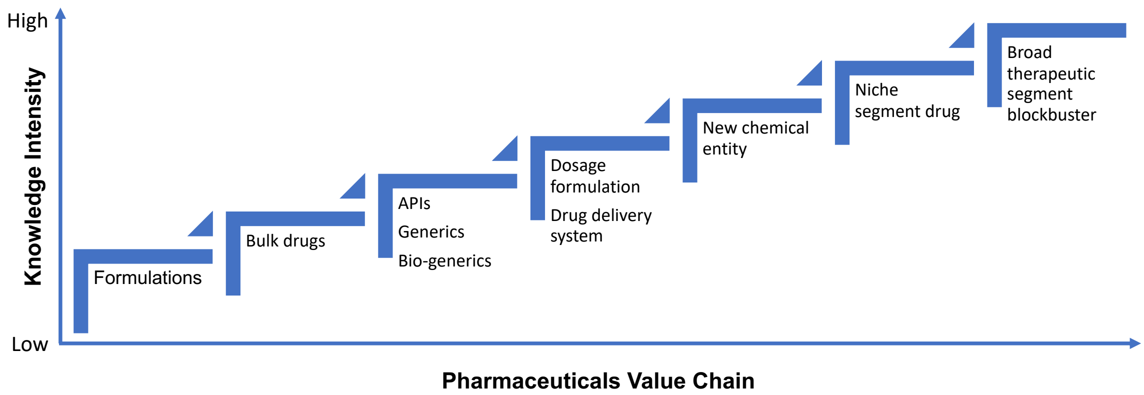

Figure 2.2. Knowledge intensity of the pharmaceuticals value chain. Source: Adapted from (Ramani & Guennif, 2012)

A countries progress in terms of developing capabilities in pharmaceuticals, ranging from the most to the least advanced, can be further categorized as per table 2.1. below.

Table 2.1. Level of capabilities in Pharmaceuticals. Source: Adapted from (Ramani & Guennif, 2012)

Level of advancement	Nature of existing capabilities
Most advanced	Capabilities in bulk drugs, formulations, and displays promising innovation capabilities
	Capacity for manufacturing formulations, competent production in bulk drugs, but replies on imported APIs
	Competence in formulations and packaging of imported drugs
Least advanced	Dependence on imported drugs

In the Global North, the United States of America and Europe have generated the largest number of pharmaceutical patents thus demonstrating their ability to innovate and dictate competition within the sector (Akkari et al., 2016), whereas developing countries were found to be less advanced due to their inferior levels of science and technology and it is also generally assumed that developing countries simply introduce incremental innovations to existing technologies and adapt them to their domestic conditions as opposed to engaging in R&D efforts that could result in new technologies (Mani, 2006).

In the Global South, India has proven to be the exception. The pharmaceutical industry in India has positioned itself as a leading supplier of generic drugs as they possess the advantage of cheaper manufacturing facilities and world-class skills in medicinal chemistry gained from years of know-how in reverse engineering (Kale & Little, 2007). By leveraging new technologies in its pharmaceutical sector, India was also able shift its drug development strategy from being chemistry-based to one focused on biotechnology and genomics in the hopes that the introduction of biotechnology into the pharmaceutical sector would promote innovation (Chaturvedi, 2007).

In the context of the South African Pharmaceutical sector, a recent study by Horner (2022) has shown that, despite being the largest industry in terms of revenue in sub-Saharan-Africa, the country is experiencing a decline in its manufacturing capacity which is predominantly focused on the formulation stages of the drug development value chain, with all APIs currently being sourced from abroad as entry barriers are relatively high for local production. Horner (2022) also notes that the lack of local API manufacturing capabilities in South Africa is restricting the country from expanding its capabilities beyond that of formulations production and states that South Africa’s growth in this sector has been further inhibited by its reliance on imported products. However, Ramani & Guennif (2012) have stressed that manufacturing capabilities in APIs require significant investments due to the high costs of equipment and installations and further emphasized that it must also be produced in large enough quantities to lower costs of production which is currently only achievable in foreign countries.

2.3.2.1. Application of Synthetic Biology in Pharmaceuticals

Synthetic Biology has been heralded as a viable and novel solution for addressing global health challenges by enabling the development of vaccines, drugs, and diagnostics in a practical and affordable way (Rooke, 2013). As an emerging technology, some of its key attributes include its radical novelty as well as relatively fast growth (Rotolo et al., 2015) with the capacity to spread across multiple sectors while also having the potential to be improved over time at lower costs (Mazzucato, 2011). It is a discipline that combines the sciences of biology and engineering in an endeavour to make synthetic organisms (Andrianantoandro et al., 2006) and has the ability to turn a single biological cell into an 'industrial biofactory' (Trosset & Carbonell, 2015) that allows for the production of complex molecules that are either too expensive or difficult to manufacture using standard means (Clarke & Kitney, 2016). Core engineering and design principles are applied to biological systems such that the resulting products are more predictable and developed at higher speeds but at lower costs (Clarke & Kitney, 2016).

In terms of the establishment of capabilities in Synthetic Biology, the United States is the leader in the field owing to significant investments by the government in dedicated research programs and centres that focus on basic and applied research as well as on the training of students in the field (Si & Zhao, 2016). In the United Kingdom (UK), investments have been made into research centres, a centre of training doctoral students was established, and the country has also made an effort to create a national network of infrastructure and expertise (Clarke & Kitney, 2016). The cost-effectiveness of Synthetic Biology applications is of particular value to developing countries where there is a dire need for solutions that can effectively diagnose illnesses as well as provide adequate protection against infectious diseases despite the limitations of their healthcare systems and infrastructure (Rooke, 2013).

The adoption and use of Synthetic Biology, however, as an innovative intervention to challenges in the area of pharmaceuticals, faces its own hurdles in relation to safety concerns around vaccine development, delivery of interventions in developing countries with limited technological resources and expertise, the high costs associated with biological interventions, and ethical and legal concerns with regards to genetic engineering (Rooke, 2013).

2.4 INNOVATION CAPABILITY

Innovation capability is stated as the ability to transform absorbed and adapted technologies into profits using innovation (Zawislak et al., 2012). It is generally characteristic of latecomer countries to perform minor adaptions on technologies imported from advanced countries, which is indicative of their low levels of innovation capability, but deeper levels of innovation capability can still be obtained if these latecomers begin to conduct even basic innovation by creating and managing changes in their own technologies (Bell & Figueiredo, 2012). Holtzman (2014) has also affirmed that an innovative culture further enhances innovative capabilities thus enabling radical improvements to technologies as well as to overall competitiveness.

Learning processes have been identified as a key source of establishing innovation capabilities in developing countries but while learning in advanced countries leads to a deepening of existing innovation capabilities, developing nations are at a disadvantage as they are faced with the challenge of learning how to develop several capabilities that are predominantly non-existent (Bell & Figueiredo, 2012). Knowledge, however, is best absorbed by individuals through internal organizational channels (Huang, 2011) therefore it is essential for firms and organizations of a country to stimulate the pursuit of learning activities by its employees which can enhance its overall commitment to innovation thereby leading to increased innovation capability (Calantone et al., 2002). Additionally, it was found that organizations will experience slow development of their innovation capabilities if they do not make a concerted effort to equip themselves with the knowledge and resources that are necessary for innovation to take place (Bell & Figueiredo, 2012).

2.4.1. Technological innovation capability

It was inferred by Bell & Figueiredo (2012) that innovation capability can be more accurately described in terms of increasing levels of novelty in their innovative activities. Bell & Figueiredo (2012) and Figueiredo et al. (2020) have proffered that once adequate capabilties in initial production activities have been developed, there is an opportunity to accumulate innovation capabilties along four increasing levels of progression. This framework, as depicted in table 2.2. below, facilitates the determination of innovative progress, in terms of technological innovation capability, given the levels of technological novelty and complexity (Figueiredo et al., 2020). The framework has been successfully applied by other scholars similarly investigating technological and innovation capability levels at sectoral levels within developing countries (Davy et al., 2021; Hansen et al., 2020; Peerally et al., 2019; Peerally et al., 2022).

Table 2.2. Levels of innovation capability: the ‘technological’ dimension. Source: Adapted from (Bell & Figueiredo, 2012)

Level of innovation activity	Elements of capabilities
World Leading	- Internationally recognized R&D personnel - Teams of highly specialised professionals - Undertaking cutting-edge and forefront research - Collaborations with other organisations
Advanced	- Variety of engineers, researchers, and specialised professionals - Development of technologies or products that are close to the international frontier
Incremental/ Intermediate	- High number of specialized engineers and technicians - Undertaking activities related to imitation or advanced modification of existing products or systems
Basic	- Groups of qualified engineers and technicians - Engaging in informal R&D activities - Implementing minor adaptations to existing products or systems

Zawislak et al. (2012) have also presented a model that identifies four main building blocks that are necessary, at an organizational level, to create technical change that will result in profits gained through innovation. Four components of innovation capability have been put forward and it is further stated that, while all four are present in every organization, innovation can only be attained if at least one of these capabilities are predominant (Zawislak et al., 2012). This framework was extensively applied in a study to assess the capabilities of over 1000 Brazilian firms in order to determine their innovation and dynamics (Alves et al., 2017) and was also used to explore the interactions between strategy, knowledge management, and emerging technologies in order to improve overall performance (Nascimento et al., 2021).

This paper aims to discuss the dynamic interactions among knowledge management, strategic foresight and emerging technologies, resulting in a framework that can help companies to shape these interactions for achieving positive outcomes.

Table 2.3. Dimensions of innovation capability. Source: Adapted from (Zawislak et al., 2012)

	Dimensions of innovation capability	
Technology driven capabilities	Technology development	Arises from learning processes Leads to technical change necessary for successful innovation
	Operations	Necessary for the efficient production of goods and services from the technologies developed
Business driven capabilities	Management	Responsible for the integration and co-ordination of operations, technology development, and transactions
	Transactions	Enables the sale of the final technologies or products

Overall, innovation capability is, therefore, an important capability for global competitiveness (Holtzman, 2014) especially for countries intending to increase their productivity by promoting innovation (Azubuike, 2013).

2.5 TECHNOLOGICAL CATCH-UP

The fast growth of newly industrialised economies (NIEs), after gaining their independence following World War II, had garnered significant interest over the years and stimulated a surge in research efforts to understand the mechanisms employed by these countries to grow their economies at such fast rates (Lee & Lim, 2001). The theory of catch-up suggested that catch-up is attained when economic growth rates exceed that of the global average or a relevant comparison group (Lee, 2013) but, while catch-up by way of increasing economic growth is necessary for the advancement of any developing country, it can only be sustained if accompanied by increases in technological capabilities (Lee & Lim, 2001).

Lee & Lim (2001) further implore that increased economic growth that results from a reliance on cheap labour that is combined with imported technology without an enhancement of domestic technological capabilities will eventually become difficult and expensive in the long-term. The theory also assumes that developing countries can boost the rate of their growth due to better opportunities to access economies of scale as well as their ability to absorb and adapt new technologies faster than the developed world where older technology systems are seen as an inhibitor to the introduction of new technologies (Abramovitz, 1986). Other common assumptions in literature states that countries that were successful in achieving catch-up had built endogenous technological capabilities and know-how needed to allow them to exploit modern technologies to an advanced degree and adapt them to their domestic environments (Abramovitz, 1986; Lee, 2005; Lee & Lim, 2001; Lee & Malerba, 2017; Malerba, 2005; Malerba & Nelson, 2011). However, while initial studies may have been focused on how NIEs were able to access and adapt foreign technologies for the purpose of growth, focus has since shifted towards the alternate routes that developing nations could take to grow their economies as opposed to merely following the same technology developmental pathways as the advanced nations (Lee & Lim, 2001).

2.5.1. Patterns of technological catch-up

It was emphasized by Malerba & Nelson (2011) that catch-up is mainly achieved at sectoral levels within countries and that the higher the level of technological capabilities possessed within an industry, the more likely it will be to achieve catch-up in that given industry or sector. This is evidenced by the fact that significant differences exist between sectors in terms of their knowledge base, industry actors and networks, as well as in their government policies (Majidpour et al., 2021). The literature was further extended by Malerba and Lee (2017) to show that leadership, when achieved by catch-up activities, is not permanent and that technological development within an industry is subject to catch-up cycles whereby a leader that loses sight of changes in technological trends, market demands, and institutional changes will be overtaken by a newcomer in the industry that exploited a widow of opportunity for the purpose of faster growth.

As newly industrialised economies began to mature, observations of the experiences of some Korean industries had shown that the path to catching-up could be achieved in several ways whereby latecomers were able to avoid following the exact path of advanced countries by skipping some of the stages along the way and even created their own pathways (Lee & Lim, 2001). Lee & Lim (2001) were then subsequently able to identify specific technological capability building processes through which catch-up could occur.

Table 2.4. Patterns of technological catch-up. Source: Adapted from (Lee & Lim, 2001)

Catch-up Pattern	Description
Path following	- This stage is indicative of a latecomer that replicates the same stages in the pathway that is taken by the leader, however, it is able do so in a shorter period.
Stage skipping	- The same path as the leader is initially followed but the latecomer manages to save time by skipping a development stage along the way.
Path creating	- Arises when the latecomer, after initially following the path of the leader, creates an entirely new development pathway.

The pathways followed during stage-skipping and path-creating phases are considered forms of leapfrogging (Lee, 2005; Lee & Lim, 2001) which occurs when a latecomer experiences rapid technological advances in the catch-up process towards the frontier (Chen & Li-Hua, 2011). Lee (2005) suggests, however, that developing countries that intend to adopt leapfrogging strategies are faced with the challenge of which technologies to choose, and risks associated with trying to create an initial market.

To understand the opportunities and challenges facing latecomer countries attempting to catch-up, Lee (2005) highlighted the difficulties that are experienced with regards to the acquisition of design capabilities in technology development beyond mere production capabilities. The three patterns of catch-up, initially identified by Lee & Lim (2001), were combined with the patterns for technology development (Kim, 1997) to yield a revision of the catch-up pathways with each new stage differentiated further according to their modes of learning. Lee (2005) reasoned that while progress during the duplicative imitation stages is relatively easy to achieve in most developing countries, these countries are still generally unable to progress towards stages for creative imitation and real innovation. In a more recent undertaking, Lee (2019) has proposed that additional obstacles to catch-up also arise in the form of capability failures in developing countries, as well as intellectual property rights (IPR) of their advanced counterparts. Lee (2019) offers that, to overcome these hinderances, developing countries should find a detour along catch-up pathways that can enable the development of endogenous innovation capabilities, or that they should attempt leapfrogging in the presence of windows of opportunities as new and emerging technologies can provide them with a leading advantage (Lee, 2005).

2.5.2. The role of public research organisations in catching-up

Key to the success of catching-up is the existence of public research organizations that enable learning and serve as a channel for accessing foreign knowledge bases (Lee, 2013) through the provision of practical skills and hands on training (Mazzoleni & Nelson, 2007). Governments and public research organisations have been identified as key role players in leapfrogging as they are viewed as having the ability to influence market formation and can facilitate the adoption of specific technologies and standards (Lee, 2005). Public research organisations exist to improve the industrial competitiveness within economies by developing technology platforms, and exploiting knowledge through collaborations with industry, licensing of technologies, consulting, as well as the creation of spin-out companies (Holtzman, 2014). In areas that are research intensive and highly complex when it comes to product innovation the requirements for innovation capability in organisations that conduct this type of work are high (Olsson et al., 2010). Universities and public research laboratories are, however, faced with the arduous task of ensuring that there is an ample supply of skilled scientific labour in the form of quality scientists, that knowledge is efficiently transformed into technologies, and that innovation system actors are incentivised to provide investments for building innovation capabilities (Ramani & Guennif, 2012).

Given the nature of innovation processes in pharmaceuticals, the role of public research is mainly to provide foundational knowledge for the pharmaceutical industry from which new therapies and treatments can be created when public knowledge is absorbed and subsequently developed into commercially viable products (Gassmann & Reepmeyer, 2005). An example of the value added by public research organisations can be seen in the cases of Brazil where technological capabilities in formulations and drug production was developed by their public research laboratories, and in India where its public laboratories undertook contract research and aided in the development of pilot scale manufacturing capabilities (Ramani & Guennif, 2012).

2.6 STATEMENT OF PROPOSITIONS

Following the in-depth literature review above it is evident that there is a significant need for developing countries to make efforts to catch-up with advanced nations. Global health challenges in particular pose a serious threat to the livelihood of people and calls for cost-effective and accessible treatments and therapies by leveraging new technological developments. Synthetic biology is one such avenue that displays the potential to alleviate many such challenges. Its adoption and effectiveness in developing countries that have their own unique challenges is, however, not well researched. An innovation capability framework and model has therefore been introduced that will be used to assess the progress that has been made in South Africa with regards to the attainment of innovation capabilities in synthetic biology for its application in the pharmaceuticals sector.

2.7 SUMMARY

This chapter describes the areas of innovation systems, innovation capability, and technological catch-up. It highlights the significance of emerging technologies in the pharmaceutical sectors of the global south and presents a framework for the assessment of its innovation capability.

3 CHAPTER 3: RESEARCH STRATEGY AND METHODOLOGY

3.1 INTRODUCTION

This study adopts an interpretivist paradigm informed by a subjective view that is rooted in the belief that there are numerous realities which are created, and not merely discovered, and that these phenomena must be understood in that context (Rehman & Alharthi, 2016). A research paradigm is a school of thought, or set of beliefs that guides a researchers investigative actions (Guba & Lincoln, 1994; Krauss, 2005). This research style was chosen due to its methodological approach which is oriented towards qualitative research methods requiring that the researcher uses inductive reasoning to analyse data thereby allowing for the identification of patterns and themes from which theoretical findings can ultimately be constructed (Rehman & Alharthi, 2016).

3.2 RESEARCH STRATEGY AND DESIGN

This study is geared towards understanding how the development of capabilities in synthetic biology have evolved since its inception in South Africa. This evolution has taken place over a significant period and its assessment therefore requires a research strategy that allows for an in-depth investigation into the nature of its establishment and implementation. A case study method was chosen, and this approach is aptly aligned to the interpretivist research paradigm owing to the qualitative methods that are employed when adopting this kind of methodology. Yin (2011) defines a case study as an empirical method, relying on multiple evidentiary sources, that allows social phenomena to be investigated in their real-world context. For this study, the case is longitudinal in nature which implies that the study must involve investigating a particular phenomenon at multiple points in time, or over a long period of development (Yin, 2011). Thus, this requirement directly aligns with the research questions that intend to be answered. For this study, the longitudinal investigation will involve the systematic analysis of the strategies developed for the CSIR centre over its full implementation period from 2007 to 2021. Furthermore, the potential for technological catch-up to occur will be dependent on the levels of innovation capability that the centre is shown to possess based on the findings of the study.

3.3 SELECTION OF PARTICIPANTS

The Centre for Synthetic Biology and Precision Medicine, housed within the Next Generation Health cluster of the CSIR, has been selected as the studies research instrument. The focus of the centre is to build deep world-class capabilities in synthetic biology for providing support to the pharmaceuticals sector (CSIR, 2020a). It is a scientifically robust research centre that is rich in data sources that span over more than 10 years and, given that the CSIR is a publicly funded government research organisation, information can be easily obtained thereby making it a feasible and viable site for conducting a longitudinal single-case study.

The study will utilize data from three main sources, namely, in-depth interviews with key stakeholders and CSIR staff that are directly involved with the centre's activities, a categorical questionnaire, and organizational documents. The table below provides details on the data sources that will be used.

Table 3.1. Sources of information

Data Source:	Information obtained from:
1. In-depth interviews	Representatives from the DSI CSIR Executive Leadership CSIR Senior Management
2. Categorical questionnaires	CSIR Research Centre staff
3. Organizational documents	Research proposals Strategic and Operational plans Annual progress reports

3.4 RESEARCH METHODOLOGY

A qualitative research methodology was chosen for this study as it involves iterative processes to improve the understanding of studied phenomena in the scientific community (Aspers & Corte, 2019). This iterative learning approach (Rossman & Rallis, 2016) is in line with the requirements when taking an interpretivist position to the research design as it involves the generation and analysis of empirical information that will lead to an improved understanding of the phenomenon within the research community (Aspers & Corte, 2019). The use of this research design in conducting a study on synthetic biology capabilities in south Africa will allow for the experiences of the CSIR staff and stakeholders to be adequately captured and portrayed in a non-numerical way to ensure that the findings contain and element of value and richness. Conducting qualitative research affords the researcher the opportunity to also utilize multiple data sources, such as documents and material culture, as supplementary to the data gathered during interviews (Rossman & Rallis, 2016).

3.4.1 Data collection and instrument

Following the identification of the CSIR Synthetic Biology research centre as the unit of analysis to be used, research instruments were designed in line with the framework and model on innovation capabilities, as described in section 2.4. The relevant stages of innovation capability will be evaluated against the criteria provided in the framework developed by Figueiredo et al. (2020). The innovation capability is also assessed in line with framework proposed by Zawislak et al. (2012) which the key components that contribute towards the establishment of innovation capabilities. As such, the reseach instruments have been designed as follows:

- The interview protocol (see Appendix A) is comprised of 3 different sets of interview questions. This was done to accommodate the varying levels of seniority of the participants that will be interviewed and was also based on the nature of their involvement with the centre. Question set 1 aims to determine the strategic intent and priorities associated with the establishment of the centre at national, sectoral, and CSIR executive levels. Question set 2 aims to understand how the CSIR management has supported the establishment of the area. Lastly, question set 3 deals with the nature of the operations of the centre itself and the activities that have been undertaken that provide support the pharmaceutical sector.
- The questionnaire (see Appendix B) was designed to target responses from key research staff within the centre. It intends to solicit information with regards to the resources, technical capabilties, knowledge base, and technology development aspects that relate to the centre.

The study will also make use of secondary data sourced from relevant organizational documents. A formal database will be developed that organizes and contains notes taken during the data collection period, documents pertaining to the centre's activities, and tabular materials.

3.5 DATA ANALYSIS

The evolution of innovation capabilities will be assessed primarily using the information solicited through the interview process. The data retrieved through interviews, questionnaires, and documents will be analysed using qualitative analysis techniques. The dataset will consist of large amounts of textual data that will be categorized, and examined for emerging patterns and themes that are aligned to the research questions and components of innovation capability. Relevant data pertaining to the levels of innovation capability will then be populated against the framework presented by Figueiredo et al. (2020) to determine its overall ranking.

3.6 LIMITATIONS OF THE STUDY

The concept of catch-up is complex and multifaceted but this study is limited to the nature of technological catch-up using emerging technologies as a means of leapfrogging. While the intention of the study is to understand how capabilities in synthetic biology have evolved in South Africa, it excludes the R&D activities taking place within private biotechnology and pharmaceutical companies nor does it account for the undertakings of South African universities in this field.

3.7 ETHICAL CONSIDERATIONS

The following ethical considerations were made during this process:

- All data will be kept confidential and discarded after a two-year time-period.
- Permissions to conduct the study at the CSIR has been obtained to ensure confidentiality of the information provided by participants.
- Data will be stored on a personal hard drive dedicated towards the research study.

– The study will not request or use names or designations of participants that could allow them to be easily identified.

3.8 RELIABILITY AND VALIDITY

The validity and reliability of qualitative research data is underpinned by the concept of trustworthiness (Jackson, 1999). The results of the case study analysis for this research are dependable as it will be based on responses garnered from experts in the field, most of which have several years of experience working at the CSIR. Given that the qualitative data gathered will be based on the lived experiences of the participants, the extent of the trustworthiness of the data will be supplemented by information obtained through the analysis of organizational documents that have been verified and approved through organisational processes. The details required regarding tangible data on skills and qualifications can be easily verified. Information on individuals' capabilities is more experience based and the responses from researchers will be documented and verified using data triangulation. The study also assumes that all the secondary data with a bibliometric nature is reliable as these numbers would have been verified through organisational auditing processes when reporting takes places. Thus, through the aspects of data triangulation using interviews, organisational documents, and quantitative outputs to provide confirmation of the qualitative data, the study will avoid any biasness that may result from the use of a singular data finding (Begley, 1996).

3.9 SUMMARY

Provided in this chapter is an account of the research methodology that has been adopted to address the propositions made. It explains that an interpretivist research paradigm has been adopted that allows for a qualitative focused research approach. The study will entail a longitudinal single-case study design approach. The data will be collected and analysed using qualitative research design strategies that will allow for the identification of recurring patterns and themes that will inform the presentation of the findings and preceding discussions.

4 CHAPTER 4: PRESENTATION OF FINDINGS / RESULTS

4.1 OVERVIEW

The findings of this study as it pertains to the proposed research questions are presented in this chapter. The data collected is presented against the format and structure of the interview protocols and questionnaire.

4.1.1 Brief introduction

This study aims to provide a view of the state of capabilities that have been developed in synthetic biology in South Africa using the CSIR and its associated research groups as the instrument of analysis. This study, which follows a qualitative analysis approach, involved identifying, selecting, and interviewing participants that have been directly involved in synthetic biology activities at the CSIR since its inception within the organisation. The dimensions of the innovation capability framework and model depicted in **section 2.4** were used as a guide to inform the types of questions that would be required for this study in pursuit of an understanding of synthetic biology's innovation capability status in South Africa.

4.1.2 Background profile of Respondents and process followed

Participants were identified and selected based on the role they have played in the establishment of synthetic biology as a capability for South Africa. Prior to the interview process, each individual was provided with an information sheet (see Appendix C) and consent form (see Appendix D) to confirm their participation. The interview and survey questions were designed along the veins of the management, operations, technology development, and transaction components of innovation capability as it relates to the activities undertaken at the CSIR. The research management team of the centre at CSIR was supplied with a brief questionnaire targeted at soliciting information pertaining specifically to the technologies that are currently being develop in the field. The general profiles of these respondents, all of whom have requested to remain anonymous, are given in the table below:

Table 4.1. Participant profiles

Respondent Identifier	Highest Qualification	Organisation	Designation	Role/s in Synthetic Biology at CSIR
1	Unknown	DSI	Director	External funder Strategic partner
2	PhD	CSIR	Senior Management	Internal funder Strategic partner
3	PhD	CSIR	Executive Management Scientist	Leadership
4	PhD	CSIR	Senior Management Scientist	Leadership Management
5	PhD	CSIR	Senior Management Scientist	Internal Funder Leadership Management
6	PhD	CSIR	Senior Management Scientist	Management Researcher
7	PhD	CSIR	Senior Management	Management Researcher

4.2 PRESENTATION OF FINDINGS AND DATA

The presentation of the data gathered will follow the format and structure of the interview protocols and questionnaire. Preceding the investigation of the components of innovation capability, the first section deals with the responses related to the strategy and rationale behind the introduction of synthetic biology in South Africa**.** The sections that follow attempts to further categorize the responses obtained according to the four components of innovation capability as it relates to CSIR Centre being analysed.

4.2.1 STRATEGIC INTENT AND RATIONALE

The subset of strategy related questions was posed to senior and executive level respondents to ascertain the rationale behind the adoption of synthetic biology by South Africa and to understand its role and impact for the pharmaceuticals sector. The relevance of the CSIR as the lead implementing institution was also investigated.

- The responses received were largely related to the need for South Africa to develop its own scientific capabilities in the field. However, there were differing views with regards to what those capabilities should be.

Key responses: "…we need to put more emphasis at especially going forward with your pharmaceutical design, whether it is your drugs or whether it's even vaccines and other biologics."

"Synthetic biology is an important science, especially for industrial manufacturer, not just of pharmaceuticals, but also of reagents, biological reagents as such, for the particular reason that you can really make specialty enzymes, specialty bugs that fits specialized cells in agile systems to make pharmaceutical products. So, it's absolutely a technology that we must get into and strengthen our position in."

"It was an emerging field worldwide and you know it, it was important for South Africa to be part of that field and particularly if South Africa wanted to leapfrog into the space of health sciences and of genetic engineering."

"We needed to develop the capability for the country just to make sure that we're on par with the rest of the world."

"To shorten some of the product development cycles."

"One of the important things is when you start looking at precision medicine, that to me is really one of the areas where synthetic biology is essential…it becomes very difficult if you do not have the synthetic biology component attached to them."

"To develop your specifically new treatments and your cancers and so on are becoming more and more important within Africa and this is where we need to see what is the best way, then, to actually enhance the science."

- The majority of the responses emphasized that the CSIR is best positioned to conduct research for non-academic purposes as it serves as a link between academia and industry through its combined capabilities and expertise in directed basic research as well as product and process development.

Key responses: "One of the things that we are trying to encourage is that we go beyond research for academic purposes, but you actually start doing research with the end product in mind and this is where the CSIR is then a better place to do that because you link the bridge between academic and your actual industry components."

"It wasn't just about studying the area, but actually creating things that are useful and, you know, not necessarily making products but making you know technologies available that that can be utilized within the country and can make a difference."

"But it is in the end when you actually want to get real products out that is where the CSIR play a more important role."

"It *(CSIR)* is quite appropriate because of our position in translational research. You see one of the things that we do is directed basic research so there is an element of basic research to synthetic biology. It is when you get to the basics of re-engineering molecules, re-engineering biological pathways, re-engineering bugs, there's a lot of basic science involved, but this is very directed, and it is in keeping with our mandate to do directed basic research for the purpose of developing specific applications and industrial development that is absolutely in keeping with our mandate."

"Considering our place, CSIR place, within the national system of innovation, you know where are areas that CSIR can play a role, can develop capability that can be useful for the country, and keep the country on par with the rest of the world. There was definite need for the capability, but not an academic capability. You know, there's obviously a lot of academics there, but we needed to develop tools we needed to develop capability that could make impact."

"We needed to develop capability in that space and it's a high-end capability. It's not like your average university capability. So CSIR was the best place to have that capability."

"CSIR distinguishes itself from academics by the fact that we really do try and make technologies and processes and tools that are useful to the country, not just producing PHD's and masters."

"We needed permanent scientists involved in this and that's why we thought it would be good at CSIR and obviously that was then agreed to by DSI and that's where the funding came from to develop the capability."

- The responses further indicated that impact in the pharmaceuticals sector would be achieved mainly through the development and deployment of high-end processes and technologies that relate to precision medicine.

Key responses: "One of the important things is when you start looking at precision medicine, that to me is really one of the areas where synthetic biology is essential."

"To shorten the product development cycles"

"Repurposing of drugs by understanding how cells work"

"Screening a whole lot of drugs developed for other purposes to address specific cancers"

"High end technical tools and processes, so it's not your standard biometric biomedical processes and tools and practices"

4.2.2 CHALLENGES

As part of the study of the establishment of synthetic biology in South Africa, it was crucial to understand the challenges that are being encountered in the area that could be inhibiting the ability of the Centre to innovate.

- Two main national challenges facing the country that emanated from the responses were identified:
  - A shortage of skills in South Africa

Key responses: "We really battled to find senior level or the leadership level scientists but even from overseas is difficult. You know you're not going to get the top guys and in many of these new fields in new areas, there aren't any people in South Africa"

"We don't have the capacity to do real impact work. We don't have enough good people. We've got very good people, but we don't have enough of them and we don't have the funding"

"Developing solutions for Africa are not necessarily on the radar of people that have the funding and the people internally that have the funding don't necessarily want to fund the high tech"

- Limited national and international funding

Key responses: "Africa and South Africa have very limited funding pools as far as research is concerned."

"As a government we are risk averse to too long term funding long term research funding"

"Not enough patient capital"

"Funding cycles are getting shorter"

"Money for research in country in general is limited"

- All respondents were also in agreement with regards to their identification of the main challenges facing the CSIR Centre. The following challenges were identified:
  - Lack of funding/ financial sustainability

Key responses: "It's the funding and the leeway associated with that funding that I think holds us back the most"

"Financial sustainability, which is always the case, which makes it difficult to recruit team members"

- Inability to retain talent/ loss of key senior staff

  Key responses: "Inability to commercialize existing patents due to resignation of lead developers"

  "They (new senior employees/ foreign expertise) were not given that opportunity or that space to do things that they envisioned though that was set out or planned"

  "We (CSIR) want to mould the scientist into the CSIR, enter timesheets and overhead costs, etc"

  "Patents were generated by people who have left now there is no one else who can commercialize it"

  "Scientists don't work well in bureaucracy and we (CSIR) are a very bureaucratic organization"

- Poor organisational structure, function, and culture

  Key responses: "CSIR tends to work on their own and we (*external stakeholder*) are now basically trying to force them to collaborate…South Africa is too small to have somebody who wants to be the king of everything."

  "The freedom to innovate is severely constrained trained by systems and processes, and bureaucracy."

  "There needs to be space for people to play, to make mistakes, to fail fast and that's where you get true innovation from, and I think we are missing that. We (CSIR) are overmanaging at the moment…We gave them that space in in the early 2010's and I think that's why we did get some major breakthroughs."

"Probably the big difference to now is that we're expecting results too fast now and managing it too tightly and potentially don't have the right people to do it. There are still some brilliant people but those people might be managed too tightly."

4.2.3 INNOVATION CAPABILITY COMPONENTS AND RANKING

4.2.2.1 Technology development capability

The subset of technology development related questions was posed to senior researchers within the Centre to determine the nature of the technologies developed with regards to research and development intensity and innovativeness. Due to the technical nature of technology development, responses for this component of innovation capability were solicited through a questionnaire. A 100 % response rate was achieved from targeted recipients. The results of the questionnaire were consolidated and the final table (see Appendix E) presents the classification of activities being undertaken by the various research groups of the present-day configuration of the CSIR Synthetic Biology and Precision Medicine Research Centre. It must be noted that each group develops numerous technologies and the responses do not relate to one specific technology but to the general activities of each group. It was found that:

- The centre is comprised of four main research groups each with differing levels of capabilities.
- All groups are strategically aligned.
- Research activities are skewed towards applied and experimental type of work.
- Innovation activities are a combination of incremental technology development as well as radical developments.
- Equipment has been sourced internationally and modified or enhanced to suit the necessary conditions of the centre.
- Innovation capability of the activities is perceived as intermediate and advanced.

4.2.2.2 Operations capability

The subset of operations related questions was posed to senior research management respondents to understand the nature of how the centre operates within the structure and culture of the CSIR and its subsequent host operating unit/ cluster. It further aimed to investigate the operational elements of the Centre with regards to its financial resources, personnel and skills, infrastructure, as well as its strategic partnerships. The data gathered was as follows:

- Financial resources
  - It was reported that the Centre is currently receiving R10 million per annum from the CSIR to operate.
  - It was estimated that an additional R20 million per annum would be required to realise real impact.

  However, Respondent 4 had an interesting view in terms of the funding that is allocated to a group.

  Key responses: "When you had less people, it didn't really warrant additional money, they couldn't really probably spend all of it."

  "It's a bit difficult to justify funding things where you might not get a return. Actually, it's very difficult to get decent funding in that space considering that Africa and South Africa have very limited funding pools as far as research is concerned."

Conversely, Respondent 5 was of the view that the amount of funding disbursed for research is inadequate.

Key responses: "We give people a little bit of money in South Africa and expect the world back from them."

- Personnel and skills
  - It was generally agreed that there is a lack of necessary skills and personnel in the Centre. This is compounded by the national level skills shortage as well as national policies.

  Key responses: "There is lot of skills development that needs to be done within the Centre as well because some of the skill sets the scientists currently have are not that effective if you want to compete globally."

"Certain groups are well resourced, certain groups or not."

"We don't have the capacity to do real impact work. We don't have enough good people. We've got very good people, but we don't have enough of them, and we don't have the funding."

"Getting the right candidates also with transformation has been challenging."

- The need to avoid the duplication of skills within the Centre was also highlighted.

  Key responses: "If you've got a research group leader, at principal scientist level, you're not going to go and find another research group leader or another person at principal scientist level with those same skills.

- Infrastructure

The responses yielded significantly negative results.

- It highlighted a clear lack of understanding by the organisation's procurement function of the nature and significance of scientific equipment for research.
- It indicated that equipment is mainly sourced through competitive infrastructure calls.
- It indicated that the host cluster does not provide funding to the Centre to support the purchase of equipment.

  Key responses: "We (the Centre) follow the CSIR procurement process which includes purchasing equipment, the process is time consuming and laborious."

“A lack of understanding that basic infrastructure (like back up plugs; leaking, rusted taps which shut down 6 weeks of stem cell culture because they trip a switch over a weekend ends up costing us R100k in running costs of reagents never mind the time of the scientists needed to repeat the experiments).”

“Writing 52-page grants defending the upgrading of 10-year-old microscopes fall on flat ears, procurement bureaucracies of the support team not understanding just because something is cheaper doesn’t mean it’s the better option – scientists know better.

- Strategic Partnerships

The views expressed were that the CSIR’s primary partnerships are will public sector institutions.

- The primary stakeholders are the South African Department of Health (DoH) as well as the DSI.
- Based on some of the responses, partnerships with South African universities could have significant potential for the field however implementation in this regard is still lacking.

Key responses: “University wanted to have a new masters of biomedical engineering, so we wanted to support them inbuilding on the curriculum and also training students.”

“We also wanted to partner with the universities and also historical disadvantaged hospitals…we can use the patient samples to test our parts of the projects at the centre thereby we can train Masters, PHD's and hopefully build human capital up to principal scientist level.”

- There are no tangible partnerships with the South African private sector at present. It was also reported that the Centre has not been successful in establishing relationships with SMMEs.

  Key responses: “It's a westernized clinical trial system and it doesn't necessarily sort of suit Africa. And then you come up with a process to maybe suit Africa, but the market may not be big enough so pharmaceuticals may not want to get involved in that space.”

4.2.2.3 Management capability

The subset of management related questions was posed to senior management level respondents to understand how the CSIR, by way of the previous Biosciences operating unit and its current Next Gen Health cluster, has supported the establishment of synthetic biology efforts. The responses received were limited as respondents did not feel that the support provided has been adequate as is evident by the numerous challenges being experienced within the Cluster/ Centre.

- The respondents stated that the support processes provided by the host operating unit/ cluster to the Centre varied from inefficient to adequate. Procurement support and operational support were identified by respondents as weak or inefficient whereas project management and business development skills were highlighted as some of these that work well within the cluster.

4.2.2.4 Transaction’s capability

Questions were raised during the interview process that would investigate the success of synthetic biology with regards to technology development and the impact that had been made in the pharmaceutical sector thus far.

- The interview process resulted in many of the respondents referring to earlier technological developments that had taken place during the formative years of

Synthetic Biology. Emphasis was also largely placed on the establishment of key capabilities and on ‘first-in-the-world’ technologies that were developed.

Key responses: “CSIR was publishing in cell. Cell, in the context of life sciences, is as good as it gets in nature. In in this we were like trail blazers in that area.”

“The genes scissors technology that we developed in 2013, I believe that was first in the world and that was a precursor to the clustered regularly interspaced short palindromic repeats (CRISPR) technology which is now the genetic standard and it's one of the key tools in the world.”

“The ability to visualize at a molecular level that was first in the world...our visualization capabilities using the high-end microscopes and laser systems that we had that was on par with only a couple of laboratories in the world that could do it.”

“Stem cells work and liver biobank are trailblazing.”

“If you look at something like Resyn which is part of molecular biology and synthetic biology, the Resyn technology is a world leader still and that's why we have a company that's formed from it.”

“The key research focus in two of the research groups actually resulted in the creation of spin out companies, which was Resyn and Persomics.

4.2.2.5 Innovation capability ranking

Respondents that were interviewed were asked to rank the level of innovation capability that they perceive the centre to be at currently. The ratings revealed an average raking of 4 out of 10 indicating positioning the present innovation capability of the centre as incremental/ intermediate.

Table 4.3. Ranking of the current level of innovation capability of Synthetic Biology at CSIR

Respondent	Ranking (1 = basic; 5 = incremental/ intermediate; 10 = world leading)
1	4
2	<5
3	3
4	5
5	2
6	5

4.3 SUMMARY OF DATA PRESENTATION

The information gathered from the interviews and questionnaires were reviewed and the relevant findings were categorised based on recurring themes that were identified during the data collection process. These themes showed strong alignment with the dimensions of innovation capability, described in **section 2.4,** subsequently leading to the structure and presentation of the discussions that follow.

5 CHAPTER FIVE: ANALYSIS AND DISCUSSION OF THE RESEARCH FINDINGS

5.1 INTRODUCTION

This study investigated the establishment of synthetic biology in South Africa to highlight its role in resolving the challenges of the South African pharmaceuticals sector. The study followed a predominantly qualitative research approach whereby information was obtained mainly through interviews with key individuals involved in Synthetic biology activities in South Africa. The data gathered during the process was reviewed and categorised along the four dimensions of innovation capability. Using the findings presented in **Chapter 4**, combined with information contained within organisational plans and progress reports, this chapter will:

- Provide an account of the evolution of Synthetic biology as a capability developed by the CSIR.
- Discuss the dimensions of innovation capability, as it relates to Synthetic biology at CSIR, and determine the current level of innovation capability of this CSIR Research Centre.
- Suggest potential pathways that can be taken to facilitate improved efforts of catching-up within the pharmaceuticals sector.

5.2 DISCUSSION: EVOLUTION AND STRATEGIC FOCUS OF SYNTHETIC BIOLOGY IN SOUTH AFRICA

During the early 2000's, developments in synthetic biology was in its infancy and the global research community was still in the process of organizing itself around this topic thus presenting a new entrant with an opportunity to become a world leader in the field (CSIR, 2007). The rationale for the introduction of Synthetic Biology to South Africa was emphasized in the data obtained from the respondents and largely related to the need for the country to gain a foothold in this emerging field. It has been highlighted by the respondents that the focus of the research and of technology development activities should be on pharmaceutical design for drugs, biologics or vaccines, industrial manufacture, efficiency and streamlining of product development cycles, as well as precision medicine. As a developing country, these focus areas would be well positioned to respond to the domestic issues of reliable access to medicine and lack of industrial competence, as identified by Ramani & Guennif (2012).

In 2006, the CSIR embarked on a new organisational strategy and vision and one of the goals of this strategy was to strengthen its weakening science, engineering, and technology (SET) base (CSIR, 2006). As an intervention, the organisation aimed to establish a new research program, called 'Emerging Research Areas (ERAs)', which was geared towards performing novel research in areas that would have the highest relevance to South Africa and also provide the country with the opportunity to participate and contribute towards making discoveries in global frontier science (CSIR, 2006). The ERA for Synthetic Biology was officially launched in April 2007 (CSIR, 2009). The ERA program was aligned to the overall strategy of the organisation and was initially mandated to conduct basic research in novel areas with the added advantage of serving as a vehicle for the training of new PhD and post-doctoral students in the field. It was further understood that the activities of the group would be purely research based and its success would not necessarily depend on market driven financial returns, such as those emanating from experimental or translational research.

The appropriateness of the CSIR as the host institution for the establishment of capabilities in synthetic biology was stated in the CSIR science and technology strategy of 2006 which positioned science councils, such as the CSIR, as the bridge between universities and the business sector and highlighted its role as a custodian of national scientific infrastructure owing to its secure environment and its ability to invest in large infrastructure which other NSI and private sectors actors could not afford. The intent of the CSIR was to facilitate the development of end products, technologies, processes, and tools that would be useful to South Africa and make an impact. Despite its original mandate to conduct basic research and discovery in synthetic biology, the CSIR strived to distinguish itself from universities by developing high-end capabilities in the form of tools and processes as opposed to the academic inclination that usually resulted in the creation of postgraduate students alone. Over the years, the strategic focus of the area has often shifted. More recently, it is the view of its stakeholders that while the centre has been able to demonstrate sound capabilities, it is now time for those capabilities to be put to better use in the pharmaceutical value chain by improving the efficiencies in drug development and discovery. Conversely, it is the view of a field expert that applications for drug discovery are laborious and expensive for the organisation and that the objectives to conduct such research should be repositioned. Given the consistent depletion of R&D funding in South Africa, this view is in keeping with the findings of Gassmann et al. (2008) and Wang et al. (2021) which alluded to the high costs of R&D associated with developing new drugs for the market.

As of 2022, research in synthetic biology at the CSIR had been taking place for a period of approximately 15 years. Upon review of the data, it became evident that the activities undertaken during this time could be grouped according to three main developmental periods with each time-period having its own distinct strategic intent. The findings for each developmental period are elaborated on below and are intended to describe the key endeavours of the CSIR in the pursuit of innovative competence in this dynamic field.

5.2.1 2007 – 2011: The Synthetic Biology Emerging Research Area

In response to the CSIR Science and Technology Strategy of 2006, a proposal to establish an ERA group with a specialized focus on Synthetic Biology was conceptualized by a team of scientists within the CSIR Biosciences operating unit (as it was known under the organisation's structural configuration at that time). The group was provided with funding by the CSIR for a term of 5 years following which a decision would be taken at the end of the term to decide whether the ERA should be (i) separated from the host operating unit and allowed to operate independently; (ii) retained by the host unit, or (iii) the researcher activities be discontinued. At the mid-point of the 5-year term, the leadership of the CSIR Biosciences unit had been opposed to the release of the ERA to operate independently leading to the subsequent retention of the research group within the boundaries of Biosciences (CSIR, 2010a). The main objectives of the Synthetic Biology ERA for the period are captured in the table below.

Table 5.1. Objectives of the Synthetic Biology Emerging Research Area

Period	Strategic Objectives
2007 – 2011	• To be the leading Synthetic Biology Centre in an R&D organisation in South Africa and to play a leading role in developing the South African multi-disciplinary field of Synthetic Biology through local and international partnerships with institutions and government bodies. • High impact scientific content transformed to publications in highly cited peer reviewed journals leading to knowledge generation in the field • To entrench the highest level of human capital development as a key focus and output of the ERA. • To build relevant national and international networks and partnerships as an integral component of a world class knowledge centre in aspects of Synthetic Biology.

As can be seen from the table above, the objectives of this period appeared to place significant emphasis on building a foundation for synthetic biology that was grounded in elements that are required for knowledge generation i.e., basic novel research, human capital, and partnerships. As identified by Malerba (2005), it is these elements that are needed to foster innovation within a sectoral innovation system. When considering the elements of innovation capability, the ambitious goals of the ERA during these years were largely aligned to establishing competence in the technology development, operations, and management aspects of the area. With this targeted focus, by 2011, the ERA had achieved immense technological and transactional success in Synthetic Biology through the creation of a patent, 2 spin-out companies, and numerous publications in world leading accredited academic journals to name a few. It becomes clears then, that innovation capability and its subsequent successes might depend significantly on more than just technological discoveries alone.

5.2.2 2012 – 2019: The Emerging Health Technologies/ Pioneering Health Sciences

Following a restructuring exercise undertaken by the CSIR Biosciences unit in 2011 and 2012 the original objectives of the ERA were redesigned to better align with the overall CSIR objectives leading to a transitioning within the ERA from early-stage basic research activities to later stage developmental research with a revised focus on experimental and translational technology development. The original activities of the ERA program were re-established under a new research portfolio called Emerging Health Technologies (EHT) (CSIR, 2010b). The newly established EHT group aimed to leverage off the existing skills and infrastructure of the ERA and pursue specific capabilities that could help to understand human health for the treatment and diagnosis of important South African diseases. With the rest of the South African NSI focused on vaccines and new drug development at the time, the CSIR focus was alternatively on understanding how to unlock new ways of fighting infectious diseases at a cellular level. In 2013, the completion of the National Bioeconomy Strategy called for another revision of the strategic intent of activities that related to resolving the national challenges in health and pharmaceuticals. By 2015, the EHT group was once again reconfigured into a new area, Pioneering Health Sciences (PHS) (CSIR, 2015) which continued to house most of the existing synthetic biology capabilities.

By 2016, synthetic biology research activities at Biosciences reverted to the original structure and intent of the 2007 ERA but with a revised focus on translational research activities. It was envisaged that new waves of synthetic biology focus areas would be incorporated into the existing capabilities to enable the development of processes and tools that could support the R&D efforts of pharmaceutical and biotechnology companies. The table below provides an overview of how the strategic objectives of synthetic biology has evolved over this period.

Table 5.2. Objectives of Emerging Health Technologies/ Pioneering Health Sciences

Period	Strategic Objectives
2012 – 2014	• To reduce and terminate research initiatives that do not align with new strategy such as early stage, long term and high-risk new vaccines, new therapeutics, new stem cell therapeutics, drug discovery. • Focusing R&D in EHT to develop diagnostics solutions and reagents.
2015	• Contribute to reducing the national disease burden through support of sustainable manufacture of APIs, vaccines, biopharmaceuticals, diagnostics, and medical devices and performing oriented basic and applied research to help advance new knowledge for identification of alternative prophylactics, diagnostics, and therapeutic solutions. • Develop and transfer diagnostic and prophylactic technologies and products to contribute to reducing the incidence of priority diseases affecting the people of SA and Africa. • Execute oriented basic research to understand pathogenicity of national priority diseases and thereby advance development of new prophylactics, diagnostics and therapeutics for major diseases affecting ppl in SA.
2016 – 2019	• Implementation of ERA as per original intent with a strong focus on generating excellent SET outputs and translation of Synthetic Biology R&D into relevant solutions. • Deepening and strengthening of the capabilities in drug screening and establish a high throughput screening platform. • Focus on translation of key technologies and on building bioengineering capability.

The period between 2012 and 2019 appeared to be fraught with frequent instability largely due to a continuously changing organisational landscape. The first period saw a significant reduction in novel basic research, a vital component of endogenous innovation capability building, and the renewed focus on commercially viable tools and products to satisfy the organisations new strategy and requirements came at the expense of potential novel discoveries. This decision to terminate early-stage and long-term activities can be viewed as a decision to minimize the pursuit of synthetic biology itself. The long lead times associated with novel discoveries were a deterrent to the organisation which seemed to be chasing immediate financial returns at the expense of cutting-edge research activities. The research priorities during the second period revolved around addressing the burden of diseases in Africa and circled back to basic research activities in some areas. These disease burden focused objectives were designed to align to national strategies. The decision to return to the original intent of synthetic biology in the last period is somewhat indicative of instability within this space and it is relatively unclear as to what prompted yet another strategic shift.

Due to the constant changes that took place, it is difficult to gauge the actual efforts geared solely towards synthetic biology as all biotechnology activities were grouped together under the various research areas. A comparative difference between the objectives of the initial ERA and the EHT/PHS periods is that the EHS/PHS objectives predominantly focused on specific technology development activities. There was minimal emphasis on plans to increase personnel capacity or develop tangible partnerships. Although these activities did take place, it appeared to be done on the backdrop of research activities. The primary objectives of the initial ERA were geared towards building sound operational and management capability which led to novel technological and innovative outcomes. It may be necessary to consider whether having objectives that are too specific and only technologically focused may restrict innovation potential within these research spaces with the understanding that innovation is an all-encompassing field that relies on more than just technological success and novel discoveries.

5.2.3 2020 – Present: The Centre for Synthetic Biology and Precision Medicine

The year 2019 ushered in the development and implementation of a new CSIR-wide organisational strategy which focused on innovation-led activities that would drive the re-industrialization of South Africa by embedding the capabilities of emerging technology platforms across all of its R&D operations (CSIR, 2020a). Implementation of the new strategy led to the re-prioritisation of the organisations research activities by enforcing a shift from the original CSIR structure of operating units towards an industry informed cluster approach. One of the new clusters created is the Next Generation Health Cluster under which the current research centre for synthetic biology was established. The centre was formally launched in 2020. The solutions developed in the centre are aimed at supporting the South African national health care systems goal of providing access to health care services. The table below outlines the main objectives of the research centre.

Table 5.3. Objectives of the Centre for Synthetic Biology and Precision Medicine

Period	Strategic Objectives
2020 - Present	• Improvement of access to healthcare services and products. • To support the state to reduce cost to the national health system due to Adverse Drug Reactions. • To support industry with cheaper and shorter ways for drug discovery. • To provide local and international pharmaceutical industries with improved processing techniques that enable them to be more competitive.

The objectives put forward do aim to address larger national priorities as well as the global challenges associated with high R&D costs and access to healthcare. While the external impact that is intended by the Centre is well articulated and appreciated, the objectives lack an element of specificity from an internal organisational perspective as it is unclear how the Centre plans to achieve the necessary outcomes that have been listed. Overall, the many years of activities in the area of synthetic biology has been significantly disrupted by frequent strategic changes. The objectives of the different periods clearly show a continuous redesign of the activities and approaches in the development of synthetic biology capabilities. Given that the current Centre was only recently established, it is difficult to ascertain its progress towards the attainment of the goals set out, but it is anticipated that, as this study delves deeper into the elements of synthetic biology's innovation capabilities in the sections below, new learnings may arise that can aid the current Centre in enhancing the continuity, delivery, and impact of activities within this space.

5.3 DISCUSSION: THE DIMENSIONS OF INNOVATION CAPABILITY

The discussion that follows sets out to describe the status of innovation capability at the Centre along the dimensions put forward in the framework developed by Zawislak et al. (2012) which aims to explain why investment in technology alone will not lead to innovation. Thereafter the overall innovation capability of the Centre will be determined according to the framework developed by Figueredo et al. (2020) and any shortcomings that are identified will be presented as learnings for future improvement of the Centre's activities.

5.3.1 The technology development capability

The importance of building capabilities in emerging technologies, and in synthetic biology, has been substantiated in **section 2** above. As the CSIR embarked on this initiative it held some key advantages that could play a role in giving South Africa a head-start in becoming a leader in this field. Figure 5.1. below illustrates the evolution of the synthetic biology research focus areas adopted by CSIR from its inception to date.

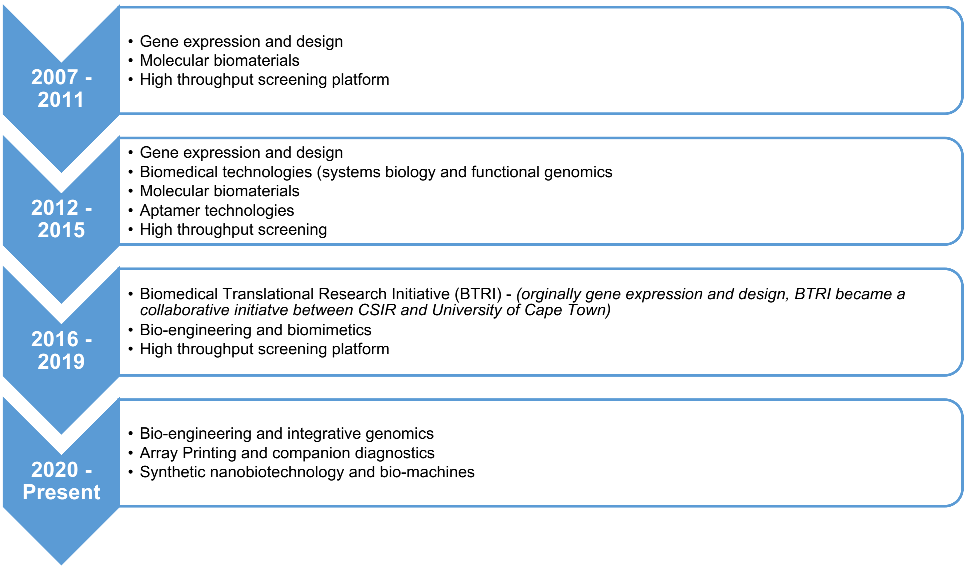

Figure 5.1. Synthetic Biology focus areas at CSIR

The technology development trajectory of synthetic biology is described in more detail below.

- **2007 – 2011: The Synthetic Biology Emerging Research Area**

One of the main advantages available to the country at the onset of this initiative was that collaborating South African scientists at the CSIR and North-West University were already in possession of patents for technologies that were key to synthetic biology (CSIR, 2007) and which formed the basis for the establishment of two main research focus areas within the Synthetic Biology ERA. Building on the foundation of these patents the team was able to make novel strides in the development of diagnostics tools, capabilities in single molecule imaging and super resolution, microspheres, stem cells, microarray printing, and high throughput screening. Many of these activities were also identified by Gassmann & Reepmeyer (2005) as viable new opportunities for pharmaceuticals. Respondent 3 described the work being done at that time as "trail blazing" supported by the fact that the group was publishing articles in internationally accredited high impact journals such as Nature and Cell which said respondent stated was "as good as it gets" in the context of life sciences (Respondent 3, personal communication, March 17, 2022). Much of the work undertaken in these formative years resulted in numerous knowledge generation outputs as the group was involved in extensive basic research to get a better understanding of this novel area. This was validated by Respondent 4 who indicated that the senior researchers that were employed in the area were highly focused on science and research, more so than in other areas of CSIR Biosciences (Respondent 4, personal communication, March 14, 2022). The activities during this period focused on the development of enabling tools and process techniques as opposed to direct drug development. This focus on early stage novel research was a key starting point in the development of endogenous capabilities in synthetic biology especially given the role that should be played by public research organisations in the provision of foundational knowledge for pharmaceutical developments (Gassmann & Reepmeyer, 2005). Furthermore, the CSIR had proved that leapfrogging was indeed a possibility for a developing country given how fast it was able to demonstrate its leadership in this field through the rapid attainment of technological capabilities to become a serious contender at the global frontier, a feat that is characteristic of catching up in industries and sectors (Malerba & Nelson, 2011).

2012 – 2019: The Emerging Health Sciences/ Pioneering Health Technologies

The goal of the post ERA stage between 2012 and 2019 was for research activities to be focused primarily on diagnostic solutions for HIV, TB, and malaria. These included the development of diagnostic reagents and kits as these were viewed as an easier and cheaper approach to getting developed solutions into the marketplace as compared to therapeutics and vaccines. Research areas that lacked a competitive advantage were reduced and a significant amount of basic research activities were transferred to university partners while activities involving drug discovery and development were terminated. Furthermore, innovation approaches were described as incremental during this period with the exception of some remaining early-stage research activities where the approaches were viewed as being more radical (CSIR, 2013). Respondent 5 had however highlighted one of the major successes during this period by affirming that a gene editing technology developed in 2013 was in fact a first in the world and became a precursor to the globally recognised CRISPR genetic standard (Respondent 5, personal communication, March 11, 2022). This technology culminated from work that was initiated under the initial ERA.

The technology development activities that took place during the period shifted drastically from early-stage research to a renewed focus on generating tangible outputs that resided closer to the commercial end of the technology value chain. This decision appeared to be largely driven by organisational pressures for the group to generate more returns on investment as well as by the newly developed national bioeconomy strategy that was geared towards addressing specific African heath challenges. It is likely that limited available research funding spurred the aggressive decisions to begin terminating many of the long-term pharmaceutical research activities with the unintended consequences of compromising pharmaceutical innovation itself. As stated by Wang et al. (2021), success in pharmaceutical innovation will unequivocally involve high levels of investment coupled with long-term investment returns.

Furthermore, the unstable organisational restructuring environment resulted in the disaggregation and fragmentation of synthetic biology activities making its overall impact during this period difficult to ascertain. Notwithstanding this instability, the need for synthetic biology research was eventually revisited and new research opportunities were identified. During 2016, the team identified that the next advances in synthetic biology would be in the areas of bioengineering, biomimetics, and biophysics and it was decided that the introduction of these new areas could enable the research in this field at CSIR to evolve and lead to new opportunities in personalized medicine for individuals with specific genetic backgrounds as well as in predictive models for drug screening. This shift in research focus resulted in the re-establishment of the original ERA but with the added focus on bioengineering and biomimetics.

2020 – Present: The Centre for Synthetic Biology and Precision Medicine

The year 2020 saw the repositioning of the ERA into a fully-fledged formal research centre. The focus of the centre, which now aligned to the new industrialization strategy of the CSIR, aimed to interface the existing synthetic biology platforms with technologies characteristic of the fourth industrial revolution resulting in new technology platforms geared towards digital health, drug screening and repurposing, as well as industrial synthetic biology that could improve the production capacities associated with biopharmaceutical production (CSIR, 2020b). The main technology development activities include improving the effectiveness of anti-retroviral regimes by tailoring them to the correct patient, building a digital platform embedded with artificial intelligence for large amounts of genetic, protein, and microbiome data, developing high throughput screening technologies, and establishing a cost-effective synthetic biology expression platform that will enable a cancer precision medicine platform. The current work has the potential to address some of the main challenges facing the pharmaceuticals sector. Activities that relate to the repurposing of existing drugs can inevitably bypass the issues of long lead times associated with drug development (Akkari et al., 2016; Gassmann & Reepmeyer, 2005) as it intends to determine whether existing drugs can have alternate applications for current disease burdens in Africa. In addition, while the high costs associated with drug development is a known hinderance to the sector (Gassmann & Reepmeyer, 2005; Wang et al., 2021b), the strides made by this group in precision medicine can yield positive benefits with regards to rising cost of healthcare for citizens (Lakdawalla, 2018).

It is evident from the sequence of technology development activities described above that the formative years of synthetic biology focused on developing capabilities that could be comparable with global leaders. However, a clear shift can be seen that redirected research impact towards addressing specific issues facing the African continent. The existence of endogenous capabilities is therefore evident as these are the capabilities that are necessary for South Africa to be able to tailor and adapt existing foreign technologies to create innovation and impact for its own domestic context (Bell & Figueiredo, 2012). The trajectory illustrated above further supports the pattern of path-creating catch-up (Lee & Lim, 2001) whereby continuing to follow the technology developments of leading countries is no longer a viable strategy for addressing the unique challenges of Africa.

5.3.2 The operations capability

The operations capability, as defined by Zawislak et al. (2012), is responsible for the efficient operation and commercial production of developed technologies given the available resources, skills, and embedded knowledge of the organisation. The study has identified that financial resources, personnel and skills, infrastructure, and strategic partnerships are some of the key aspects in relation to the operations capabilities of the centre and the efficiency and effectiveness of each are discussed below.

- Financial resources

Since the start of synthetic biology activities at the CSIR in 2007, progress reports have indicated that the area has received an approximate funding amount allocated as follows:

- **2007 – 2011:** R75 million in total invested by the CSIR i.e., R15 million per annum, and R23 million from the DSI.
- **2011 – 2019:** CSIR funding during this period was estimated to be at R 15 million per annum. The DSI eventually withdrew their funding commitments during the period.
- **2020 – present:** CSIR investment was reduced to R 10 million per annum.

It is a widely accepted fact that funding for R&D in South Africa is limited but the challenges associated with this limited availability of funds have been cited by respondents as a major factor that is holding South Africa back from creating impact in Synthetic Biology. Additionally, the overall South African funding landscape was identified as having a short-term funding horizon that is further compounded by impatient expectations for capital returns. The funding allocations made towards synthetic biology research efforts at the CSIR were initially informed by the strategy put forward to establish the ERA program in 2007. Thereafter disbursements were made based on the historical allocations and research activities were planned according to what was feasible within the R15 million annual budget. By 2020, it was the view of CSIR’s leadership that the area should have, by now, developed adequate capabilities in the field to be able to attract sufficient external income so that the reliance on internal funding could be minimized. This partly informed the reduction of the allocation to R10 million. However, emerging technologies are also considered long-cycle technologies that yield results in the long-term but external investments in the form of private sector funding tends to favour technologies that will be commercially viable in approximately 3 to 5 years, a time limit that is relatively unrealistic for areas like synthetic biology whereby scientific exploration usually requires a longer time horizon (Mazzucato, 2011). Ultimately, longer term financial commitments are therefore required, especially in developing countries, if they are to build sufficient technical competence in new technological areas (Heertje et al., 1988)

Regardless of the sources of income, CSIR researchers are still required to motivate and compete for funding. This presents additional hurdles as most funders do not understand the technicalities accompanying high risk and research-intensive fields. Those scientists that have the daunting task of lobbying for funding are required to first educate decision makers on how the technology works at the expense of time that could be better spent on justifying the real business case, a point that was illustrated by Respondent 5. Decision makers should also be cognisant of the fact that the amount of time passed since the inceptions of synthetic biology at CSIR is relatively inconsequential, and consideration should be given to fact that strategic changes over the years have resulted in the area having to continuously change its research focus which resulted in starting new R&D efforts from scratch. Mazzucato (2011) further states that governments have an opportunity to create innovation in high growth areas by funding the early stages of such research that are too risk-averse for private investors.

- Personnel and skills

Skilled human capital is an essential component of learning processes that are necessary for developing technological capabilities given the individuals strong background in science and engineering as well as their roles in accessing foreign knowledge (Mazzoleni & Nelson, 2007). From the responses garnered in this study, it was commonplace understanding that South Africa possesses a high calibre of scientists and expertise however, there are just not enough of them to be able to produce significant impact. The composition of skills in synthetic biology at CSIR are described below.

- **2007 – 2011:** The process to establish the ERA involved capacitating the area with the right set of skilled individuals. International experts in the field were subsequently recruited as leaders of the ERA. The overall team appointed during this period was a mixture of masters, doctorate, and post-doctoral students, senior scientists, and engineers. A noteworthy observation provided by Respondent 3 indicated that the research team was comprised of staff with creative personal skills, some of whom could even read and write music. This is a significant observation as creativity has been identified as one the key factors that are responsible for the growth of economies as it equips people with the ability to spawn new ideas (Hennessey & Amabile, 2010). An important component of the strategy for this period was to develop a programme designed specifically for training South African post-doctoral students to become future leaders of the ERA. Unfortunately, this initiative did not materialize due to challenges in finding highly skilled research staff that could be recruited into the programme further emphasizing the issues of skill shortages on the African continent. To mitigate this problem, the group set out to build a strong pipeline of human capital through the development of degree level courses in synthetic biology related fields for South African universities. Several skills transfer activities took place during this period. Senior ERA research staff provided lectures on synthetic biology and an internationally recognized training course on imaging and microscopy was developed by the team. There was also a strong focus on enabling South African researchers to receive training from abroad allowing them to access foreign knowledge from leading countries. The activities were pivotal for the development of endogenous capabilities particularly for a SSI (Mazzoleni & Nelson, 2007).

- **2012 – 2019:** The impact of organizational instability on the research area during the period was met with resignations of vital research leaders, some of whom were principal inventors of key technologies underpinning the research at CSIR. These individuals were nearly impossible to replace due to the absence of local expertise in new and upcoming research fields and the group was also unable to attract and retain top international talent as it was unaffordable for the organisation. It was also reported that the quality of some personnel recruited displayed deficiencies in their productivity when compared to domestic and global counterparts therefore internal candidates were not an adequate option. In response to the questions on the reasons for the inability to retain staff, it was indicated by respondents that a misalignment between the strategy that is set out and the people that are hired are a contributing factor to this issue. It was also noted that, while skills transfer did take place, a duplication of skill sets among many people was not feasible for the organisation and a diverse set of skills would be more optimal for the group given the limitations on capacity and resources.

- **2020 – Present:** The ambitious plans to recapacitate the area, as laid out in the original strategy eventually lost its momentum largely due to loss of key staff as well as continuous changes in leadership and strategic focus. Insufficient researcher capacity has been prevalent for many years in the area and the matter continues to persist. It was stated by Respondent 6 that the current Centre is not well resourced and still requires a lot of skills development to be done if the goal is to be globally competitive.

- Infrastructure

Infrastructure for the purpose of research in areas that are research-intensive are associated with very high costs (Gassmann et al., 2008). A large proportion of the initial funding for synthetic biology was earmarked for the purchase of new equipment and the refurbishment of existing laboratories and by the end of the first 5 years the ERA had developed world class capabilities in automated imaging and high-resolution microscopy as well as computational tools for super-resolution microscopy. An example of learning by DUI during this period was put forward by Respondent 3 who described how researchers were effectively rebuilding imported modern equipment. Respondent 5 also confirmed that the visualization and imaging capabilities that were developed using in-house high end microscopes were on par with the few laboratories in world with similar expertise. The existence of endogenous capabilities were clearly evident at this stage as proven by the abilities of the team to modify and enhance existing technologies. Mazzoleni and Nelson (2007) states that this ability to re-engineer foreign technology is generally supported by highly skilled individuals with strong science and engineering know-how. At present, current platforms for array technologies and high-throughput screening were cited as being amongst the most sophisticated and advanced in the world containing infrastructure that is unique to South Africa. However, while the centre was historically well equipped with the necessary infrastructure that allowed it to maintain a competitive advantage, much of that equipment is now in urgent need of upgrading rendering them unable to operate at maximum capacity. Newer investments in infrastructure are however being informed by current market and industry trends but the acquisition of equipment is faced with numerous challenges. The procurement policies and procedures of the CSIR exhibit a bias as cheaper options are preferred for cost-saving purposes. This approach is met with significant dissatisfaction from in-house research experts who expressed that these processes are time-consuming and laborious which creates barriers to research activities. To overcome this barrier, it was indicated by Respondent 3 that the nature of the infrastructure, as it relates to pharmaceuticals, needs to be smaller, adaptable, as well as mobile to minimize the reliance of the sector on predominantly large and expensive equipment thereby providing more cost-effective alternatives. However, the development of these agile systems is not exempt of its own expenses. Given that the current activities of the area are fairly new, the provision of additional funds may be warranted particularly considering the urgent need to upgrade outdated infrastructure.

- Strategic partnerships

Partnerships and collaborations between actors in sectoral innovation systems are a vital component of success in building necessary endogenous capabilities (Malerba, 2005; Mazzoleni & Nelson, 2007). The networks for synthetic biology at CSIR have varied significantly over the years. During the first period the need to establish strong collaborative partnerships was viewed as essential. As such, the group had established a strong network of international partners that could provide South Africa with access to expertise and equipment the country had been lacking. International partnerships were fostered with research institutions in USA, Canada, UK, France, Germany, and Portugal. The nature of these partnerships were to provide South Africa with access to expertise and equipment and to facilitate skills transfer to the country. While, locally, a strong network was enforced with several South African universities, government entities as well as with private laboratories. The relationship with the universities were important and it would serve to develop an effective local skills pipeline and during the period of organisational restructuring that followed, basic research activities were subsequently transferred to collaborating university partners. With the resignations of individuals who served as lead contact points to these partners, many of the partnerships have since come to an end. At present, partnerships have been established mainly with local government departments, some South African universities, and a few small businesses in the private sector. The minimal partnerships that are available to date are not adequate enough if the centre intends to make impact in the new areas of this emerging research field. Furthermore, the existence of local and international partnerships are a prerequisite for accessing government funding, as was confirmed by a respondent from the DSI.

5.3.3 The management capability

Zawislak et al. (2012) states that it is an efficient management capability that creates a conducive environment for innovation to take place and that is it the responsibility of managers to coordinate and integrate resources that are required for technology development and transactions to take place. This capability is meant to bridge the gap between what is operationally undertaken and the technologies that are developed.

Investigation into the status of the synthetic biology management capability was two-fold as it entailed (i) obtaining an understanding of the decision-making processes that resulted in commitment to the strategic objectives listed above, and (ii) determining how management, by way of the organisations leaders, provided support for the establishment of capabilities in synthetic biology. The management structure under which activities for synthetic biology takes place is comprised of an Executive Director/ Executive Cluster Manager of the host unit and a Research Group Leader/ Centre Manager for the Synthetic Biology area. It was reported that, over the past 15 years, the area had appointed several different Executive Directors/ Executive Cluster Managers as well as numerous Centre Managers/ Research Group Leaders. Resignations were largely by key individuals whose institutional and technical knowledge served as the foundation for much of the research that was undertaken during their tenure. The frequent changes in leadership since the inception of Synthetic Biology at the CSIR resulted in pockets of instability over the duration of its existence. This matter was further compounded by indecisiveness with regards to the strategic direction that synthetic biology should follow as is evident from the back-and-forth decision-making that took place with regards to the perceived purpose that the Centre should fulfil thereby making it challenging for the area to stay committed towards long-term objectives.

In the case of the CSIR, there appeared to be a visible disconnect between the leadership of the host unit/ Cluster and the management capacity installed to oversee synthetic biology research. The information that was given by the respondents with regards to how the area is supported by the broader organisation is indicative of a space where the technical and operational staff feel unsupported. The coordination function that managers are expected to fulfil are also inadequate because the direct management of synthetic biology has minimal control over the administration of the resources within the centre as final approvals must always be obtained from higher levels of management. A further point of contention lies in the appointment of researchers who are also expected to carry out managerial functions. The administrative burden imposed on these individuals creates frustration as they are unable to focus fully on conducting scientific research. Individuals who are filling a dual role of manager and researcher are therefore faced with contradictions by having to comply first with the managerial bureaucracy imposed on them and are left to be researchers second. Having an individual perform these dual functions can lead to a bias that restricts an individual's ability to exercise their creative potential to the fullest which will compromise the potential for innovation.

Ultimately, efforts in synthetic biology at CSIR have been deeply impacted by organisational decisions, unplanned reviews, and restructuring processes. The effects of these processes on the area have been further compounded by a continuously changing national landscape. Organisational bureaucracy, systems, and processes have been identified as one of the main inhibitors restricting the freedom of scientists to innovate. Respondent 2 had observed that earlier international recruitments were made to appoint a high stature of expertise, but it became evident that the individuals were stifled as they were not given an opportunity to put down their own stamp of authority. Respondent 3 and 4 echoed these sentiments by stating that the organisation wants to mould individuals according to its own norms and boundaries through its laborious processes and reporting requirements as opposed to allowing them to be who they are. In terms of support, the CSIR, the Biosciences, and now the Next Generation Health Cluster, host departments do provide management support to the area in the form of business development, funding, and project management among others. However, much of the earlier successes that the area had achieved was attributed to a people driven environment, and to the space that people were given to make mistakes and fail fast. Current organisation barriers to innovation and technological success were highlighted as organisational-wide over-management, groups operating in silos, insufficient funding, organisational expectations to produce results faster, huge administration burdens placed on scientists that is reducing the time available to do real science, a lack of strong and decisive leadership, and a lack of centralized reporting systems to facilitate easy access to project information. The centre is therefore lacking true autonomy which is critical in an area where decisions must be made fast. Slow decision making has been known to have an adverse effect on innovation as projects that start will need to end later that planned but research staff are instead put under pressure to still deliver on-time leading to temptations to cut corners (Goffin & Mitchell, 2016), which will inevitably compromise innovation.

5.3.4 The transactions capability

The transactions capability is a final important component of innovation capability as it is needed to facilitate the sale of technologies that are produced by an organisation (Zawislak et al., 2012). The technologies developed by the CSIR are made available to users either by licensing a technology to a collaborating partner, using the technology to provide a service to government or industry, or through the creation of a spin-out company that is responsible for the sale of the technology. Due the constantly changing R&D landscape at CSIR, the transactions capability at the Centre appears to be weak. Naturally, the sale and transfer technologies can only take place once a technology has reached the end of the developmental cycle, however long that may take, but activities within the centre have changed so often that most technologies have not been afforded the chance to develop to its fullest capacity and the loss of key research staff further impacts any momentum they may have gathered. The commercialisation activities of synthetic biology varied over the years. In its formative years between 2007 and 2011, the group delivered huge successes through the establishment of two spin-out companies, namely, ReSyn Biosciences (Pty) Ltd and Persomics (Pty) Ltd, led by the inventor of the technology. These companies resulted from technologies that were developed and advanced in a very short period despite the conventional long-cycle nature of synthetic biology research activities. However, in the years that followed, it was highlighted by a respondent that while these groups had initially generated numerous other patents, the resignations by the relevant patent inventors created a limitation in the area as their absence rendered the patents useless. More recently, commercialisation activities have stagnated although activities within the bioengineering liver groups on the research centre have reportedly been described by Respondent 6 as being close to commercialization.

5.4 DISCUSSION: OVERALL INNOVATION CAPABILITY AND RANKING

This study proposed the use of two innovation capability related frameworks to assess the level at which synthetic biology at the CSIR ranks in terms of its level of innovation capability. Bell & Figueiredo (2012) have outlined a framework showing that innovation in an organisation is largely based on increases in the novelty of its technologies. However, this framework does not account for the dimensions of business outside of technology development that also have a significant impact on innovation. To address this shortcoming, the framework developed by Zawislak et al. (2012) was adopted to compliment Bell & Figueiredo (2012) as it distills innovation capability into four dimensions that cater for broader activities within an organisation. Zawislak et al. (2012) states that firms must possess a combination of all four innovation capability components but that innovation will only be attained if at least one of these capabilties is predominant. Zawislak et al. (2012) argues further that dominance in technical ability alone does not guarantee operational efficiency and any firm that priortizes one of these capabilities at the expense of the others will likely experience market failure. . The Bell & Figueiredo (2012) framework does not provide requirements for management or transaction capabilties along the various levels of innovation capability, but it must be noted that innovation is more likely to occur when firms are enlarged as additional operations and transactions would increase. These diemensions were incorporated into the framework to give a holistic view of innovation capability for the study.

It was anticipated that by combining both of these frameworks (see Table 5.4), one would be able to asess the overall levels of innovation capabilty at the CSIR Centre against the dimensions of innovation capability in relation to the current activities that are taking place in order to determine how the synthetic biology at the CSIR is currently performing in relation to these elements The table below provides a snapsot of an assessment of its overall innovation capability.

Table 5.4. The Innovation Capability Framework for Synthetic Biology at CSIR

Level of innovation capability (Bell & Figueiredo, 2012)	**Dimensions of innovation capability (Zawislak et al., 2012)**			
	Technology dev.	Operations	Management	Transactions
World Leading				
Advanced	High throughput screening New technology platforms geared towards digital health. Development of a novel bioengineered liver model.			
Incremental/ Intermediate	Platform for drug screening and drug repurposing			
Basic		Low levels of funding Low number of specialized researchers working in groups Most equipment is in urgent need of upgrading and not operating at maximum capacity Partnerships with local government and a few universities, no tangible international partnerships	High staff turnover Frequent changes in management Lack of autonomy of direct centre management Bureaucratic approval processes resulting in delayed decision making	Weak transactional capability due to constant restructuring and strategic shifts resulting in many technologies not being fully developed for commercialisation

The perceived ranking by respondents of the centre having intermediate innovation capability is further supported by the observations made in the discussions above. It must be noted, however, that while the level of innovation capabilty varies across the different research groups within the centre, table 5.4 above has attempted to illustrate the status of innovation capability of the centre as a whole. With the exception of the management and transactions dimensions of innovation capability, the innovation capability framework set out by Bell & Figueiredo (2012) assumes that all activities related to technology development and operations would have reached a particular level of innovation capabilty simulataneously. However, as is evident from the assessment above, one could rank the innovation capability of each dimension individually. As indicated above, the predominant focus on technology development has seen the centre produce some technologies that are significantly innovative and classified as advanced in comparision to rest of the globe and could therefore be considered intermediate to advanced. A stark contrast can be seen in the state of the operations capabilities of the centre. Numerous areas of the centre's operations are in need of vital improvements and these range from much needed increases in funding, recruitment of additional staff, refurbished equipment, as well as new and strategic partnerships. It is justifable then for this capability to be ranked as basic due to its evident limitations for innovation. The management and transactions capability dimensions could not be adequately assessed using the innovation capability framework of Bell & Figueiredo (2012) as it does not specify organisational requirements that could cater for these dimensions.

Based on the observations made in the above discussion it is clear that at the CSIR, a fundamentally research-based organisation, technology development is, without a doubt, its most advanced and predominant capability in relation to synthetic biology. In contrast, its management, operations, and transactions capabilties exhibit significant weaknesses and the apparent priortization of technology development over the others has indeed resulted in some form of market failure given that most of the technologies are still facing challenges in crossing the threshold to commercial sales and impact in the sector.

5.5 SUMMARY OF THE DISCUSSION

The discussion above provides an outline of the activities that have been taken by the CSIR to develop capabilities in synthetic biology for South Africa. It categorically shows how the area has evolved in terms of its objectives and technological development activities. The discussion goes on to illustrate the specific findings that have resulted from the study that describes the centres key technological developments, its operations in terms of infrastructure establishment and collaborative partnerships, the nature and function of the management of the host departments as well as the CSIR as a whole, and the transaction capability that has been established to facilitate the transfer of developed technologies into the marketplace. The discussion concludes with an overall assessment of the innovation capability of synthetic biology against the frameworks developed by Bell & Figueiredo (2012) and Zawislak et al. (2012).

6 CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS

6.1 INTRODUCTION

STI is recognized as key pillars for the success, productivity, and economic growth of countries (Freeman, 1995). However, the significant gaps that exist between the growth rates of global leaders and that of countries in the developing world sheds a spotlight on the disparities between their inherent domestic innovation capabilities (Fagerberg & Srholec, 2008). While it is not possible for a country to be a leader in every industry or sector, most countries tend to leverage the resources at their disposal by focusing their attention on increasing the rates of technical change with the aim of catching up to leaders in specific industries or sectors (Malerba, 2002). Historically, countries that have been successful at closing these gaps utilized various mechanisms, modelled on the path taken by leading nations, thus enabling them to match, if not bypass, technical advancements made by the frontrunners (Lee, 2013). One of the main pathways identified that was of most benefit to developing countries involved the use of emerging technologies as developing countries are better positioned to adopt and implement these technologies because they do not experience the limitations associated with having older technologies that are already embedded in their systems, as is the case for advanced nations (Lee, 2005). This affords the developing country with an opportunity to fast track their technical progress and catch up to leaders at a faster rate.

Using a South Africa research Centre based at the CSIR as the research instrument, this study investigated the establishment and evolution of innovation capabilities in synthetic biology, focusing specifically on the application of developed technologies in alleviating the challenges facing the South African pharmaceuticals sector. Developing countries are confronted with issues of ineffective healthcare systems, limited access to healthcare, as well as insufficient funding for research. In attempting to address what is being done to resolve these problems, this study applied the theoretical frameworks for sectoral innovation systems, technological catch-up, and innovation capability to gain and understanding on how effectively synthetic biology is being used as the vehicle for catching-up by way of leapfrogging in pharmaceutical sectoral innovation systems. A qualitative research design was adopted involving interviews with key stakeholders which led to the identification of recurring patterns and themes that informed the basis for discussion of the results which were also strongly aligned to the relevant innovation capability frameworks identified in the literature.

6.2 MAJOR FINDINGS

As indicated in **section 2.3**, despite the benefits that can arise with the adoption and use of emerging technologies, its establishment as a capability in developing countries is not without challenges. The main findings emanating from the study in relation to synthetic biology in South Africa were as follows:

- South Africa has a shortage of skills in the area, an issue that is further compounded by its comparatively small research base in relation to other developing countries.
- There is poor collaboration between actors within the NSI.
- Due to the numerous changes imposed on the synthetic biology research areas, the groups were unable to gain enough momentum to be able to create tangible impact for the sector.
- The overall innovation capability of the CSIR Centre for Synthetic Biology and Precisions Medicine is ranked as intermediate/ incremental.
- The national impact of synthetic biology on the pharmaceutical sector has not yet been realized.
- The chosen framework for the assessment of the levels of innovation capability is heavily skewed towards increasing novelty in research and does not fully cater for business activities outside of technology development or operations.

6.3 KEY CONCLUSION OF THE STUDY

The proposed research questions of the study are addressed as follows:

A. How has South Africa developed innovation capabilities in Synthetic Biology for the pharmaceuticals sector?

The introduction of synthetic biology to South Africa was initiated by key researchers at the CSIR in 2007 who were of the view that South Africa needed to develop capabilities in this area to participate in this worldwide emerging field. A research area dedicated solely to synthetic biology was then established at the CSIR with long-term funding secured directly from the CSIR as well as from the Department for Science and Innovation.

A.1. How has the development of capabilities in synthetic biology evolved in South Africa?

The original ERA functioned well when CSIR was driven by basic and applied research as this us the purpose of research-intensive areas. Synthetic biology initiatives implemented at the CSIR underwent numerous changes because of the strategic shifts experienced by either Biosciences or the CSIR. As such, it was apparent that many research activities were unable to deliver on its original objectives and those activities were rather repurposed or adapted to suit newer scientific directions put forward. While it is understood that emerging technologies are a continuously evolving field, most of the preceding evolution should still be built on an existing foundation of knowledge and expertise. This especially holds true for the attainment of technological catch-up by developing countries which is reliant on the accumulation of technological capabilities (Lee & Lim, 2001). With regards to skills in synthetic biology, it is unfortunate that the group lost many scarce skills, and this loss of top tier scientists caused the work to dwindle. The resulting effect of this was seen in the loss of institutional knowledge that is difficult to transfer and replicate. It must be noted that these research areas are highly specialized and knowledge intensive and it is unrealistic to expect that new graduates would be in immediate possession of skills which require that individuals have an interest in pursuing such expertise which can only be developed over time and through learning on the job. Furthermore, the capabilities developed up until the point of their departure were effectively lost and newly appointed senior staff have had to reconceptualize research efforts and develop new capabilities from scratch. The case of the CSIR seems comprised of activities that are mostly vast in terms of variety and fails to demonstrate how the trajectory of capability accumulation in any area could have evolved. It is my view that the issues raised above are preventing the area from improving their innovation capabilities.

A.2. What is its current level of innovation capability i.e., basic, intermediate, advanced, or world leading?

It was found that overall innovation capability at the CSIR is largely ranked as intermediate/ incremental. Despite its advanced capabilities in technology development, innovation is not fully attainable due to the weaknesses present in its operations and management capabilities which have ultimately resulted in a deficient transactions' capability whereby the translation of these technologies into market ready offerings are still lacking. . At this present level, technological catch-up by means of leapfrogging, remains out of reach, and will hinder the countries progress in closing the gap between itself and leading countries in terms of the rates of technical change with respect to synthetic biology.

A.3. What are the future potential pathways that South Africa can take to improve its catch-up efforts in the sector using synthetic biology?

This research question will be addressed under the recommendations for the business/ stakeholder in **section 6.4** below.

6.4 RECOMMENDATIONS FOR THE BUSINESS/ STAKEHOLDER

6.4.1. Create a balanced portfolio of innovation activities

For CSIR to be truly competitive in synthetic biology, it is important that novel research groups be allowed to pursue different types of innovation activities simultaneously if they wish to effectively serve existing markets as well create technologies for new markets (O Reilly & Tushman, 2004), which is incidentally the aim of emerging technologies. A balanced portfolio approach should largely consist of incremental innovations with a smaller percentage of the activities geared towards the pursuit of radical and disruptive technologies. Incremental innovations will lead to tangible outputs that can be delivered on in the short term. This is vital for developing countries whose stakeholders are in desperate need of solutions with a faster turn-around-times that can address its most immediate challenges. Realizing such impact in the short term will ultimately lead to increased stakeholder confidence which can ultimately be leveraged for future financial support.

6.4.2. Develop strategic objectives that cater for each dimension of innovation capability

Objectives should be able to illustrate how certain outcomes are planned to be achieved and not only describe the final anticipated outcome. Having strategic objectives in place that cater for the planned improvement of technology development, operations, management processes, and transactions will ensure that there is accountability and commitment towards achieving these objectives. If the main outcome will be a technology that is developed and ready for commercial application, it will be important to also specify what the necessary requirements will be from the remaining components of innovation capability that will allow for the achievement of said main outcome.

6.4.3. Avoid dual functions by separating the role of managers from the role of researchers

It is important to differentiate the expectations of managers from researchers. The current structure of having researchers also perform managerial functions is inhibiting progress on the technology development front largely due to the frustration is causes individuals in these positions. The research centre should be directly managed by one individual who is solely responsible for ensuring the coordination and integration of resources within operations with technology development activities. A separate role must be considered for an individual that is dedicated primarily to driving research activities.

6.4.4. Establish strategic collaborative partnerships based on existing operational gaps

In terms of collaborative efforts, and considering the national concerns surrounding brain drains, a lack of relevant skills, and capacity constraints, it is pertinent for the group to seek out and maximise on collaborations to be able to leverage off the strengths of these partnerships as opposed to viewing them as competitors. Given the current absence of fully functioning equipment and the limited financial resources, there are opportunities for the centre to strategically collaborate with partners who are in possession of these needed capabilities to ensure business continuity.

6.5 SUGGESTIONS FOR FUTURE RESEARCH

Future research can be extended to include synthetic biology activities that are taking place within universities as well as in private pharmaceutical companies so that a wholistic view of capabilities in synthetic biology in South Africa can be better understood. In doing so, one could determine the complementarities of activities between all these actors and identify areas for collaboration that can lead to the identification of a broader network of actors in the system as well as provide sight of a full national value chain that ranges from technology development to commercialisation.

REFERENCES

Abramovitz, M. (1986). Catching up, forging ahead, and falling behind. *The journal of economic history*, *46*(2), 385-406.

Akkari, A. C. S., Munhoz, I. P., Tomioka, J., Santos, N. M. B. F. d., & Santos, R. F. d. (2016). Pharmaceutical innovation: differences between Europe, USA and 'pharmerging'countries. *Gestão & Produção*, *23*, 365-380.

Alves, A. C., Barbieux, D., Reichert, F. M., Tello-Gamarra, J., & Zawislak, P. A. (2017). Innovation and dynamic capabilities of the firm: Defining an assessment model. *Revista de Administração de Empresas*, *57*, 232-244.

Andrianantoandro, E., Basu, S., Karig, D. K., & Weiss, R. (2006). Synthetic biology: new engineering rules for an emerging discipline. *Molecular systems biology*, *2*(1), 2006.0028.

Arocena, R., & Sutz, J. (1999). Looking at national innovation systems from the South. *Industry and innovation*, *7*(1), 55-75.

Arocena, R., & Sutz, J. (2010). Weak knowledge demand in the South: learning divides and innovation policies. *Science and Public Policy*, *37*(8), 571-582.

Aspers, P., & Corte, U. (2019). What is qualitative in qualitative research. *Qualitative sociology*, *42*(2), 139-160.

Azubuike, V. M. (2013). Technological innovation capability and firm's performance in new product development. *Communications of the IIMA*, *13*(1), 4.

Begley, C. M. (1996). Using triangulation in nursing research. *Journal of advanced nursing*, *24*(1), 122-128.

Bell, M., & Figueiredo, P. N. (2012). Innovation capability building and learning mechanisms in latecomer firms: recent empirical contributions and implications for research. *Canadian Journal of Development Studies/Revue canadienne d'études du développement*, *33*(1), 14-40.

Calantone, R. J., Cavusgil, S. T., & Zhao, Y. (2002). Learning orientation, firm innovation capability, and firm performance. *Industrial marketing management*, *31*(6), 515-524.

Chaturvedi, S. (2007). Exploring interlinkages between national and sectoral innovation systems for rapid technological catch-up: case of Indian biopharmaceutical industry. *Technology Analysis & Strategic Management*, *19*(5), 643-657.

Chen, D., & Li-Hua, R. (2011). Modes of technological leapfrogging: Five case studies from China. *Journal of Engineering and Technology Management*, *28*(1), 93-108. https://doi.org/10.1016/j.jengtecman.2010.12.006

Clarke, L. J., & Kitney, R. I. (2016). Synthetic biology in the UK–an outline of plans and progress. *Synthetic and systems biotechnology*, *1*(4), 243-257.

Coombs, R., & Metcalfe, J. S. (2002). Innovation in pharmaceuticals: perspectives on the co-ordination, combination and creation of capabilities. *Technology Analysis & Strategic Management*, *14*(3), 261-271.

CSIR. (2006). *CSIR Science & Technology Strategy*

CSIR. (2007). *CSIR Emerging Research Area: Synthetic Biology Final Plan*

CSIR. (2009). *CSIR Biosciences: Synthetic Biology Competency Area Strategic and Operational Plan for the 2009/10 to 2011/12 planning cycle*.

CSIR. (2010a). *CSIR Synthetic Biology ERA Progress and self-assessment report: 2009/10*.

CSIR. (2010b). *CSIR Synthetic Biology ERA Strategic and operational plan for the 2011/12 to 2013/14 planning cycle*

CSIR. (2013). *CSIR Biosciences: Research Portfolio Report*.

CSIR. (2015). *CSIR Biosciences Quarter 4 and Annual self-assessment report: 2014/15*.

CSIR. (2020a). An overview of the CSIR strategy. In.

CSIR. (2020b). *Strategic and Operational Plan 2020/21: Synthetic Biology Centre*.

CSIR. (2021). *Annual report 2020/21*. https://www.csir.co.za/annual-report-202021

Davy, E., Hansen, U. E., & Nygaard, I. (2021). Dual embeddedness? Innovation capabilities, multinational subsidiaries, and solar power development in South Africa. *Energy Research & Social Science*, *78*, 102145.

Department of Science and Innovation. (2021). *Annual Report 2020/2021*. Retrieved from https://www.dst.gov.za/index.php/resource-center/annual-reports/3525-annual-report-2020-2021

EFPIA. (2021). *The Pharmaceutical Industry in Figures*. https://www.efpia.eu/publications/downloads/efpia/the-pharmaceutical-industry-in-figures-2021/

Fagerberg, J., & Srholec, M. (2008). National innovation systems, capabilities and economic development. *Research policy*, *37*(9), 1417-1435.

Figueiredo, P. N., Larsen, H., & Hansen, U. E. (2020). The role of interactive learning in innovation capability building in multinational subsidiaries: A micro-level study of biotechnology in Brazil. *Research policy*, *49*(6), 103995.

Freeman, C. (1995). The 'National System of Innovation'in historical perspective. *Cambridge Journal of economics*, *19*(1), 5-24.

Gassmann, O., & Reepmeyer, G. (2005). Organizing pharmaceutical innovation: from science-based knowledge creators to drug-oriented knowledge brokers. *Creativity and Innovation Management*, *14*(3), 233-245.

Gassmann, O., Reepmeyer, G., & Von Zedtwitz, M. (2008). Leading pharmaceutical innovation. *Berlin/Heidelberg*.

Geels, F. W. (2004). From sectoral systems of innovation to socio-technical systems: Insights about dynamics and change from sociology and institutional theory. *Research policy*, *33*(6-7), 897-920.

Goffin, K., & Mitchell, R. (2016). *Innovation management: effective strategy and implementation*. Bloomsbury Publishing.

Guba, E. G., & Lincoln, Y. S. (1994). Competing paradigms in qualitative research. *Handbook of qualitative research*, *2*(163-194), 105.

Hansen, U. E., Larsen, T. H., Bhasin, S., Burgers, R., & Larsen, H. (2020). Innovation capability building in subsidiaries of multinational companies in emerging economies: Insights from the wind turbine industry. *Journal of cleaner production*, *244*, 118746.

Heertje, A., Artus, P., & European Investment, B. (1988). *Innovation, technology, and finance*. B. Blackwell for the European Investment Bank. https://go.exlibris.link/cq807cmv

Hennessey, B. A., & Amabile, T. M. (2010). Creativity. *Annual review of psychology*, *61*, 569-598.

Holtzman, Y. (2014). A strategy of innovation through the development of a portfolio of innovation capabilities. *Journal of Management Development*.

Huang, H.-C. (2011). Technological innovation capability creation potential of open innovation: a cross-level analysis in the biotechnology industry. *Technology Analysis & Strategic Management*, *23*(1), 49-63.

Human Sciences Research Council. (2022). *SA sciences shines, depsite sharp fall in R&D expenditure*. http://www.hsrc.ac.za/en/media-briefs/cestii/sa-shines-rd

Hung, S.-C., & Chu, Y.-Y. (2006). Stimulating new industries from emerging technologies: challenges for the public sector. *Technovation*, *26*(1), 104-110.

Jackson, W. (1999). *Methods: Doing social research*. Scarborough, Ont.: Prentice Hall Allyn and Bacon Canada.

Jensen, M. B., Johnson, B., Lorenz, E., Lundvall, B.-Å., & Lundvall, B. (2007). Forms of knowledge and modes of innovation. *The learning economy and the economics of hope*, *155*.

Kale, D., & Little, S. (2007). From imitation to innovation: The evolution of R&D capabilities and learning processes in the Indian pharmaceutical industry. *Technology Analysis & Strategic Management*, *19*(5), 589-609.

Kim, L. (1997). *Imitation to innovation: the dynamics of Koreas's technological learning*. Harvard Business School Press. https://go.exlibris.link/QPsQyv6C
Krauss, S. E. (2005). Research paradigms and meaning making: A primer. *The qualitative report*, *10*(4), 758-770.
Lakdawalla, D. N. (2018). Economics of the pharmaceutical industry. *Journal of Economic Literature*, *56*(2), 397-449.
Lee, K. (2005). Making a Technological Catch-up: Barriers and opportunities. *Asian Journal of Technology Innovation*, *13*(2), 97-131.
Lee, K. (2013). *Schumpeterian analysis of economic catch-up: Knowledge, path-creation, and the middle-income trap*. Cambridge University Press.
Lee, K., & Lim, C. (2001). Technological regimes, catching-up and leapfrogging: findings from the Korean industries. *Research policy*, *30*(3), 459-483.
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.
Li, D., Liang, Z., Tell, F., & Xue, L. (2021). Sectoral systems of innovation in the era of the fourth industrial revolution: an introduction to the special section. *Industrial and Corporate Change*, *30*(1), 123-135.
Lundvall, B.-A. (1992). National systems of innovation: An analytical framework. *London: Pinter*.
Lundvall, B.-Å., Joseph, K., Chaminade, C., & Vang, J. (2011). *Handbook of innovation systems and developing countries: building domestic capabilities in a global setting*. Edward Elgar Publishing.
Lundvall, B. Å. (2007). National innovation systems—analytical concept and development tool. *Industry and innovation*, *14*(1), 95-119.
Majidpour, M., Saber, A., Elahi, S., Shayan, A., & Sahebkar Khorasani, S. M. (2021). Technological catch-up in the biopharmaceutical sector: Evidence from Iran. *67*.
Malerba, F. (2002). Sectoral systems of innovation and production. *Research policy*, *31*(2), 247-264.
Malerba, F. (2005). Sectoral systems of innovation: a framework for linking innovation to the knowledge base, structure and dynamics of sectors. *Economics of innovation and New Technology*, *14*(1-2), 63-82.
Malerba, F., & Nelson, R. (2011). Learning and catching up in different sectoral systems: evidence from six industries. *Industrial and Corporate Change*, *20*(6), 1645-1675.
Malerba, F., & Niosi, J. (2018). Moving Forward in Sectoral Systems Research. In (pp. 27-52): Cambridge University Press Cambridge.
Mani, S. (2006). The sectoral system of innovation of Indian pharmaceutical industry.
Mazzoleni, R., & Nelson, R. R. (2007). Public research institutions and economic catch-up. *Research policy*, *36*(10), 1512-1528.
Mazzucato, M. (2011). The entrepreneurial state. *Soundings*, *49*(49), 131-142.
Metcalfe, S. (1995). The economic foundations of technology policy: equilibrium and evolutionary perspectives. *Handbook of the economics of innovation and technological change*.
Mouton, J. (2006). Science for transformation: Research agendas and priorities in South Africa. *Science and technology policy for development: Dialogues at the interface*, 89-106.
Nascimento, L. d. S., Reichert, F. M., Janissek-Muniz, R., & Zawislak, P. A. (2021). Dynamic interactions among knowledge management, strategic foresight and emerging technologies. *Journal of knowledge management*, *25*(2), 275-297. https://doi.org/10.1108/JKM-01-2020-0044
Nelson, R. R. (1993). *National innovation systems: a comparative analysis*. Oxford University Press on Demand.
O Reilly, C. A., & Tushman, M. L. (2004). The ambidextrous organization. *Harvard business review*, *82*(4), 74-83.

Olsson, A., Wadell, C., Odenrick, P., & Bergendahl, M. N. (2010). An action learning method for increased innovation capability in organisations. *Action Learning: Research and Practice*, *7*(2), 167-179.

Peerally, J. A., De Fuentes, C., & Figueiredo, P. N. (2019). Inclusive innovation and the role of technological capability-building: The social business Grameen Danone Foods Limited in Bangladesh. *Long Range Planning*, *52*(6), 101843.

Peerally, J. A., Santiago, F., De Fuentes, C., & Moghavvemi, S. (2022). Towards a firm-level technological capability framework to endorse and actualize the Fourth Industrial Revolution in developing countries. *Research policy*, *51*(10), 104563.

Ramani, S. V., & Guennif, S. (2012). Catching up in the pharmaceutical sector: Lessons from case studies of India and Brazil. In *Economic Development as a Learning Process*. Edward Elgar Publishing.

Rehman, A. A., & Alharthi, K. (2016). An introduction to research paradigms. *International Journal of Educational Investigations*, *3*(8), 51-59.

Rooke, J. (2013). Synthetic biology as a source of global health innovation. *Systems and Synthetic Biology*, *7*(3), 67-72.

Rossman, G. B., & Rallis, S. F. (2016). *An introduction to qualitative research: Learning in the field*. Sage Publications.

Rotolo, D., Hicks, D., & Martin, B. R. (2015). What is an emerging technology? *Research policy*, *44*(10), 1827-1843.

Schuhmacher, A., Wilisch, L., Kuss, M., Kandelbauer, A., Hinder, M., & Gassmann, O. (2021). R&D efficiency of leading pharmaceutical companies–a 20-year analysis. *Drug discovery today*, *26*(8), 1784-1789.

Si, T., & Zhao, H. (2016). A brief overview of synthetic biology research programs and roadmap studies in the United States. *Synthetic and systems biotechnology*, *1*(4), 258-264.

Trosset, J.-Y., & Carbonell, P. (2015). Synthetic biology for pharmaceutical drug discovery. *Drug design, development and therapy*, *9*, 6285.

Viotti, E. B. (2002). National learning systems: a new approach on technological change in late industrializing economies and evidences from the cases of Brazil and South Korea. *Technological Forecasting and Social Change*, *69*(7), 653-680.

Walwyn, D., & Cloete, L. (2018). Draft White Paper on Science, Technology and Innovation neglects to prioritise issues of performance and human capability. *South African Journal of Science*, *114*(11-12), 1-6.

Wang, X., Zhang, S., Liu, Y., Du, J., & Huang, H. (2021a). How pharmaceutical innovation evolves: The path from science to technological development to marketable drugs. *Technological Forecasting and Social Change*, *167*, 120698.

Wang, X., Zhang, S., Liu, Y., Du, J., & Huang, H. (2021b). How pharmaceutical innovation evolves: The path from science to technological development to marketable drugs. *Technological forecasting & social change*, *167*, 120698. https://doi.org/10.1016/j.techfore.2021.120698

World Bank. (2010). *Innovation Policy: A guide for developing countries.* https://elibrary.worldbank.org/doi/abs/10.1596/978-0-8213-8269-1

World Intellectual Property Organization. (2021). *Global Innovation Index 2021*. https://www.wipo.int/global_innovation_index/en/2021/

Yin, R. K. (2011). *Applications of case study research*. sage.

Zawislak, P. A., Cherubini Alves, A., Tello-Gamarra, J., Barbieux, D., & Reichert, F. M. (2012). Innovation capability: From technology development to transaction capability. *Journal of technology management & innovation*, *7*(2), 14-27.

APPENDICES

APPENDIX A. INTERVIEW PROTOCOLS

SET 1 – STRATEGY

1. What is the relevance of Synthetic biology to the South African landscape?
2. What was the rationale for the selection of CSIR as the host institution to establish capabilities in Synthetic Biology?
3. What is the envisaged impact that the Centre will make in the pharmaceutical sector?
4. How would you describe the success rate with regards to the impact that CSIR has made in this field to date?
5. In your view, what are the main challenges facing South Africa that may negatively affect progress in the development of world-class capabilities in Synthetic Biology?
6. How would you rank the innovation capability of Synthetic Biology at CSIR in relation to similar organizations in the rest of the world?

SET 2 – MANAGEMENT

1. What are the key drivers informing the strategic objectives of the Next Gen Health Cluster?
2. What was the rationale for the selection of this cluster as the host of the SynBio Research Centre?
3. How is the Centre positioned to address the strategic objectives of the Cluster?
4. What form of support does the Cluster provide to the Centre in relation to technology, finance, and human capital?
5. How would you describe the success rate of the Centre in creating impact in the health industry?
6. In your view, what are the main challenges facing the Cluster that may negatively affect progress in the development of world-class capabilities in Synthetic Biology?
7. How would you rank the innovation capability of Synthetic Biology at CSIR in relation to similar organizations in the rest of the world?

SET 3 – OPERATIONS

1. What are the key drivers that inform the strategic objectives of the Centre? Who are the Centre’s key strategic partners in the public and private sector?

2. How has the Centre positioned itself to improve the performance of the pharmaceuticals sector in South Africa?
3. How would you describe the role that relevant strategic partners play in the Centre’s technology development activities?
4. What are the main challenges/risks facing the Centre that may negatively affect progress in the development of world-class capabilities in Synthetic Biology?
5. Would you agree that the Centre is well resourced in terms of personnel? If not, what are the scarce skills currently?
6. How does the centre source the technical and business knowledge needed to successfully develop and commercialise products?
7. What is the process for sourcing equipment/ key infrastructure?
8. What support is provided to the researchers to ensure that they are able to effectively and efficiently develop technologies?
9. How much of funding do you think is required annually for the centre to make an impact in the sector compared to what is currently received?
10. How would you describe the success rate of the Centre in creating impact in the pharmaceuticals sector?
11. How would you rank the innovation capability of Synthetic Biology at CSIR in relation to similar organizations in the rest of the world?

APPENDIX B. QUESTIONNAIRE

SECTION A – GENERAL INFORMATION

Research group *(mark with an X)*	Bioengineering and genomics						
	Array printing						
	Companion diagnostics						
	Synthetic nanotechnology and biomachines						
Job title							
Job type	technician		scientist		engineer		manager	
Highest qualification	diploma		degree		masters		phd	
Total years of experience							
Total years of industry experience							

SECTION B – RESOURCES AND EXPERTISE

Area of expertise			
Have you participated in any visiting researcher/ exchange programs?	Yes/no	**Specify location**	
If yes above, what experience did you gain that has enabled you to significantly contribute to the South African knowledge base?			

How would you classify the structure of your research team? *(mark with an X)*	Specialized teams working across different functional areas and organisational units	
	Structured R&D, engineering and technical organizational units	
	Informal/ adhoc group structures	
How effectively has the group been in developing its own technological know-how and technology assets *(mark with an X)*	Highly effective	
	Moderately effective	
	Not effective	
How would you describe the level of support that you receive in the Centre? *(mark with an X)*	High	
	Moderate	
	Low	

SECTION C - INFRASTRUCTURE	
What process is followed when purchasing equipment/ infrastructure and what are the bottlenecks (if any)?	
In your view, what improvements could be made in the Centre to improve the efficiency with which you conduct your work?	

SECTION D – TECHNOLOGY DEVELOPMENT

***The questions in this section are specific to the project that you are leading that addresses a need in the pharmaceutical sector. Please replicate this section if more than one project is being led by you.**

Project title						
Project strategic fit *(mark with an X)*	Project is clearly outside our strategic intent and fits not product vision					
	Some doubts about how it fits into existing strategies					
	fits strategic intent and specific product vision					
	fit strategic intent at a high level of ambition and meets more than one specific vision					
Technical capabilities available to execute the project *(mark with an X)*	We will have to buy in new major capabilities, or recruit a new technical team, or rely on a partner					
	we lack some important capabilities, and a plan is needed to acquire them					
	existing staff can acquire capabilities in three months or less or by recruiting one or two new people					
	some new skills required but they can be acquired in time					
	well within our capability no new skills or knowledge required					
Research type	basic		applied		experimental	
Innovation type	incremental		radical		disruptive	
Technology differentiation *(mark with an X)*	No features that are better than competition					
	at least one feature is better than offered by the competition					
	we have some minor features that are better than the competition					
	at least one important feature is significantly better than the competition					

	several important features are much better than the competition							
Sustainability of competitive advantage *(mark with an X)*	Key differentiating features will be easy to copy or serious concerns about IP against us							
	we are six to 12 months ahead of the competition no serious IPR concerns							
	competitive advantage can be maintained with continuous effort							
	we are at least two years ahead of the competition							
	key features are protected by IPR or unique capabilities that are not easy to copy here							
Industry/ market readiness *(mark with an X)*	No express demand or requires major change of customer behavior							
	some customers have asked for this but requires some change in customer behavior							
	definitely attractive to most customers no change to customer behavior required							
	there is a pent up demand for this							
How would you rank the innovation capability of your research group in relation to similar organisations in the rest of the world?	basic		intermediate		advanced		world leading	
How would you classify the nature the strategic partnerships related to your project/ technology?	Collaboration with leading knowledge institutions							
	Strategic partnering with forward looking producers							
	user-producer interactions with local customers and suppliers							
	No partnerships							
Categorize the mode of adoption for the infrastructure/ equipment required to develop your technology	built in-house							
	Imported and adopted as is							
	Imported and modified/ enhanced							
	Purchased locally							

APPENDIX C. PARTICIPANT INFORMATION SHEET

Good day,

My name is Vyasha Singh and I am a Masters of Management student in Innovation Studies at the University of the Witwatersrand, Johannesburg and an employee of the CSIR. As part of my studies, I am conducting research on a topic related to innovation entitled "Emerging technologies and technological catch-up in the pharmaceutical sector in South Africa" under the supervision of Prof. Thembela Hillie. The purpose of the study is to investigate the establishment and subsequent evolution of emerging technologies in South Africa in the context of technological capabilities and innovation systems. The study will consider the specific role of synthetic biology in enabling the South African pharmaceuticals sector to achieve technological catch-up with leading countries. The main aim of the research will be to understand how technological capabilities, with respect to synthetic biology in South Africa, have been established and what capabilities have been responsible for achieving success in the Pharmaceutical sector. The study will conclude by providing recommendations in relation to future potential pathways that can be followed whereby technological catch-up in the sector can be achieved.

As part of this project, I would like to invite you to take part in a short survey. This activity will involve completing the attached questionnaire and should take around 20 minutes.

Yours sincerely,

Researcher:	**Supervisor:**
Vyasha Singh	Thembela Hillie
1801223@students.wits.ac.za	Thembela.hillie@wits.ac.za

NB: There will be no personal costs to you if you participate in this project. You will not receive any direct benefits from participation but there are no disadvantages or penalties if you do not choose to participate or if you withdraw from the study. You may withdraw at any time or not answer any question if you do not want to. The responses will be completely confidential and anonymous as I will not be asking for your name or any identifying information, and the information you give to me will be held securely and not disclosed to anyone else.

If you have any questions during or afterwards about this research, feel free to contact me. This study will be written up as a research report which will be available online through the university library website. If you wish to receive a summary of this report, I will be happy to send it to you. The data collected from this research project will be stored in a secure database and will be kept for 1 year. If you have any concerns or complaints regarding the ethical procedures of this study, you are welcome to contact the University Human Research Ethics Committee (Non-Medical), telephone +27(0) 11 717 1408, email hrec-medical.researchoffice@wits.ac.za

APPENDIX D. PARTICIPANT CONSENT FORM

Title of project: Emerging Technologies and technological catch-up in the pharmaceuticals sector in South Africa

Name of researcher: Vyasha Singh

I, …………………………………….., agree to participate in this research project. The research has been explained to me and I understand what my participation will involve. I agree to the following:

(Please circle the relevant options below).

I agree that my participation will remain anonymous	YES	NO
I agree that the researcher may use anonymous quotes in his / her research report	YES	NO
I agree that the interview may be audio recorded	YES	NO
I agree that the information I provide may be used anonymously after this project has ended, for academic purposes by other researchers, subject to their own ethics clearance being obtained.	YES	NO

…………………………………… (signature)
…………………………………… (name of participant)
…………………………………… (date)

…………………………………… (signature)
…………………………………… (name of person seeking consent)
…………………………………… (date)

APPENDIX E. CLASSIFICATION OF TECHNOLOGY DEVELOPMENT ACTIVITIES

Research Group	Project strategic fit	Technical capabilties to execute project	Research type	Innovation type	Technology differentiation	Sustainability of competitive advantage	Industry/ market readiness	IC ranking	Classification of strategic partnerships	mode of adoption for the infrastrucure/ euipement required to development technology
bioengineering liver	fit strategic intent at a high level of ambition and meets more than one specific vision	some new skills required but they can be acquired in time well within our capability no new skills or knowledge required existing staff can acquire capabilities in three months or less or by recruiting one or two new people	Applied Experimental		at least one important feature is significantly better than the competition	Key differentiating features will be easy to copy or serious concerns about IP against us we are at least two years ahead of the competition key features are protected by IPR or unique capabilities that are not easy to copy here	there is a pent up demand for this	Advanced	Collaboration with leading knowledge institutions	Imported and modified/ enhanced
Synthetic nanobiotechnology and biomachines group	fit strategic intent at a high level of ambition and meets more than one specific vision	existing staff can acquire capabilities in three months or less or by recruiting one or two new people	Applied Experimental	Incremental radical disruptive	several important features are much better than the competition	competitive advantage can be maintained with continuous effort	definitely attractive to most customers no change to customer behavior required	Intermediate Advanced	Strategic partnering with forward looking producers	Imported and modified/ enhanced
companion diagnostics	fit strategic intent at a high level of ambition and meets more than one specific vision	existing staff can acquire capabilities in three months or less or by recruiting one or two new people	Applied Experimental	Incremental radical disruptive	several important features are much better than the competition	competitive advantage can be maintained with continuous effort	definitely attractive to most customers no change to customer behavior required	Intermediate Advanced	Strategic partnering with forward looking producers	Imported and modified/ enhanced
Array technology	fits strategic intent and specific product vision	existing staff can acquire capabilities in three months or less or by recruiting one or two new people	Applied Experimental	Incremental radical disruptive	at least one important feature is significantly better than the competition	competitive advantage can be maintained with continuous effort	definitely attractive to most customers no change to customer behavior required	Intermediate Advanced	Strategic partnering with forward looking producers	Imported and modified/ enhanced