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New Business Models for Technology Innovation in Healthcare: A Value Network Perspective

by

AIRA PATRICE RUEDA ONG

A thesis submitted to the University of Plymouth

in partial fulfilment for the degree of

DOCTOR OF PHILOSOPHY

Plymouth Business School

May 2024

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Dedication

To my mother, Aura and my father, Eugene. To my daughter, Airia, and my husband, Jiang. To my siblings, Aaron, and Aien, and all my family in the Philippines. To my supervisors: Professor Shaofeng, Professor Genhua & Professor Xinzhong.

To God Almighty.

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To my parents, Aura Ong and Harwen Eugene Ong, thank you for always being there for me and for your unconditional love. I am truly grateful for the way you brought me up, especially for instilling in me the values of positivity and independence, which were crucial as I undertook this journey miles from home. To my siblings, Harwen Aaron Ong and Mary Airen Ong, thank you for doing your best in your studies and taking care of our parents while I'm away.

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Of course, to God. I am profoundly thankful for His guidance and the countless blessings I have received throughout this journey. This accomplishment would not have been possible without the strength and wisdom He has bestowed upon me.

Author's declaration

At no time during the registration for the degree of Doctor of Philosophy has the author been registered for any other University award without prior agreement of the Doctoral College Quality Sub-Committee.

Work submitted for this research degree at the University of Plymouth has not formed part of any other degree either at Plymouth University or at another establishment.

Publications:

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- B. Gao, S. Liu, G. Pan and A.P.R. Ong, 2019 "Concept and Building Blocks of Business Model: A Systematic Literature Review," 2019 The 6th International Conference on Economics, Society and Management (ICESM 2019), Journal of Economics, Business and Management (JOEBM). DOI: <u>https://doi.org/10.18178/joebm.2020.8.2.616</u> PEARL (OA): <u>http://hdl.handle.net/10026.1/19297</u>

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- A.P.R. Ong, S. Liu, G. Pan, X. Li, 2019, Poster presentation. "Business Model Innovation -Addressing the Full Value Circle for Technology Development in Brain Cancer Diagnosis and Healthcare", Postgraduate Research Showcase, 17 June 2019, University of Plymouth, UK.

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New Business Models for Technology Innovation in Healthcare: A Value Network Perspective

AIRA PATRICE RUEDA ONG

Abstract

Business models (BMs) play an important role in facilitating the delivery and integration of technological innovations within the healthcare sector, catering the needs of healthtech entrepreneurs, managers, healthcare providers, researchers and policy makers. However, despite the BM's significance, existing conceptualisations of BM do not adequately guide in designing them taking into account the complexities of the healthcare environment. This demands a dynamic approach in designing BM, considering the healthcare value chain stakeholders' thoughts, values, prejudices, views, feelings and perspectives. With the exploratory nature and lack of research in this area, the overall aim of the study is to design an innovative BM founded on the concept of value co-creation and will seek to provide a holistic view of the healthcare technology value chain. Specific objectives include to establish and prioritise the key factors of innovative BM development in healthcare diagnostic technologies.

Based on the systematic literature review, this study has developed a conceptual BM formed with four value dimensions: the (1) value offering, (2) value delivery, (3) value network, (4) value capture. This has been used to synthesise the empirical study which is conducted in 3 phases. First, thematic analysis was conducted on thirty in-depth semi-structured interviews involving experienced stakeholders in the healthcare value chain. This process led to the identification of 34 BM factors. Subsequently, a second round of data collection employed structured interviews to apply Total Interpretive Structural Modelling (TISM) in order to uncover the interrelationships among the identified BM factors. The resulting TISM model was formed to visualise the factor dependencies. Finally, the output of TISM forms the input for Matrice d'Impacts croises-multipication appliqu'ean classment (cross-impact matrix multiplication applied to classification) MICMAC analysis to classify and prioritise the factors based on their ability to influence other factors. The findings highlight indicate that the certain factors including Meeting the needs of the current standard of care, Satisfied regulatory clearance, Earning trust of stakeholders, Effective sales channel, Regulatory approval, Managing costs, and Economical and political environment, possess the highest driving power and are situated at the lowest level of the TISM hierarchy. Thus, they should be given top priority in healthtech BM.

This study has a number of theoretical contributions including the development of an BM framework incorporating the full value circle for healthcare technology. Secondly, it provides empirical evidence in identifying BM factors incorporating healthcare stakeholders' views. Thirdly, it prioritises BM factors by establishing interrelationships among them through TISM and categorising them with MICMAC analysis. Finally, this research serves guidance to practitioners and biotech entrepreneurs to help them to make better decisions in addressing BM related priorities by using the BM framework developed.

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List of abbreviations

Biotech	Biotechnology	
BM	Business Model	
BMC	Business Model Canvas	
DTC	direct-to-consumer	
DEMATEL	Decision making trial and evaluation laboratory	
FDA	Food and Drug Administration	
GDP	gross domestic product	
Healthtech	health technology	
ICT	Information and Communication Technology	
IRP	Interpretive ranking process	
IS	Information Systems	
IT	Information Technology	
IVD	in vitro diagnostic	
MICMAC	Cross-impact matrix multiplication applied to classification	
NIH	National Institutes of Health	
РОСТ	point of care testing	
SME	Small and medium sized enterprise	
BMI	Business Model Innovation	
B2B	Business-to-Business	
B2C	Business-to-Customer	
R&D	Research and Development	

Chapter 1 Introduction

1.1 Research context, motivation and industry justification

1.1.1 Author's background relative to the research

The author's professional experience played a significant role in shaping the topic of this research, and this connection will be briefly explained. In this section, the author steps aside from the study by delving into personal experiences with the phenomenon (Creswell and Poth, 2023).

To introduce, I am Aira Ong, an engineer with a background in Manufacturing Engineering and Management specialising in Mechatronics and Robotics Engineering. My research journey began with a focus on the development of robotic exoskeletons for rehabilitation during my BS/MS studies. As the lead researcher of the <u>AGAPAY Project</u>, I was deeply involved in its development, testing the safety of the device, conducting pre-clinical trials, and engaging with stakeholders to enhance its design. With some of our inventions receiving patents, the project naturally progressed towards considerations of commercialisation, prompting our participation in various networking workshops dedicated to this endeavour. It was through these experiences that I came to appreciate the critical role of business model (BM) thinking, particularly within the area of healthcare technology innovation.

Then, an opportunity came up to be a Marie Curie Early Stage Research Fellow in BM for the AiPBAND Project (read further in Appendix I), funded by Horizon 2020. This is when I formally studied BMs for healthcare technologies that formed this PhD research. My journey into this field was not just an academic pursuit but stemmed from a personal passion and a profound sense of purpose in advancing BM for healthcare technologies.

In formulating this thesis, my aim is to open a discourse that speaks to a multidisciplinary audience, including both business entrepreneurs and healthcare technology stakeholders. The nature of this

study is purposeful, conceived to bridge different domains of expertise and develop a unified understanding of BM design within the context of healthcare technology.

1.1.2 Role of business models

Business model (BM) research on healthcare business is needed in order to gain an understanding of the current competitive landscape, identify areas of growth, and inform strategic decision making (Fredriksson *et al.*, 2017; Perju-Mitran, 2019; Tyagi, Sengar and Kumar, 2019). One of the primary goals of the healthcare industry is to provide the most suitable healthcare treatments and medical solutions to each patients' needs. Healthcare diagnostics is an evolving field of medical research, which is making tremendous progress in terms of technological advancements, resulting in a range of new and improved diagnostic tools. Healthcare providers, such as hospitals and clinics, use these technologies to provide accurate and timely diagnosis for their patients. As healthcare delivery becomes increasingly complex, the accuracy and reliability of these technologies is essential for improved outcomes and patient safety. However, the success of these technologies, particularly in the healthcare industry, requires a holistic approach to generating value for all stakeholders complemented with a sustainable BM for commercialisation (Dijkman *et al.*, 2015; Talari, Rehman and Rehman, 2019; Van Velthoven and Cordon, 2019; Khatab and Yousef, 2021).

BM design and innovation play a pivotal roles in determining the performance and success of a firm (Morris, Schindehutte and Allen, 2005; Zott and Amit, 2007; Zott, Amit and Massa, 2011; Kesting and Günzel-Jensen, 2015; Tyagi, Sengar and Kumar, 2019) and to adapt to changing environments (Gioia, Schultz and Corley, 2000; Bohmer and Edmondson, 2001; Kelley *et al.*, 2020; Korsgaard, Hasenkam and Vesterby, 2021; Oderanti *et al.*, 2021; Vimarlund, Nikula and Nøhr, 2021). While it is often unclear why certain BMs are successful and others are not, there is widespread

acknowledgement that a functioning BM is necessary for any commercial entity to be successful and a venture to become viable (Magretta, 2002; Doganova and Eyquem-Renault, 2009; Marcos-Pablos, García-Holgado and García-Pẽalvo, 2019; Pundziene, Heaton and Teece, 2019; Terra, Rodrigues and Maia, 2019). In every business venture established, whether it be a small family business or a large multinational corporation, it will have an implicit or explicit BM in place. This BM outlines the way the business is structured, with a focus on the type of products and services the business will provide, how those will be produced and delivered, and the type of customers that will be served (Teece, 2010; Laya, Markendahl and Lundberg, 2018; Tyagi, Sengar and Kumar, 2019).

In the business literature, BM frameworks have been used to understand how organisations are aligned to achieve their goals, with subsequent theorists contributing to the development of the model, such as Peter F. Drucker and Michael Porter (Osterwalder and Pigneur, 2010; Fredriksson et al., 2017; Terra, Rodrigues and Maia, 2019). Based on extant literature, BM has its origins in strategic management (Myers and Chandler, 1962; Prahalad and Bettis, 1986; Amit and Zott, 2001; Hedman and Kalling, 2003) as well as technology management literature (Henderson and Clark, 1990; Tripsas, 2009). The BM concept has also been denoted as a blueprint, description, statement, etc. A commonly cited definition, provided by Chesbrough and Rosenbloom (2002), characterises it as "a blueprint for how a network of organisations co-operates in creating and capturing value from technological innovation". Due to the diverse contexts under which BMs are discussed, there exists no universally accepted definition of BM (Zott, Amit and Massa, 2011). Despite the diversity of perspectives and approaches to the notion of a BM, there is general agreement among researchers and practitioners that at its core, a BM outlines how a company creates, captures and delivers value (Linner et al., 2017; Tyagi, Sengar and Kumar, 2019). Studies also reviewed definitions of BMs from existing literature and identified four dimensions shared by all or most of the definitions: creating value, capturing value, value network and strategic choices (Shafer, Smith and Linder,

2005; Kyhnau and Nielsen, 2015). Appendix A presents the most cited definitions of the BM and how each definition encompasses the BM dimensions: (1) Value offering, (2) Value delivery, (3) Value network, and (4) Value capture.. Additionally, studies on BM literature has shifted away from an isolated firm approach and towards a firm-centric view that extends beyond various boundaries and is focused on an activity system perspective, with a shift in emphasis from value capture to value creation (Schiavone *et al.*, 2021; Viswanadham, 2021; Chen, 2022). More recent research on BM has focused on the impact of technology on BMs utilising the concept of the business model canvas (BMC) by Osterwalder and Pigneur (2010), which provides a framework for understanding how technology can be used. In this research, a BM is conceptualised as an integrated set of decision variables in the strategic, operational and economic areas that explain how an organisation creates and delivers value to both customers and network of partners (Chesbrough and Rosenbloom, 2002; Magretta, 2002) and, importantly, capture value within the 'value network' or 'activity system' of the business (Shafer, Smith and Linder, 2005; Zott and Amit, 2010; Harrington and Burge, 2018). Analysing these key aspects is fundamental to this study focusing on emerging healthcare technologies

1.1.3 Advances in healthcare technology

Emerging technologies, indeed, create new market and entrepreneurial opportunities (Verhees, van Kuijk and Simonse, 2017; Tyagi, Sengar and Kumar, 2019; Nigam, Mbarek and Boughanmi, 2021; Palas and Bunduchi, 2021; Sibalija *et al.*, 2021). Health research from various fields such as genomics, information science, artificial intelligence, imaging, nanotechnologies and the advancement of existing technologies are facilitating the discovery of better biomarkers that can significantly change the way of medicine and clinical patient care pathways (Ivan and Velicanu, 2015; Yu, Beam and Kohane, 2018; Denicolai and Previtali, 2020; Hofmann *et al.*, 2020; van Dijk-De Vries *et al.*, 2020). Advances in diagnostic tools and biomedicine as a result of basic

research have a transformative impact on prediction, diagnosis and monitoring in healthcare. Early and accurate diagnosis of diseases is critical for timely treatment particularly for cancer. Because if care is delayed or inaccessible, the chance of survival is lower, treatment plans get more complicated and result in higher costs of care (WHO, 2022).

It is ideal that these scientific discoveries are to be translated into clinical practice to benefit humanity. In the United Kingdom, the development of medical devices follows a structured process to ensure safety and regulatory compliance. The specific stages of medical device development in the UK are influenced by the regulatory framework set by the Medicines and Healthcare products Regulatory Agency (MHRA) and the conformity assessment procedures under the UK Conformity Assessment (UKCA) marking scheme, which is the UK's equivalent to the CE marking used in the European Union (Bhattacharya, Wainwright and Whalley, 2021; Oderanti *et al.*, 2021). Here are the stages of medical device development in the UK:

- 1. **Conceptualization and Feasibility Assessment**: This initial phase involves identifying a medical need, conducting market research, and defining the device's purpose and target audience.
- Planning and Design Inputs: Planning encompasses project timelines, budgets, and assembling the necessary expertise. It also involves documenting user needs and design inputs in line with MHRA regulations.
- 3. **Design and Development**: This phase includes creating design specifications, prototyping, iterative design refinements, and risk assessment to mitigate potential hazards.
- Verification and Validation: Verification confirms design compliance, while validation evaluates real-world performance, involving usability testing and comprehensive documentation.
- 5. **Regulatory Submission and Conformity Assessment**: Prepare technical documentation and, if necessary, seek UKCA marking through conformity assessment procedures.

- 6. **Conformity Assessment** (if required): Undergo assessments by an Approved Body to ensure compliance with regulatory requirements.
- Clinical Trials (if required): Conduct trials to demonstrate safety and efficacy, adhering to MHRA guidelines.
- 8. **Manufacturing and Quality Control:** Establish manufacturing processes and quality control systems, adhering to Good Manufacturing Practice (GMP) standards.
- 9. **Market Launch**: Prepare marketing materials, train healthcare professionals, and introduce the device to the UK market.
- 10. **Post-Market Surveillance**: Continuously monitor the device's performance, collect post-market data, and respond to safety concerns or issues.
- 11. Lifecycle Management: Continuously improve design and manufacturing, adapt to changing regulations, and plan for device enhancements or updates.

All biotechnology businesses can be perceived as certain processes consisting of these stages of development: research, expansion, testing and registration, production and trade (Marceglia *et al.*, 2018; Marcos-Pablos, García-Holgado and García-Pẽalvo, 2019; Oshaviani Annisya and Rochman, 2020; Korsgaard, Hasenkam and Vesterby, 2021; Oderanti *et al.*, 2021; Chen, 2022).

As a result, companies and organisations are investing more into research and development (R&D) to identify and exploit these innovations (Schiavone *et al.*, 2021; Viswanadham, 2021). Figure 1.1 illustrates a general course from discovery to market of healthcare innovations in medical diagnostic technology. Understanding the value chain is an essential step to designing a viable BM in any particular area of focus. The healthcare technology development value chain describes the process of developing new technology for use in the healthcare sector. This value chain outlines the steps that a business should take when creating a new healthcare technology product, from the initial concept and research stage, to the development and launch of the product.

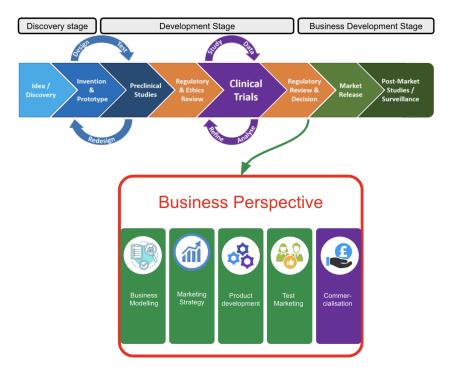


Figure 1.1. Medical diagnostic technology stages from discovery to clinical trials to market (image adopted from (Kaplan *et al.*, 2004)

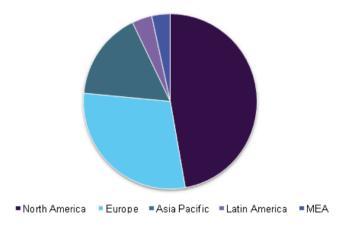
The first two stages primarily focus on the life sciences perspective, encompassing the discovery and clinical validation phases. The first stage involves researching the current healthcare sector to identify areas that could benefit from new technology. The research should also include understanding the needs of different stakeholders in the sector, such as doctors, nurses, and patients, so that the new technology can be tailored to meet their requirements (Bhattacharya, Wainwright and Whalley, 2021; Denoo, Yli-Renko and Clarysse, 2021; Fürstenau *et al.*, 2021; Oderanti *et al.*, 2021; Schiavone *et al.*, 2021). After the research is completed, the concept for the new technology is developed and refined. In the development of these devices, collaborations are essential among academia, healthcare providers (e.g. hospitals and clinicians) and industry in the development of these devices. Adoption decisions for medical and information technology may vary depending on whether they are made by individuals or organisations. The second stage of the healthcare technology development value chain is design and development. This stage involves designing the product and developing the technology in line with the initial concept. It involves creating

prototypes and testing them to ensure that the product meets the requirements of the healthcare sector (Nikou and Bouwman, 2017; Chen, Liu and Hu, 2020; Mueller, 2020; Oshaviani Annisya and Rochman, 2020). Once the design and development process is complete, the product is ready for launch.

The third stage of the healthcare technology development value chain is launch and marketing. This stage involves launching the product to the market and marketing it to the end users. Overall, the adoption of health technology involves multidisciplinary collaborations, coordinated solutions to key aspects of the clinical process, including creating successful business models, and innovative accreditation and regulatory oversight. involves a wide range of inputs and stakeholders such as scientists, engineers, clinicians and indeed patients (Gand, 2018; Fürstenau *et al.*, 2021; Lehoux *et al.*, 2021; Oderanti *et al.*, 2021).

1.1.4 Market trends and statistics

By 2023, the global brain tumour therapeutics market is projected to experience a compound annual growth rate (CAGR) of 12.9% (BCC Publishing, 2019). Worldwide, spending on cancer therapies and supportive care drugs has surpassed £100 (\$133) billion, reflecting the recognised value of these medicines and the allocation of a greater share of drug budgets to these products. Over the next five years, this amount is projected to reach £140—£155 (\$180—200) billion (IQVIA Institute for Human Data Science, 2018).



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Figure. 1.2. Global brain tumour diagnosis market, by region, 2015 (Grand View Research, 2017) In 2015, North America, Europe and Asia Pacific are the top three brain diagnostics markets (Grand View Research, 2017), as shown in Figure 1.2 The medical technology industry is a major part of the UK economy with over 2,900 companies with a combined turnover of £22 billion in 2020 (Office for Life Sciences, 2022). Current understanding of cancer has been advanced by biomarker research as initial success in biotechnology can be evidenced with therapeutic drugs like Erbitux®, Gleevec® and Herceptin®, already on the market (Nature, 2005; Baker and Reddy, 2010; Nath, Cohen and Bild, 2021; Yu *et al.*, 2022). Furthermore, patients would benefit from the use of biomarker tests that can identify those most likely to respond. Thus, the diagnostic component is becoming a necessity rather than an option as required by FDA for biologics (Center for Devices and Radiological Health, 2023).

Reportedly, the medical device market is one that can never reach stagnation, as it is characterised by continuous development, inherently evolving in tandem with advancements in medical practices (World Intellectual Property Organization, INSEAD and Cornell University, 2019). Technological advances, disease outbreak, demographics, or patient demands serve as primary drivers of innovations in this segment. However, due to the complex nature of the healthcare environment encompassing technical, societal, institutional, and political considerations creates difficulties for diffusion of innovations (Plsek and Wilson, 2001; Berwick, 2003; Greenhalgh and Papoutsi, 2018; Van Velthoven and Cordon, 2019; Christie *et al.*, 2020; Denicolai and Previtali, 2020; Kelley *et al.*, 2020; Mueller, 2020; van Dijk-De Vries *et al.*, 2020) and change initiatives intended to make improvements (Glouberman and Zimmerman, 2002; Braithwaite, 2018; Korsgaard, Hasenkam and Vesterby, 2021; Chen, 2022).

1.2 Research problem

As expounded in the previous section, healthcare is a complex and ever-evolving sector that needs to be constantly monitored and updated in order to ensure the best possible outcomes for patients and the public. The development of new healthcare technologies come with a range of challenges, including the difficulty of developing BMs (Białek-Jaworska and Gabryelczyk, 2016; Khatab and Yousef, 2021; Lehoux *et al.*, 2021; Nigam, Mbarek and Boughanmi, 2021; Sibalija *et al.*, 2021). Chesbrough and Rosenbloom (2002) define BM innovation as a mediator between technical and economic domains for successful commercialisation of new technology. Without BM innovation, it is not feasible to commercialise the technology innovation.

In addition, the lack of an appropriate BM can limit the success of medtech innovations, especially when securing funding and engaging potential investors (Korsgaard, Hasenkam and Vesterby, 2021; Oderanti *et al.*, 2021; Vimarlund, Nikula and Nøhr, 2021). BM is essential for the long-term sustainability of any healthcare innovation that aims to be commercialised and brought to the market to address a clinical need.

There is an increasing need for an effective framework to guide the development of these technologies (Mueller, 2020; van Dijk-De Vries *et al.*, 2020). While there are many traditional BMs used in other industries, they may not be as applicable when it comes to medical technologies. This is due to the fact that health technologies are highly specialised as a BM that works for one type of technology may not be suitable for another. Therefore, a more empirical investigation is needed to design an innovative BM framework that incorporates the full value circle of healthcare technology development, which includes the development, deployment, management and evaluation of the technology. With the lack of research into BM for healthcare technology developments there is still no overarching framework or guideline that provides healthtech researchers/ entrepreneurs the necessary direction to design their BM, particularly in the diagnostic field.

Another challenge is to take into account the various stakeholders' perspectives and their needs in developing effective BMs (Marcos-Pablos, García-Holgado and García-Pẽalvo, 2019; Terra, Rodrigues and Maia, 2019; Fürstenau *et al.*, 2021; Palas and Bunduchi, 2021; Vimarlund, Nikula and Nøhr, 2021; Viswanadham, 2021). This considers the different BM elements, such as customer segmentation, pricing, and operations. By taking a holistic view of the BM, researchers can uncover opportunities for improvement and develop strategies that create value for all stakeholders involved. Chapter 2 provides a comprehensive overview of the components of a BM, including the different aspects of the customer, product, operations, pricing, and marketing that must be considered when designing a BM for healthcare technologies.

1.3 Research Aim, Objectives and Questions

The above context leads to the following aim of this study, to design an innovative BM founded on the concept of value co-creation and will seek to provide a holistic view of the healthcare technology value chain. Hence, this study has four objectives, they are to:

- To understand and identify the key BM value dimensions, components and factors that can be used by stakeholders associated with the development of medical technology for diagnosis and healthcare
- 2. To explore and establish relationships among the identified BM factors
- 3. To prioritise the BM factors based on their driving and dependence power.
- 4. To develop an innovative BM for emerging healthcare technologies integrating multiple perspectives.
- 5. To derive recommendations for management practice on BM development.

In order to achieve the research aim and objectives, three clear research questions have been formulated:

- 1. What are the components and its key factors of a BM that exist in healthcare diagnostic technologies?
- 2. What are the relationships that exist among the BM factors?
- 3. What are the most important factors in designing a BM for healthcare diagnostic technologies?

This thesis will provide a detailed account of how each research question was addressed by following rigorous scientific research protocols. The following sections will outline the justification behind conducting research of this nature and the key contributions made to existing knowledge.

1.4 Key contributions

This study makes significant contributions to both theoretical and practical aspects of the healthcare diagnostic technologies industry and its BM development. The key findings of this research have several implications across various dimensions:

Firstly, this research expands the literature on BM for the healthcare domain and conceptualises a BM for diagnostic healthcare technologies by identifying a total of thirty-four (34) BM factors. Although prior literature using systematic literature review (SLR) has identified some factors in designing BMs, a total of fifteen new factors were identified that were not previously considered across different dimensions (Lee, Park and Lee, 2019; Pundziene, Heaton and Teece, 2019; Terra, Rodrigues and Maia, 2019; Oshaviani Annisya and Rochman, 2020; Nigam, Mbarek and Boughanmi, 2021; Palas and Bunduchi, 2021). This study also confirms that these factors are useful for designing BMs in the healthcare industry during the interviews with experts. In the context of business ecosystems within the biotech industry, this research offers practical contributions. The study contributes to the theoretical understanding of BM in the diagnostic healthcare sector by identifying and validating key BM components and

factors. These insights serve as a foundational framework for further research in the industry. These insights guide the development of organisational structures, management approaches, and operational strategies, therefore enhancing the performance of biotech firms and organisations.

- Secondly, relationships have been established among the BM factors in the TISM hierarchy that are crucial in understanding their interdependencies. The model highlights how factors at lower levels influence and shape those at higher levels, and vice versa. It further captures the influences of how various factors collaboratively contribute to the overall success of the BM for diagnostic healthcare technologies, which hasn't been explored previously in depth.
- Thirdly, the prioritisation of BM factors using MICMAC was done based on both driving power and dependence power, making a significant contribution to the existing literature. This contribution not only enhances scholarly discourse but also offers practical insights for stakeholders seeking to optimise their BM design in the diagnostic healthcare technology domain.
- Finally, a novel business model (BM) framework has been developed, encompassing the full value circle and integrating all four key BM dimensions: value offering, value delivery, value network, and value capture. This framework addresses the need for an effective guide to the development of healthcare technologies. While prior literature often relied on the Business Model Canvas (BMC), which lacked specificity for the healthcare sector, this study fills the gap by refining the model and incorporating a network perspective into BM design (Gand, 2018; Denicolai and Previtali, 2020; Palas and Bunduchi, 2021; Ong et al., 2022). Beyond the academic and industrial context, this study has a profound socio economic dimension. Its findings are poised to benefit patients, their families, and healthcare communities by enabling early diagnosis and

improved access to care. Furthermore, the research's emphasis on BMs can facilitate the creation of new services and products that enhance patient outcomes and overall healthcare delivery.

Nowadays, healthcare organisations and entrepreneurs are increasingly turning to BMs to guide their operations. This research provides a valuable insight into the development of such models, with a focus on the various components that contribute to their success. It highlights the importance of considering the needs of the organisation and its stakeholders in the development of the BM. Furthermore, it emphasises the need to have an understanding of the wider healthcare environment and its impact on the model. By doing so, healthcare organisations and entrepreneurs are better equipped to craft effective BMs that are tailored to their specific needs.

Finally, BM research is also needed to better understand the economic and regulatory environment in which healthcare businesses operate. It is important to understand the legal requirements of different countries and sectors, as well as the economic incentives in place, in order to develop effective strategies that can ensure the long-term viability and sustainability of healthcare businesses. Through this research, it is possible to identify opportunities for improving efficiency and reducing costs, while at the same time providing high quality care to patients.

1.7 Structure of the thesis

This section gives an overview of the seven chapters in this thesis. Figure 1.3 presents the chapters and links associated with each other and overall thesis structure.

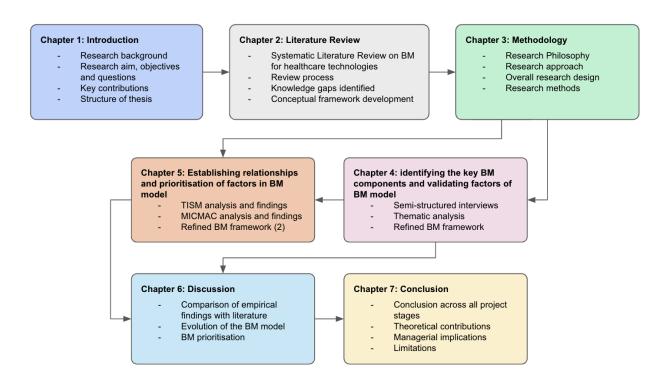


Figure 1.3 Structure of thesis

Chapter 1: Introduction presents an overview of the research topic. It introduces the problem statement, objectives of the study, research questions, and rationale of the study.

Chapter 2: Literature review provides a comprehensive review of the related literature using systematic literature review methodology. It includes a comprehensive analysis of the current research and knowledge on the topic. It also provides the knowledge gaps that this thesis aims to address. Finally, it introduces a conceptual framework for research needs of this study which addresses the design of BM in healthcare technology.

Chapter 3: Methodology describes the research philosophy, approach, overall research design, data collection methods and analysis techniques. It also provides an overview of ethical considerations. Chapter 4: identifying the key BM components and validating factors of BM.

Chapter 5: establishes relationships and prioritisation of factors in BM with the combination of Total Interpretive Structural Modelling (TISM) and *Matrice d'Impacts croises-multipication appliqu'ean classment* (cross-impact matrix multiplication applied to classification) MICMAC analysis

Chapter 6: summarises and discusses the findings of chapter four and five in relation to the prior research and theories presented in chapter two.

Chapter 7: provides a comprehensive overview of the conclusions drawn from all stages of the project. It examines the theoretical contributions by comparing them with existing literature for theorisation and delves into the managerial implications of the findings. Additionally, the chapter addresses the study's limitations and puts forward suggestions for future areas of research.

Chapter 2 Literature Review

2.1 Introduction

This chapter reviews prior literature on the BM domain centred on healthcare technologies using the systematic literature review (SLR) methodology. Section 2.2 elaborates on the SLR concept and illustrates the benefits associated with justification for this study. Then, Section 2.3, presents the review method adopted from (Denyer and Tranfield, 2009) as applied in this research. SLR findings in the form of descriptive and thematic analysis are presented in Section 2.4 and 2.5, respectively. The research gaps were also identified, which better signifies the contributions of this study in Section 2.7. Next, a conceptual framework is developed based on the SLR and how it helps to fill several knowledge gaps in the field with the originality of the study. Finally, the summary of the chapter is presented in Section 2.8.

2.2 Systematic literature review (SLR)

2.2.1 SLR background and concept

The systematic (also known as "structured") literature review (SLR) have initially been developed in the field of medicine as a way to synthesise research findings in a systematic, transparent, and reproducible way and have been referred to as the gold standard among reviews (Davis *et al.*, 2014; Ahn and Kang, 2018). It can be explained as a research method and process for identifying and critically evaluating data from relevant research (Liberati *et al.*, 2009). SLRs are a specific methodology that differ from traditional narrative reviews in that they adopt a replicable, scientific and transparent process, intended to minimise bias through extensive searches and by providing an audit trail of the reviewers' steps, strategies, procedures and decisions (Rousseau, 2006). <u>Table 2.1</u> presents the key differences between a systematic review versus a traditional review. The purpose of conducting a systematic review is to identify all relevant empirical evidence that aligns with predetermined inclusion criteria, allowing for the investigation of a specific research question or hypothesis. Employing explicit and systematic methods in the review process serves to reduce bias, thus ensuring the generation of reliable findings that can be used to draw conclusions and inform decision-making (Moher *et al.*, 2009). Furthermore, SLR helps identify emerging paths, opportunities, relevant issues, contradictions and limitations based on previous studies. It also ensures that no relevant research is overlooked and allows replicability (Pereira, Christopher and Da Silva, 2014; Ahn and Kang, 2018). With the advantages of the SLR method, its use is becoming more prevalent in business research (Snyder, 2019).

Table 2.1 Comparison between systematic vs traditional literature review (views from (Tranfield, Denyer and Smart, 2003)).

Approach	Systematic Reviews	Traditional Literature Reviews
Definition	Clearly defined and agreed methodology which is reproducible.	Summarises research on a topic using subjective methods to identify and interpret studies. There is no agreed methodology for literature reviews. Methodology is not reproducible.
Purpose	Answer a research question, create evidence and eliminate bias. Publish a paper	To set a foundation of the literature on a research topic
Question	Clearly defined question.	Can be on a general topic or a specific question
Search Approach	Structured, replicable and transparent process. Attempts to find all existing published and unpublished literature. The search process is well-documented following formal guidance documentation and reported using established guidelines.	Subjective process. Searches can be ad hoc and attempts have not been made to be fully comprehensive. Methods are not always explicit. The author takes the literature that helps to support their hypotheses
Assessing Quality of Studies	Assessing studies individually and overall quality of evidence. Inclusion and exclusion criteria are expressed in the protocol to ensure a review of the best available evidence	Often does not consider study quality or potential biases in study design. Based on studies that appear relevant or interesting. Researchers bias disables critical appraisal. Decisions regarding choice are not recorded precluding any audit trails 'Raw data' is often not available in academic articles, which usually represent 'partial studies'. Precise inclusion/exclusion criteria are often not formally agreed, applied, recorded or monitored.
Time	Very time consuming	Less consuming than an SLR

2.2.2 The need for SLR in emerging topics

The business model (BM) research associated with healthcare technology is still relatively young. So, in emerging topics such as this, papers published in journals can be scarce (Tranfield, Denyer and Smart, 2003). However, recent studies have applied SLR successfully to emerging themes in management. For instance, an SLR with the aim to understand procurement and supply chain resilience, reviewed literature published between 2000 and 2013 with a selection of 30 papers for in-depth analysis (Pereira, Christopher and Da Silva, 2014). Another recent SLR study with a small sample in an emergent field was conducted by (Acheampong and Vimarlund, 2015), who reviewed BM components for telemedicine services using 22 papers. Drawing on previous literature, SLR is a timely and effective approach for developing the field. It provides a systematic method to identify issues that have not been covered, introduces new methodologies to the field, and opens up new avenues for research. Thus, SLR is a suitable approach to understanding BM in healthcare medical technology. Several SLRs in BM context have been published in recent years (Pateli and Giaglis, 2004; Wirtz *et al.*, 2016; Fredriksson *et al.*, 2017; Maucuer and Renaud, 2019; Guzzo *et al.*, 2020; Rashdan and Csepy, 2022).

2.3 Review Process

Healthcare and BM are two key concepts in this research, which requires a review strategy designed for topics that have been conceptualised differently and studied by various groups of researchers within multiple disciplines (Wong *et al.*, 2013). Therefore, this study adopts the SLR guidelines set by (Tranfield, Denyer and Smart, 2003) that offers researchers a framework to select, analyse, and assess papers ensuring robust and defensible results through reliability and repeatability, as shown in Figure 2.1 The five main phases in conducting the SLR are: (1) question formulation, (2) locating

papers, (3) conducting the review, (4) analysis and (5) writing up the review (Tranfield, Denyer and Smart, 2003; Liberati *et al.*, 2009; Wong *et al.*, 2013).

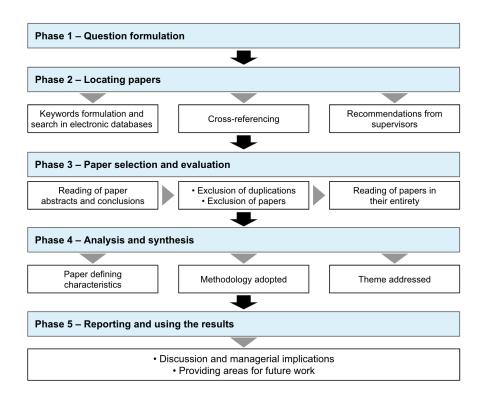


Figure 2.1. The process of systematic literature review (adopted from (Tranfield, Denyer and Smart, 2003; Denyer and Tranfield, 2009))

The SLR involves the following key actions: state research questions, develop guidelines for collecting literature, develop a comprehensive search plan for finding literature, decide on inclusion and exclusion criteria, develop a codebook for classifying and describing literature, code the literature, and synthesise the literature. The following subsections incorporate the detailed steps undertaken for this review.

2.3.1 Question formulation

As a first step, formulating and clearly defining the purpose, scope, and specific research questions are important (Tranfield, Denyer and Smart, 2003). The investigation, in this sense, determined and depicted what is known and not known about BM studies as applied in the healthcare technology field. This study considers the multi-disciplinary aspect in which healthcare BM has previously

been discussed in Chapter 1, and research questions that aim to bring new insights from the literature review.

2.3.2 Locating papers: keywords, database and inclusion criteria

The collection and selection of papers is done in a multi-staged process. Once the research questions have been identified and an overall review approach considered, the next step is to develop a search strategy for identifying relevant literature. This includes selecting search terms and appropriate databases and deciding on inclusion and exclusion criteria (Tranfield, Denyer and Smart, 2003). Here, a number of decisions must be made that are crucial and will eventually determine the quality and rigour of the review.

Keywords

Search terms can be words or phrases used to access appropriate articles. These terms should be based on words and concepts that are directly related to the research question. As the concept of healthcare BM is multidisciplinary and diverse in its scope, the traditional literature review is initially conducted to establish the parameters for a systematic review (Jesson *et al.*, 2011). Keywords should be carefully chosen to match the scope of the review, and Boolean logic can be used to refine the search. The list of keywords should be refined by considering the frequency of use and relevance to the topic. High frequency terms may produce too many irrelevant results, while low frequency terms may not capture the most relevant sources. It is also important to consider the context in which the keywords are used and the specific examples of usage that may be found in the literature. This will help to ensure that the most appropriate keywords are chosen to carry out the systematic literature review.

In determining the appropriate search terms for this research, the author carefully considered the multidisciplinary nature of the healthcare BM concept and its relevance to various fields such as business, management, entrepreneurship, health, strategy, and technology. After thorough

deliberation and review of relevant articles, three primary terms were identified: "business model," "healthcare," and "design."

- The term "business model" was chosen to serve as the central focus of the research, representing the strategic framework through which organisations generate and capture value. This term enables the team to identify literature related to the conceptualization, development, and implementation of BMs within diverse industries.
- "Healthcare" was included to narrow down the search scope specifically to the healthcare sector, ensuring that retrieved articles directly pertain to the research context. This term enables the team to concentrate on literature addressing healthcare delivery, services, systems, and innovations.
- Lastly, "design" was incorporated to underscore the significance of intentional planning, innovation, and strategic decision-making in shaping healthcare BMs. This term emphasises the creative and deliberate aspects of designing business models to address the unique challenges and requirements of the healthcare industry.

After much deliberation and reading through initial articles to identify keywords, a search strategy has been developed consisting of the AND combination of "business model", "healthcare" and "design" followed by an encompassing term using the star symbol (*) at the end of the term was used to make sure all relevant papers will be included.

Scopus	TITLE-ABS-KEY ("business model*" health)) AND (design)
	("healthcare diagnostic technologies" OR "medical diagnostic devices" OR "diagnostic equipment")
	AND ("business model" OR "business model components" OR "business model factors")
Science Direct	"business model*" AND health AND design
	"healthcare diagnostic technologies" OR "medical diagnostic devices" OR "diagnostic equipment"

Table 2.2. Search strings used for database search (by author)

	"business model" OR "business model components" OR "business model factors"			
EBSCO/ Business Source Premier	 TI ("business model*" AND health AND design) TI ("healthcare diagnostic technologies" OR "medical diagnostic devices" OR "diagnostic equipment") TI ("business model" OR "business model components" OR "business model factors") 			
Web of Science	TS=("business model*" AND health AND design) TS=("healthcare diagnostic technologies" OR "medical diagnostic devices" OR "diagnostic equipment")			
	TS=("business model" OR "business model components" OR "business model factors")			
SpringerLink	title:"business model*" AND title:health AND title:design title:"healthcare diagnostic technologies" OR title:"medical diagnostic devices" OR title:"diagnostic equipment"			
	title:"business model" OR title:"business model components" OR title:"business model factors"			
PubMed	("business model*" [Title/Abstract] AND health [Title/Abstract] AND design [Title/Abstract])			
	("healthcare diagnostic technologies" OR "medical diagnostic devices" OR "diagnostic equipment" [Title/Abstract])			
	("business model" OR "business model components" OR "business model factors" [Title/Abstract])			

Databases

(Kraus, Breier and Dasí-Rodríguez, 2020) suggest that for entrepreneurship studies, considering the vast majority of previous research in the field should concentrate on the main databases. However, due to the interdisciplinary nature of this research, the review sample incorporated a broad sampling frame covering a wide range of academic disciplines (e.g. business, management, entrepreneurship, health, strategy and technology) and databases related to biomedical research to be considered. Therefore, electronic literature searches were performed using the following databases: Scopus, ScienceDirect, EBSCO/ Business Source Premier, SpringerLink, Web of Science and PubMed. The

search results included resources from various disciplines, such as information science, management, and healthcare. These resources were published through diverse outlets such as academic journals, practitioners' journals, conference proceedings, and books. To facilitate the review process, the search results were initially sorted based on 'relevance' before delving into the abstracts.

Following (Denyer and Tranfield, 2009), cross-referencing has been used to gain access to additional sources of literature which had not been found through database searches. This process involves tracing the references from the identified papers returned by the database searches, to ensure that all potential relevant sources have been considered. Furthermore, expert recommendations by the researcher's PhD supervisors, expert commentators, and peer reviewers who evaluated the researcher's past publications were also included to gain access to additional sources of literature that may be relevant to the study. The search was accomplished in September 2023.

	Results	
Database (2,186 in total)	Scopus	596
	ScienceDirect	224
	EBSCO/ Business Source Premier	71
	SpringerLink	719
	Web of Science	334
	PubMed	242
Cross-referencing		15
Expert recommendations	7	
	Total	2,208

Table 2.3 Number of papers returned from specific sources

Table 2.3 presents the distribution of 2,208 academic papers and research articles that were obtained from each particular database search, cross-referencing and expert recommendations. This has

provided the researcher with a comprehensive set of papers considered into the next phase of the SLR.

2.3.3 Paper selection and evaluation

This is a crucial step in conducting a systematic literature review as it involves selecting and evaluating the retrieved articles by critically appraising their relevance, quality and accuracy in answering the research questions (Kraus, Breier and Dasí-Rodríguez, 2020). Relevance is assessed by determining whether the article is directly related to the research question. Quality is assessed by evaluating the article's rigour, reliability, validity and methodological soundness. This involves reviewing the research design, sample size, data collection methods, data analysis techniques, conclusions and other aspects of the article. Articles that do not meet the criteria for relevance and quality should be excluded from the review. The present study explores the various ways in which BM has been applied in the literature and assess which BM components are relevant. The initial inclusion criteria, as set in Table 2.4, were broad to ensure that all relevant articles were identified. In order to exclude non-relevant studies from the review, the following inclusion criteria were used: it must be peer-reviewed empirical or conceptual articles, published in English language published between 1996 and 2023, fully accessible, a study must deal with the BM construct in a non-trivial manner and centre on the provision of a healthcare technology(ies) being examined, and that the main focus was on BM design in healthcare technology. Letters, news reports, editorials, overviews, rejoinders and comments were all excluded. Exclusion criteria involved eliminating papers where business models constituted only a minor section or were primarily employed for educational or administrative purposes. When a certain research resulted in multiple publications, the main study focusing on the BM was reviewed. Initial selection of studies was made by reviewing the title and abstract of every record retrieved. In the instances where a decision on inclusion could not be made solely on title and abstract, the full article was retrieved.

#	Inclusion/exclusion criteria	Rationale
1	Articles were published in peer-reviewed journals, conference proceedings and book chapters in English	Peer-reviewed journals, conference papers and book chapters are considered to have better quality than non-peer-reviewed articles. A scholarly paper, usually on a specific topic, published in an externally circulated scholarly or professional journal that has an ISSN. (according to REF definition (University of Cambridge, 2024))
		Only publications in English are accepted since the author is able to comprehend it and this language is widely used even in non-English speaking countries.
2	Articles published between 1996 and 2023	Year 1996 was the earliest year of publication in the search results during the pilot phase. The search was conducted in September 2023.
3	The selected articles contain at least one keyword in their title or abstract	Abstracts or titles focusing on the application of business model in health diagnostic technology were selected
4	Judge relevance by fully reading all remaining abstract, introduction and conclusion	The remaining abstract, introduction and conclusion focusing on the application of business model in health technology were selected
5	Judge relevance by fully reading all remaining articles	Articles highly relevant with the SLR research question on the application of BM in health technology were included

Table 2.4 Inclusion/exclusion criteria

Due to the extensive database search, it yielded a substantial volume of publications with a considerable degree of overlap between them. In total, the database search returned 2,208 journal articles, books, and conference papers. After collecting all the articles, overlapped and duplicated articles were removed, then each paper was checked for the inclusion of keywords in the title, abstract, and keywords, in order to ensure that the articles fit the research objective of the study. This resulted in excluding 1,998 papers. Further reviewing the selected 210 articles, 155 more were excluded from the dataset. The main reasons for the exclusion were (a) lack of theoretical and

methodological rigour, and (b) lack of empirical relevance or inadequate fit with the search criteria. For example, if an article focused on healthcare innovation or technologies, but did not have a BM approach, was removed from the dataset. At the end of the screening process as visualised in Figure 2.2, the final sample included 55 research articles that were eligible for full review (see list of 55 papers included Table 1 in the Appendix A).

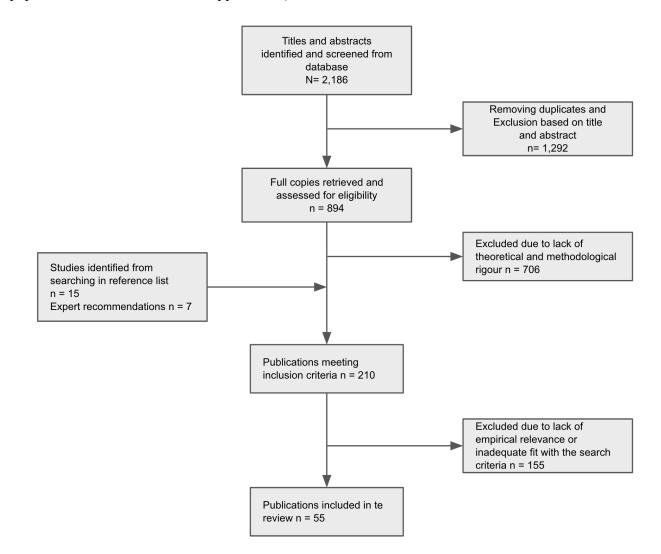


Figure 2.2 Flowchart of paper screening process

2.3.4 Analysis and synthesis

After conducting the literature review and deciding on the final sample of 55 papers, data abstracted are organised in the form of descriptive information, such as authors, years published, topic, or type of study, or in the form of effects and findings. Then, thematic analysis is used to analyse data and

integrate the findings of multiple studies. According to (Braun and Clarke, 2006) "thematic analysis is a method for identifying, analysing and reporting patterns (themes) within data, which provides core skills that will be useful for conducting many other forms of qualitative analysis". In this phase, the thematic analysis was used to allow BM themes to identify patterns and themes in the dataset with the following stages: first, reading the entire paper collected from the SLR; second, generating initial codes; third searching for themes; fourth, evaluating the themes in terms of relevance and consistency; fifth, defining and naming themes; and finally, presenting the results. The selected studies were classified according to themes using an iterative constant comparative thematic coding where texts were read, highlighted, compared and classified based on the health innovation and BM components examined using the qualitative data analysis tool NVivo QSR International Software (Version-12.6).

Nodes for coding were determined based on previous SLR studies (Shafer, Smith and Linder, 2005; Roome and Louche, 2016). Therefore, the papers were coded and classified according to the following:

- Defining characteristics: the selected contributions were classified according to their general details year of publication, bibliographic source, the country of study (study context specific, not just authors' country affiliation), and the disciplines of the studies.
- Classification of papers: each paper was classified according to the methodology used, type of healthcare technology innovation focused, stakeholders involved, theoretical perspectives. In the case of multiple methodologies, each paper was classified according to the primary methodology used.
- Themes addressed: finally, the collected papers were thematically analysed by identifying, analysing and reporting patterns (themes) within the research topic. The author followed an inductive approach that allowed the data to determine the themes. These nodes were

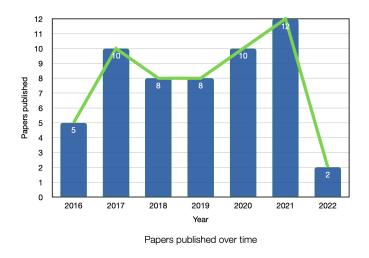
integrated into a framework that served for the coding of the papers and the analysis of the results.

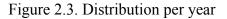
2.3.5 Reporting and using the results

Finally, the synthesis of the accepted articles and discussion of the findings are reported and presented. By summarising the systematic review, researchers can provide a comprehensive overview of the literature, identify gaps and suggest areas for future research. It is important to note that the findings of a systematic review should be interpreted in light of the available evidence. The following sections will report both the descriptive analysis and thematic analysis of the review in detail.

2.4 Descriptive analysis findings

The review sample with a total of 55 contributions consisted of 37 journal articles and 15 conference papers, 2 review papers and 1 book chapter representing a wide array of academic disciplines. On average, 8 studies per year have been published in this area between 2016 and 2022, a trend shown in Figure 2.3. In terms of the study discipline in Figure 2.4, innovation and technology (29%) and Entrepreneurship (27%) make up more than half of the sample. This means that technology innovation and entrepreneurship disciplines have a significant contribution in the business model research for this industry. A considerable portion of the publication were characterised as health/ medicine (18%), management (9%) and Engineering (7%). The sample also included studies from information systems (4%), economics (2%), as well as marketing (2%) and policy (2%). The descriptive findings demonstrated the broad range of disciplines publishing at the intersection of BMs and healthcare innovations.





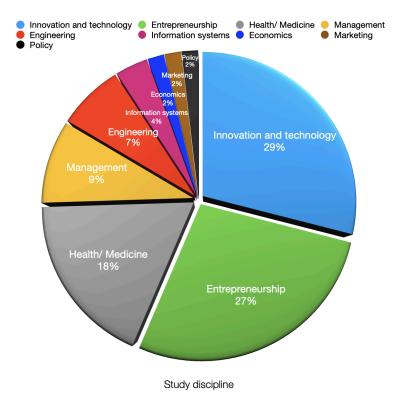
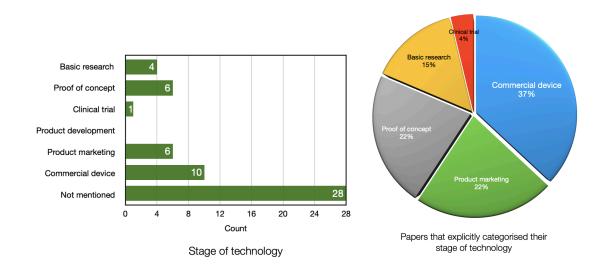
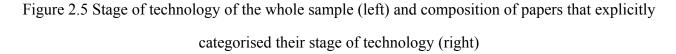


Figure 2.4. Study discipline composition

Since only 27 papers (49%) explicitly mentioned what stage of technology their studies were focused on, the percentage of its composition is visualised in Figure 2.5. Majority of the studies (37%) dealt with a non-specific commercial device/solution which included startup medical devices (Lee, Park and Lee, 2019; Terra, Rodrigues and Maia, 2019), digital technologies (Sundin, Callan and Mehta, 2016; Yang *et al.*, 2016; Khuntia, Mithas and Agarwal, 2017; Rose, Jiang and

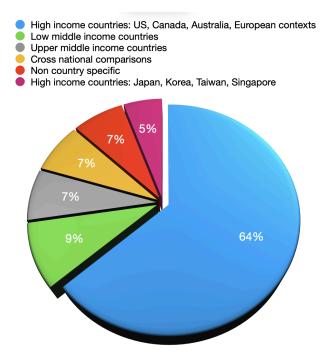
Mangematin, 2017; Laya, Markendahl and Lundberg, 2018; Chen, 2022), Precision Medicine (PM) (Denicolai and Previtali, 2020). While 22 percent in product marketing, another 22 percent in their proof of concept stage, 15 percent as basic research and 4 percent as early-stage technology development. In designing the BM, most research dealt with already existing devices, which have already passed the clinical trial stage. This means that there are less studies dealing with conceptualising the BM in the early stages of technology development.





While the country of authors' affiliated institutions and the study setting may be different, the actual setting of the study is considered in this analysis, shown in Figure 2.6. It has been found that most of the studies were mainly based on high income countries such as in Europe, Australia, Canada and the United States (64%). Therefore, a more Western view of this field is significant. Due to declining fertility and improving mortality, the ageing population has been the focus of the innovations, particularly in high income countries based on the sample. Low middle income countries represent 9% of the sample where medical market for devices (Oshaviani Annisya and Rochman, 2020), Internet of things (IOT) (Nguyen Dang Tuan, Nguyen Thanh and Le Tuan, 2019), mhealth (Sundin, Callan and Mehta, 2016) and digital platform (Viswanadham, 2021) were

focused. Furthermore, other healthcare applications on digital health, ehealth, monitoring, pathology, precision medicine and preventive care were also mentioned.



Country of study

Figure 2.6 Country of study

In terms of methodological underpinnings as shown in Figure 2.7, the majority of the studies are qualitative (67%). Then, 18 percent were conceptual in nature, including special issues, research commentaries and opinion/position papers. Followed by computer modelling (5%), quantitative (5%) and mixed methods (4%).

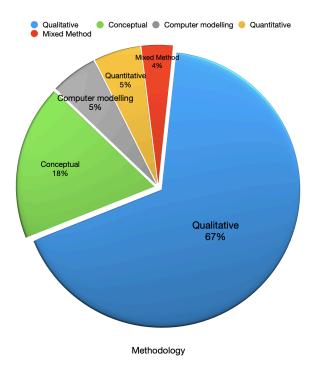


Figure 2.7. Methodology

2.5 Thematic analysis findings

BM design for healthcare technologies is a growing area of interest given the increasing demand for innovative healthcare solutions and the critical role of technology in healthcare delivery. Following the process of thematic analysis, the literature of BM in healthcare technologies was categorised based on the following themes: (1) Frameworks for designing BMs for health technologies; (2) Emerging of healthcare innovations and their BM implications; (3) Key factors in designing BM for healthcare technologies.

Based on the synthesis of the literature, the review is organised into four thematic categories: 1) frameworks for designing business models for health technologies 2) Dimensions of successful business models 3) Challenges and barriers in designing and implementing effective business models 4) Future trends and opportunities. By understanding the key concepts, ideas, and arguments presented in the literature, this review will offer a foundation for further research and contribute to a better understanding of the subject matter.

2.5.1 Business model (BM) foundations as applied in healthcare technologies

In the studies included for this review, depicted in Table 2.5, a BM is conceptualised as an integrated set of decision variables in the strategic, economic and operational areas that explain how an organisation creates and delivers value to both customers and network of partners (Chesbrough and Rosenbloom, 2002; Magretta, 2002; Lee, Park and Lee, 2019; Fürstenau *et al.*, 2021; Korsgaard, Hasenkam and Vesterby, 2021; Oderanti *et al.*, 2021; Schiavone *et al.*, 2021; Sibalija *et al.*, 2021; Viswanadham, 2021) and, importantly, capture value within the 'value network' or 'activity system' of the business (Shafer, Smith and Linder, 2005; Zott and Amit, 2010; Laya, Markendahl and Lundberg, 2018; Fürstenau *et al.*, 2021; Schiavone *et al.*, 2021; Viswanadham, 2021; Chen, 2022). The healthcare technologies in the review BM for healthcare technologies are designed to identify and evaluate the economic, operational, and performance benefits of the technology.

#	Authors	Year	Title	BM value components studied	Level of analysis employed in each study	Theoretical Framework	Study Discipline
1	Al Thawadi M., Sallabi F., Awad M., Shuaib K.	2019	Disruptive IoT-based healthcare insurance business model	value proposition, financial proposition, and the partner chains.	firm/ organisation	business model canvas (BMC)	Innovation and technology
	Bhattacharya S., Wainwright D., Whalley J.	2022	Value and sustainability in technology-enabled care services: a case study from north-east England	Value proposition, Value architecture, Value network, Value realisation	firm/ organisation	value-driven approach: business model based thinking, which identifies four components of a business model	Management
3	Chen N.	2022	Stakeholder Power Analysis of the Facilitators and Barriers for Telehealth Solution Implementation in China: A Qualitative Study of Individual Users in Beijing and Interviews with Institutional Stakeholders	value proposition, customer relationships, and partnerships	institutional	Stakeholder mapping, power analysis business model loT Quadruple aim	Health/ Medicine
4	Chen S.CI., Liu C., Hu R.	2020	Fad or trend? Rethinking the sustainability of connected health	Value proposition, Patients' role, Structure of industry chain, payment, technology	firm/ organisation	value-centric, Connected Health, Business model	Health/ Medicine

5	Christie H.L., Boots L.M.M., Peetoom K., Tange H.J., Verhey F.R.J., de Vugt M.E.	2020	Developing a plan for the sustainable implementation of an electronic health intervention (partner in balance) to support caregivers of people with dementia: Case study	BMC	network	BMC	Health/ Medicine
6	Coan K., Aggoune-Mtalaa W., Bond R., Khadraoui D.	2018	Discussing an economic perspective for MAESTRO, an assessment platform for ambient assisted living products	BM dimensions, strategic	network	-	Innovation and technology
7	Denicolai S., Previtali P.	2020	Precision Medicine: Implications for value chains and business models in life sciences	value architecture, value network	firm/ organisation	Precision Medicine, processed based view of PM	Innovation and technology
8	Denoo L., Yli-Renko H., Clarysse B.	2021	The impact of customer ties and industry segment maturity on business model adaptation in an emerging industry	offering and its value proposition, the market, internal processes and competencies, and economic factor	network	BM adaptation interorganizatio nal learning	Entrepreneurship

9	Dupont D., Beresniak A., Sundgren M., Schmidt A., Ainsworth J., Coorevits P., Kalra D., Dewispelaere M., De Moor G.	2017	Business analysis for a sustainable, multi-stakeholder ecosystem for leveraging the Electronic Health Records for Clinical Research (EHR4CR) platform in Europe	sustainable business model (i.e. definition of the strategic plan, vision, mission and core values, multi-stakeholder value chain, value propositions adapted by stakeholder group, sustainability strategies, business model framework, and market assumptions for conducting advanced business model simulations).	network	Business model innovation	Health/ Medicine
10	Fidrich M., Gyimothy T., Borbas J., Stubnya G.	2018	Structured telemedicine: Economic aspects	key activities, network, revenue, costs	Individual	-	Information systems
11	Fürstenau D., Klein S., Vogel A., Auschra C.	2021	Multi-sided platform and data-driven care research: A longitudinal case study on business model innovation for improving care in complex neurological diseases	value creation, value delivery and value capturing	network	Platform BM, value-based healthcare (VBHC), Business models of multi-sided health platforms	Entrepreneurship

12	Gand K.	2018	Towards conceptual enhancements of the business model canvas: The case of health information technology	BMC	Individual	business model canvas, business model representation as conceptual models	Information systems
13	García-Holgado A., Marcos-Pablos S., García-Peñalvo F.J.	2019	A model to define an ehealth technological ecosystem for caregivers	BMC	Individual	business model canvas	Innovation and technology
14	Garmann-Johnsen N.F., Eikebrokk T.R.	2017	Dynamic capabilities in e-health innovation: Implications for policies	business model (value creation, delivery, and capture)	Individual	Enterprise architecture, Business Process Management	Policy
15	Harrington T.S., Burge T.A.	2018	Connecting digital pharma and e-healthcare value networks through product-service design: A conceptual model	Liu andJia (2010)	institutional	Technology developments, PSS, Value network, Future (digital) business models	Innovation and technology
16	Hofmann P., Oesterle S., Rust P., Urbach N.	2020	Machine learning approaches along the radiology value chain - Rethinking value propositions	Value proposition, value chain	Individual	Radiology value chain	Innovation and technology

17	livari M., Pikkarainen M., Koivumäki T.	2017	How mydata is transforming the business models for health insurance companies	(1) what, comprising offering, value proposition,customer segments, and differentiation, (2) how, covering key operations, basis of advantage, mode of delivery, and selling and marketing, (3) why, describing base of pricing, way of charging, cost elements, and cost drivers, and (4) where are all these items located, internally or externally to the firm, as each part of the business model can be executed through collaborating with outside partners.	firm/ organisation	business model wheel, business model transformation	Entrepreneurship
	Kaštelan Mrak M., Bodiroga Vukobrat N., Sokolić D.	2017	Personalized medicine industry model development [Razvoj modela industrije personalizirane medicine]	Transaction costs economics (TCE) institutional theory, Agency Theory	institutional	transaction costs economics (TCE) institutional theory, Agency Theory	Economics

19	Kelley L.T., Fujioka J., Liang K., Cooper M., Jamieson T., Desveaux L.	2020	Barriers to creating scalable business models for digital health innovation in public systems: Qualitative case study	Revenue/ payment model	firm/ organisation	National Health Service Evaluation Framework	Health/ Medicine
20	Khatab Z., Yousef G.M.	2021	Disruptive innovations in the clinical laboratory: catching the wave of precision diagnostics	value proposition, customer	institutional	Disruptive technologies	Health/ Medicine
21	Khuntia J., Mithas S., Agarwal R.	2017	How Service Offerings and Operational Maturity Influence the Viability of Health Information Exchanges	Service offering and revenue model	Individual	customer value proposition, HIE	Management
	Korsgaard F., Hasenkam J.M., Vesterby M.	2021	Successful implementation of telemedicine depends on personal relations between company representatives and healthcare providers: A qualitative study of business models for Danish home telemonitoring	BMC	firm/ organisation	business model canvas	Entrepreneurship
23	Laya A., Markendahl J., Lundberg S.	2018	Network-centric business models for health, social care and wellbeing solutions in the internet of things	not mentioned, focused on network level analysis	firm/ organisation	business models can be studied at a firm-level and also at a network-level.	Management

24	Lee M., Park S., Lee KS.	2019	What are the features of successful medical device start-ups? Evidence from KOREA	Entrepreneurial skills, technicality, marketability, funds	network	startups business in new market, success factors of startups	Entrepreneurship
	Lehoux P., Silva H.P., Denis JL., Miller F.A., Pozelli Sabio R., Mendell M.	2021	Moving toward responsible value creation: Business model challenges faced by organizations producing responsible health innovations	value proposition, market segments, revenues, value chain, value network ,competitive strategy	firm/ organisation	responsible value creation RRI	Innovation and technology
	León M.C., Nieto-Hipólito J.I., Garibaldi-Beltrán J., Amaya-Parra G., Luque-Morales P., Magaña-Espinoza P., Aguilar-Velazco J.	2016	Designing a Model of a Digital Ecosystem for Healthcare and Wellness Using the Business Model Canvas	BMC	institutional	business model canvas	Health/ Medicine
	Linner T., Solcanu G., van den Boom C., Lingegard H., Istamto T., Proctor G., Lu Y., Steebakkers J.	2017	Business model innovation for value and technology based preventive health care	BMC used	network	Business model	Innovation and technology
28	Malm H., Pikkarainen M., Hyrkäs E.	2020	Impacts of open innovation on company business models: A case study of demand-driven co-creation	Value creation	J	open innovation on companies' business models demand-driven open innovation approach, ecosystemic	Management
29	Marceglia S., Rigby M., Alonso A., Keeling D., Kubitschke L., Pozzi G.	2018	DEDICATE: Proposal for a conceptual framework to develop dementia-friendly integrated eCare support	Value proposition, value network	Individual	business model innovation	Engineering

30	Marcos-Pablos S., García-Holgado A., García-Pẽalvo F.J.	2019	Modelling the business structure of a digital health ecosystem	BMC	institutional	BMC initial Business Process Model and Notation tool	Innovation and technology
31	Mueller C.	2020	mHealth business model framework for the maternal and baby segment: A design science research approach	customer value proposition, value creation and value capture	Individual	business model	Innovation and technology
32	Nguyen Dang Tuan M., Nguyen Thanh N., Le Tuan L.	2019	Applying a mindfulness-based reliability strategy to the Internet of Things in healthcare – A business model in the Vietnamese market	BMC, 1) Speed of decision making; 2) Trust and Accountability; 3) Liability; 4) Workforce competency.	firm/ organisation	business model canvas Mindfulness-ba sed reliability theory	Entrepreneurship
33	Nigam N., Mbarek S., Boughanmi A.	2021	Impact of intellectual capital on the financing of startups with new business models	non specific, but focused on Intellectual property (VP, resources)	firm/ organisation	Signaling theory	Entrepreneurship
34	Nikou S., Bouwman H.	2017	Mobile health and wellness applications: A business model ontology-based review	VISOR. V = value proposition, I = interface, S = service platform, O = organising model, and R = revenue model.	Individual	business model ontology	Entrepreneurship
35	Oderanti F.O., Li F.	2016	A holistic review and framework for sustainable business models for assisted living technologies and services	Value proposition (ii) Product innovation (iii) Infrastructure management (iv) Customer relations management (v) Financial viability and sustainability (vi) Stakeholder credibility (vii) Revenue Streams	firm/ organisation	business model "Diffusion of Innovation	Management
36	Oderanti F.O., Li F., Cubric M., Shi X.	2021	Business models for sustainable commercialisation of digital healthcare (eHealth) innovations for an increasingly ageing	ВМС	firm/ organisation	business model, BM in ehealth, Information Systems (IS)	Entrepreneurship

			population: (A new business model for eHealth)			Success Model theory.	
37	Oshaviani Annisya E., Rochman T.	2020	Designing a Medical Device Marketplace Business Model Using the Lean Startup Method	BMC value proposition, customer segments, channel, customer relationship, revenue stream, key activities, key partners, key resources, and cost structure.	Individual	Business Model Canvas, Business Process Model and Notation	Engineering
38	Palas M.J.U., Bunduchi R.	2021	Exploring interpretations of blockchain's value in healthcare: a multi-stakeholder approach	value proposition, value capture, value network and value delivery	firm/ organisation	Resource-base d view to explain the business value of IT	Innovation and technology
39	Pereira S.G.M., dos Santos Medina F.A., Gonçalves R.F., da Silva M.T.	2016	System thinking and business model canvas for collaborative business models design	BMC	Individual	Systems thinking, business model canvas, Soft Systems Methodology	Entrepreneurship
40	Pundziene A., Heaton S., Teece D.J.	2019	5G, dynamic capabilities and business models innovation in healthcare industry	Target user, value in use, value exchange, compensation	firm/ organisation	Dynamic Capabilities and Business Models Innovation, 5G as an enabling technology and healthcare industry	Entrepreneurship
41	Rose J., Jiang Y., Mangematin V.	2017	Technological innovation mediated by business model innovation: App developers moving into health	four business model dimensions: identifying customers, engaging with customers, monetisation processes, and logistics and governance of the firms.	firm/ organisation	Business model innovation	Innovation and technology

42	Schiavone F., Mancini D., Leone D., Lavorato D.	2021	Digital business models and ridesharing for value co-creation in healthcare: A multi-stakeholder ecosystem analysis	BMC	firm/ organisation	Digital BM. sharing economy (SE),	Marketing
	Sibalija J., Barrett D., Subasri M., Bitacola L., Kim R.B.	2021	Understanding value in a healthcare setting: An application of the business model canvas	customer segments and value propositions BMC	Individual	business model canvas	Entrepreneurship
	Sundin P., Callan J., Mehta K.	2016	Why do entrepreneurial mHealth ventures in the developing world fail to scale?		Individual	mHealth	Engineering
45	Tao J., Yu S.	2019	Developing conceptual pss models of upper limb exoskeleton based post-stroke rehabilitation in China	Value chain, customers,	Individual	PSS	Innovation and technology
46	Terra N., Rodrigues J.C., Maia C.	2019	Business model evolution in university startups of the healthcare sector	BMC	firm/ organisation	business model canvas	Entrepreneurship
	Thamjamrassri P., Song Y., Tak J., Kang H., Kong HJ., Hong J.	2018	Customer discovery as the first essential step for successful health information technology system development	BMC	Individual	Customer discovery	Engineering
	Thiebes S., Toussaint P.A., Ju J., Ahn JH., Lyytinen K., Sunyaev A.	2020	Valuable genomes: Taxonomy and archetypes of business models in direct-to-consumer genetic testing	 (1) strategic choices (eg, customers, target markets, value propositions, revenues and pricing, competitors), (2) value creation (eg, key resources, assets, processes), (3) value network (eg, information and product flows between an organisation, its suppliers, and customers), and (4) capturing value (eg, profit-making mechanisms). 	firm/ organisation	BM, Direct to consumer	Health/ Medicine
49	van Dijk-De Vries A., Stevens A., van der	2020	How to support a co-creative research approach in order to foster impact. The development of	BMC	network	business model canvas, co creation	Health/ Medicine

	Weijden T., Beurskens A.J.H.M.		a Co-creation Impact Compass for healthcare researchers				
50	Verhees B., Van Kuijk K., Simonse L.	2018	Care model design for E-health: Integration of point-of-care testing at dutch general practices	the information and connectivity, (b) the revenue, (c) the value, (d) the transactions, and (e) actors structure, and (f) the governance	Individual	POCT	Innovation and technology
51	Vimarlund V., Mettler T.	2017	Business Models in Two-Sided Markets (Analysis of Potential Payments and Reimbursement Models That Can Be Used)	Revenue model	Individual	revenue models	Entrepreneurship
52	Vimarlund V., Nikula N., Nøhr C.	2021	Business models and eHealth social innovations for social care services: Serving the two sides of the market	Structure of the market, Customer relationship, Accessibility to brokers and/ or intermediaries, Value added	network	Social innovation, business model	Innovation and technology
53	Viswanadham N.	2021	Ecosystem model for healthcare platform	Customer value proposition (CVP), Value creation formula and Partner network	network	Platform BM 3 components, ecosystem model	Entrepreneurship
	Ward G., Fielden S., Muir H., Holliday N., Urwin G.	2017	Developing the assistive technology consumer market for people aged 50-70	BMC used	Individual	Electronic assisted living technologies (eALT)	Innovation and technology
	Yang YT., Iqbal U., Chen YM., Su S., Chang YM., Handa Y., Lin NP., Hsu YH.E.	2016	Co-creating value through demand and supply integration in senior industry-observations on 33 senior enterprises in Taiwan	ВМС	firm/ organisation	Value co-creation design, value co-creating process, BMC	Health/ Medicine

BM frameworks

One important aspect of the literature on BM design for healthcare technologies revolves around the development of various frameworks to aid in the design and implementation of successful BMs. For instance, Chesbrough (2006) suggests the adoption of the Open Innovation framework, which broadly involves collaboration with external partners to develop novel healthcare technologies, to complement traditional approaches of healthcare innovation. Similarly, studies have utilised the Business Model Canvas (BMC) by Osterwalder et al. (2005), a visual tool that outlines nine essential components of a BM and their relationships to help identify key value propositions, target customer segments, and other critical elements of a successful BM (León *et al.*, 2016; Oderanti and Li, 2016; Pereira *et al.*, 2016; Linner *et al.*, 2017; Nikou and Bouwman, 2017; Gand, 2018; García-Holgado, Marcos-Pablos and García-Peñalvo, 2019; Marcos-Pablos, García-Holgado and García-Peñalvo, 2019; Terra, Rodrigues and Maia, 2019; Korsgaard, Hasenkam and Vesterby, 2021; Sibalija *et al.*, 2021; Viswanadham, 2021). Zott et al. (2011) also suggest a framework called the Activity System Perspective to analyse and design BMs in healthcare that helps identify the interdependencies among various components.

In designing a BM for health-related ecosystems, majority of the studies in the SLR summarised in Table 2.6, utilised the concept of BMC with nine model components by Osterwalder and Pigneur. The BMC is a widely used framework which enables businesses to develop new and document existing business models by mapping the value proposition, key activities, key resources, key partners, cost structure, customer relationships, distribution channels and revenue. Particularly, it is used to develop value-driven business models (Bhattacharya, Wainwright and Whalley, 2021). While studies utilised the BMC as a foundation, they recognised the need to develop a BM specific for the healthcare technology such as in telehealth devices (Chen, 2022) and connected health (Chen, Liu and Hu, 2020).

BM definition/ framework used	References
Business model canvas (Osterwalder and Pigneur, 2010)	(León <i>et al.</i> , 2016; Pereira <i>et al.</i> , 2016; Yang <i>et al.</i> , 2016; Linner <i>et al.</i> , 2017; Ward <i>et al.</i> , 2017; Coan <i>et al.</i> , 2018; Gand, 2018; Thamjamrassri <i>et al.</i> , 2018; Al Thawadi <i>et al.</i> , 2019; García-Holgado, Marcos-Pablos and García-Peñalvo, 2019; Marcos-Pablos, García-Holgado and García-Peãlvo, 2019; Nguyen Dang Tuan, Nguyen Thanh and Le Tuan, 2019; Terra, Rodrigues and Maia, 2019; Christie <i>et al.</i> , 2020; Mueller, 2020; Oshaviani Annisya and Rochman, 2020; van Dijk-De Vries <i>et al.</i> , 2021; Oderanti <i>et al.</i> , 2021; Sibalija <i>et al.</i> , 2021; Viswanadham, 2021)
Value-driven approach (Al-Debei and Avison, 2010)	(Bhattacharya, Wainwright and Whalley, 2021)
Business model for IoT systems (Dijkman <i>et al.</i> , 2015)	(Chen, 2022)
Conventional Connected Health Business Model (Chen and Kharabsheh, 2019)	(Chen, Liu and Hu, 2020)
Business model wheel (Ahokangas, Juntunen and Myllykoski, 2014)	(Iivari, Pikkarainen and Koivumäki, 2017)
VISOR Framework (Sawy and Pereira, 2012)	Nikou2017-hz

Table 2.6 BM frameworks cited by the SLR studies

The BM for healthcare technologies is composed of a number of elements, including the technology's value offering, value delivery, value network and value capture. The first key element connecting the literature surveyed is the shared view that the value of BM is not just linked to technology, but to the identification of a supporting BM where stakeholders' interests are represented and all appropriate operational components are considered:

- customer segmentation for whom is the health solution creating value?
- value proposition what does the health solution offer to the market?

- communication and distribution channels through which communication and distribution channels is the health solution reaching the targeted users?
- customer relationships what different customer relationships are developed and maintained in the BM?
- revenue streams what are the revenue streams of the health solution?
- key resources what are the core capabilities of the health solution?
- key activities what are the main activities in developing resources into a value proposition?
- partner network with which partners have they worked together throughout the health solution process?
- cost structure what are the most important costs of the health solution?

Value co-creation for sustainable BM

SLR papers which looked at the BM in a network level encompass the subtheme of value co-creation among stakeholders in the healthcare value chain for sustainable BM development (Dupont *et al.*, 2017; Linner *et al.*, 2017; Coan *et al.*, 2018; Lee, Park and Lee, 2019; Christie *et al.*, 2020; van Dijk-De Vries *et al.*, 2020; Denoo, Yli-Renko and Clarysse, 2021; Fürstenau *et al.*, 2021; Vimarlund, Nikula and Nøhr, 2021; Viswanadham, 2021). According to the concept of value co-creation, the value is created in the process of interaction between customers and an enterprise. To assess the effects of co-creation, the enterprise should focus on the overall value in co-creating experience, with emphasis on communication, access, risk evaluation and transparency during the co-creating process. Involving all important stakeholders in a value-driven dialogue on what the technology should accomplish contributes to the whole development of health technology implementation, thus promoting value co-creation among all partners (van Dijk-De Vries *et al.*, 2020). Active participation of stakeholders in health research practice is important to generate societal impact of outcomes, as innovations will more likely be implemented and disseminated in

clinical practice (Jull, Giles and Graham, 2017). Such user-lead innovations that can arise from patients as well as healthcare professionals are an important source of ideas for incumbent firms and new entrants. Indeed, a sustainable BM must consider multiple stakeholder perspectives including customers, employees, investors, regulators, and the environment. This approach can be used to create a BM that is both financially and socially sustainable.

Generally, developing BM for healthcare requires a combination of resources and competences from different fields, particularly from biomedical sciences, engineering and clinical research. In other words, the value creation process is not limited to single firm boundaries; it is rather considered that value is co-created among different actors that belong to a network (Bhattacharya, Wainwright and Whalley, 2021). Effective co-creation requires mutual understanding and alignment of preferences, needs, and capabilities between customers and suppliers. This becomes especially relevant when solutions are developed at the convergence of diverse industries, where technological innovation intersects with novel concepts and methods of interaction among actors (Laya, Markendahl and Lundberg, 2018).

2.5.2 Emerging of healthcare innovations and their value offering

Emerging technologies in the SLR included startup medical devices (Lee, Park and Lee, 2019; Terra, Rodrigues and Maia, 2019), digital technologies (Sundin, Callan and Mehta, 2016; Yang *et al.*, 2016; Khuntia, Mithas and Agarwal, 2017; Rose, Jiang and Mangematin, 2017; Laya, Markendahl and Lundberg, 2018; Chen, 2022), Precision Medicine (PM) (Denicolai and Previtali, 2020) as presented in section 2.4. These applications vary on their stage of development and adoption. In designing the BM, the majority of research dealt with already existing devices, which have already passed the clinical trial stage. Only that there are less studies dealing with conceptualising the BM in the early stages of technology development.

The value offering dimension is defined by a unique benefit that a healthcare service offers. This benefit is expressed in outcomes and a defined user group. For example, in telemedicine, outcomes represent effects such as improved quality of life, enhanced accessibility, patient empowerment, etc (Korsgaard, Hasenkam and Vesterby, 2021). The benefits of healthcare innovation can be realised at three distinct levels: individual, health system, and societal. On an individual level, improvements in patients' health outcomes and enhanced quality of life can be achieved. At the health system level, gains in efficiency, cost reduction, and increased accessibility to healthcare, particularly for rural and underserved communities facing a shortage of health staff, can be realised. Finally, at the societal level, innovations can make significant contributions to the economy in the context of a growing global market. Some services are patient-centric, such as remote monitoring of patients from their homes through devices that acquire and transmit physiological data, while others are provider-centric and facilitate the exchange of information or medical expertise between healthcare professionals at different locations. The mode of service delivery may vary depending on the user group.

In general, patients play a key role in determining value and patient-centred care is a key consideration in designing the BM for this sector (Keeling, 2006; Lester, 2009; Ulman, Ray and Raikar, 2013; Song, 2017). This supports the fact that, indeed, healthcare systems are targeted on value and care delivery (Quinn, 2010; Verhees, van Kuijk and Simonse, 2017). It is also interesting to note that in the healthcare sector, doctors are not only the primary customers for medical devices but they are often the innovators of the technologies (Davey *et al.*, 2011).

2.5.3 Key factors influencing BM design

The healthcare industry is continuously evolving, driven by advancements in technology, increasing demand for high-quality and affordable healthcare services as well as the changing needs of patients and healthcare providers. In this context, business model design plays a critical role in the

development, commercialisation and successful adoption of healthcare technologies (Gand, 2018; Laya, Markendahl and Lundberg, 2018; Nguyen Dang Tuan, Nguyen Thanh and Le Tuan, 2019; Chen, Liu and Hu, 2020; Denicolai and Previtali, 2020; Kelley et al., 2020; Bhattacharya, Wainwright and Whalley, 2021; Fürstenau et al., 2021; Oderanti et al., 2021; Palas and Bunduchi, 2021). Several factors influence the design of healthcare technology BMs. These include technological factors (e.g., innovation type, technology maturity, and intellectual property), market segments, and regulatory factors (e.g., market size, customer environment), and organisation-specific factors (e.g., resources, capabilities, and culture) (Chesbrough, 2010; Harrington and Burge, 2018; Lee, Park and Lee, 2019; Thiebes et al., 2020; Bhattacharya, Wainwright and Whalley, 2021; Khatab and Yousef, 2021; Korsgaard, Hasenkam and Vesterby, 2021; Chen, 2022). Furthermore, stakeholder requirements, financial considerations, and unique characteristics of the healthcare industry (e.g., reimbursement systems and the role of governments and insurers) are essential aspects in shaping BM design for healthcare technologies (Teece, 2010; Fredriksson et al., 2017; Khuntia, Mithas and Agarwal, 2017; Rose, Jiang and Mangematin, 2017; Vimarlund and Mettler, 2017; Gand, 2018; Mueller, 2020; Denoo, Yli-Renko and Clarysse, 2021).

2.5.3.1 Value offering and value delivery

The value proposition and customer segmentation are another key dimension in the design of successful BMs for healthcare technologies. Numerous studies underscore the significance of organisations in clearly defining their target market and crafting products and services that align with the distinctive requirements and preferences of these customers (Dupont *et al.*, 2017; Ward *et al.*, 2017; Fidrich *et al.*, 2018; Harrington and Burge, 2018; Christie *et al.*, 2020). In the healthcare industry, identifying and prioritising customer segments can help businesses to differentiate their offerings, improve the value proposition, and ultimately, increase customer satisfaction and loyalty

(Verhees, van Kuijk and Simonse, 2017; Nguyen Dang Tuan, Nguyen Thanh and Le Tuan, 2019; Tao and Yu, 2019; Denicolai and Previtali, 2020; Khatab and Yousef, 2021).

Many studies discuss the components of successful BMs in healthcare technologies. According to Altman et al. (2015), three key dimensions should be considered in developing a successful BM in the healthcare industry: value proposition, value network, and revenue/cost structures. In a similar vein, Chatterjee (2013) emphasises the importance of customer value, strategic differentiation, and operational effectiveness as vital components of healthcare BMs. A literature review by Büyüközkan et al. (2016) stresses the importance of incorporating aspects such as technology-oriented service, integration of product life cycle, resource-based service structure, and customer-oriented business design to ensure success in the healthcare domain.

In alignment with the perspectives of Zott and Amit (2010), a BM could be perceived as an activity system that describes the set of activities that a firm performs, how they are performed and who performs them. The activity system in the framework represents how the envisaged value creation is delivered. The type of facility describes the delivery channel of healthcare technology. Factors influencing the ultimate adoption of technology in the health sector encompass several dimensions. These include the establishment of clinical standards, regulatory frameworks at the institutional level, effective management of intellectual property rights (IPR), policy considerations, interdependence among various markets (e.g., devices, insurance, clinical services), and long-term changes in service delivery. Additionally, governmental priorities at the national and regional levels play a crucial role in shaping the landscape for the innovative delivery of clinical services (Sundin, Callan and Mehta, 2016). The BM should also consider the potential risks and challenges associated with the technology, such as privacy and security of patient data, as well as regulatory and legal compliance.

2.5.3.2 Key stakeholders in the BM value network

Partnerships and networks are another important dimension in the design of successful business models for healthcare technologies. According to Baden-Fuller and Haefliger (2013), BMs should incorporate strategic partnerships and networks in order to access resources, capabilities, and market opportunities that would otherwise be unavailable to the organisation. In the healthcare industry, partnerships with key stakeholders such as hospitals, physicians, patients, payers, and regulators can facilitate the adoption and diffusion of innovative technologies and improve the overall performance of the BM (Sabatier, Craig-Kennard, & Mangematin, 2012).

The business network perspective provides a valuable framework in biotech innovations especially those that integrate digital and connected platforms. The value emerges at the intersection of the resources and the capabilities from different actors (Jaakkola and Hakanen, 2013), including customers as co-creators of value (Lusch, Vargo and O'Brien, 2007). The researcher has categorised the actors and organisations in the healthcare value network, as shown in Figure 2.8. It depicts the flow from funders to producer to provider to beneficiaries. The arrow below consists of the BM cycle: value creation, value delivery and value capture; where it has been strategically integrated in the healthcare value chain. The funders are the stakeholders who pay for the service/product. The producers are the organisations/ firms manufacturing and developing the medical device/solution. The healthcare providers are the ones mainly providing care for the patients and community. The users are considered as the people who will directly use the service/product. The beneficiaries are the stakeholders who gain benefits in terms of economics or social value.

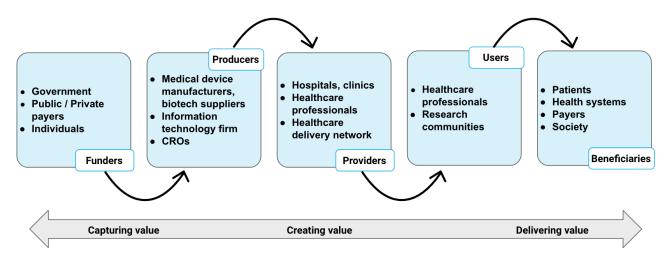


Figure 2.8 Multi-stakeholder healthcare value chain.

The stakeholders are interdependent on each other. For the BM, it is necessary to take into account the different perspectives of the available stakeholders because they influence decision making. A brief depiction of different stakeholder interests in healthcare is presented in Table 2.7. It must also be noted that not all stakeholders are equal because they will have different interests and power.

Table 2.7. Stakeholders and interests in healthcare	adopted from (Rouse, 2008).

Stakeholder	Risk Management	Prevention	Detection	Treatment
Public	e.g., buy insurance	e.g., stop smoking	e.g., get screened	
Delivery System	Delivery System		Clinicians ^a	Clinicians and providers ^b
Government	Medicare, Medicard, Congress	NIH, Government CDC, DoD, et al.	NIH, Government CDC, DoD, et al.	NIH, Government CDC, DoD, et al.
Non-Profits		American Cancer Society, American Heart Association, et al.	American Cancer Society, American Heart Association, et al.	American Cancer Society, American Heart Association, et al.
Academia	Business schools	Basic science disciplines	Technology and medical schools	Medical schools
Business	Employers, insurance companies, HMOs		Guidant, Medtronic, et al.	Lilly, Merck, Pfizer, et al.

Based on the literature review, the identification of the key stakeholders involved in the BM development is crucial along with the technological, economic and social values of healthcare innovation. Table 2.8 showcases the findings on the key actors, factors and considerations in the BM development based on selected studies. The main actors are healthcare providers (who are the end-users of the innovation and provide service to the patients), producers (who develops the medical device such as manufacturer, industry, entrepreneur) and funders (who pays for the product/service in healthcare). Their inputs in the BM is crucial since stakeholders appear to have common goals but all speak very different languages and possess different expectations since they are driven by very different goals and needs (Naylor and Cole, 2010; Fürstenau *et al.*, 2021; Lehoux *et al.*, 2021; Oderanti *et al.*, 2021; Palas and Bunduchi, 2021; Schiavone *et al.*, 2021; Chen, 2022).

Author, Year	Findings: Key actors involved in BM development	BM factors and considerations
Aspinall, et al., 2007	pharmaceutical companies, regulatory, Physicians, payers	Transforming pharmaceutical giants A subpopulation may turn out not to be so small. Focusing clinical trials on targeted subpopulations would slash their size, duration, and cost. Payers are beginning to recognize the real and increasing cost of administering Paying for performance. ineffective drugs and treating side effects Overhauling regulation Changing physicians' habits
Bradley, et al., 2015	Specialists and patient advocates, payers	Stakeholders should explore new business models and align earlier on pre- and postlaunch evidentiary requirements. regulatory and reimbursement approaches (including conditional approval, adaptive licensing, managed entry, conditional reimbursement, and risk-sharing agreements) courageous leadership, collaboration, and creativity
Carland, et al., 2018	importers, distributors, and retailers	business strategy and long-term relevance and profitability
Engel, et al., 2016	experts in diagnostics and physicians working at the front line	health system strengthening with patient centred delivery; strengthened innovation processes; improved knowledge base; harmonised guidelines and evaluation; supply

Table 2.8. Key actors involved in the BM development and factors based on SLR.

		chain innovations; and mechanisms for ensuring quality and capacity. Engaging and connecting different actors involved with diagnostic development and use is paramount for improving diagnostics.
Enzmann, et al., 2012	Radiologists	To remain relevant and competent, radiology will need to incorporate advances in molecular (and systems) biology of disease (and health) to its imaging repertoire and adapt its business model accordingly.
Fanale, et al., 2012	insurance payers, hospital partnerships, clinicians	Collaborative network
Friedman, et al., 2001	Laboratory information system/application service provider/laboratory portal vendor, in vitro diagnostic manufacturer, Pharmaceutical/biotechnology manufacturer	market forces, collaborative networks are organised and managed, and offer higher quality testing services at lower cost
Fugel, et al., 2016	manufacturers, regulators, payers and providers which must be addressed in a collaborative and synergistic way to enhance patient outcomes.	Adaptive clinical trials in cooperation with regulatory bodies will play a pivotal role in this process to reduce time to market. Alignment of incentives will be required among all stakeholders to realise the full potential of SM interventions
Garbuio, et al., 2019	payors, users	Value partnered with user, identify who will pay Identify stage of the company at, effectiveness of solution, what does the company sell, company resources and capacity clinicians acceptance
Hajiheydari, et al., 2013	health experts, traditional physicians, pharmacist, technical experts, health governance system, EHR system, finance organisation(s), healthcare database and healthcare knowledge.	key partner Healthcare database and knowledge
Housman, et al., 2011	patients, physicians, regulators, payors	Manufacturers of innovative diagnostics need to engage clinicians and other stakeholders with value propositions that are clearly communicated and supported through evidence and funding real-world population studies through manufacturer-payor partnerships. must address the evolving needs of multiple stakeholders Balancing innovation with clinical benefit
Johnson, et al., 2016	Payers, industry, vendors	Payers want to know that the fees they spend on PM testing will help them to provide quantifiably better services to their customers.
Kurtzman, et al., 2005	physician, entrepreneur	-Consumer involvement in healthcare decision making -mixed product-and service model -regulatory process that can be simpler and more straightforward -combination of proprietary technology and demonstrable clinical and economic benefits

		is key. -pipeline is essential -company's ability to generate revenues -collaborative efforts, adequate third-party payment
Lester, et al., 2009	pharma and the diagnostics industry payers, provider, Regulatory, Patients/consumers	Technology driver successful exit strategy health IT component
Masum, et al., 2013	R&D funders, global health organisations, policy makers, Technology developers, suppliers	Innovation potential
Metcalfe, et al., 2010	Academic groups, Consortia, Biotech companies, Pharma companies	Collaboration of stakeholders who are discovering and developing biomarkers with potential utility in the clinical diagnostics market
Miller, et al., 2012	pharma and in vitro diagnostics companies and payors	pharma and in vitro diagnostics companies and payors need to acquire new skills and capabilities in order to lead in future markets
Mittra, et al., 2012	Policymakers, regulators, pharmaceutical firms and diagnostic companies	Business models will require innovation in product development and also in developing closer partnerships between different types of commercial organisation (pharmaceutical firms and diagnostic companies) and the currently diverse markets that they serve. This area will also require smarter regulatory environments to facilitate co-development of a therapy and diagnostic, currently subject to quite different regulatory regimes.
Naylor, et al., 2010	pharmaceutical companies, Companion Diagnostic companies, CRO companies, CD testing laboratory, Physician/healthcare provider, Patient/consumer, Payor, Regulatory authorities	All the different stakeholders perceive different value propositions Clinical, technical, regulatory, availability, reimbursement, legal, commercial Alignment of partners with different business models Assess needs and priorities before seeking a best fit partner Consider what are potential partners' business models/risk sharing strategies; and competing products.
Pruthi, et al., 2013	Patient, provider	supported via government reimbursement and lifting of licensure barriers that discourage telehealth models of healthcare delivery Reimbursement and payment model
Quinn, et al., 2010	payer	payer decisions Pricing of novel diagnostic tests Policy-makers are necessarily penalised by creating pricing rules that prevent the development of products that do not yet exist.
Silva, et al., 2018	academic medical centres (AMCs) and molecular diagnostic companies	Open innovation is touted as a business method where channels of external cooperation can be synergistic.
Simiyu, et al., 2010	investors, research partnerships, licensing opportunities, and revenue from contract manufacturing	Technology assessment and institutional IP policy open innovation business model

So, et al., 2014	policy-makers, pharmaceutical firms	New business models should help reengineer not just the financing, but also the way novel antibiotics are developed and brought to market. This will require applying the 3Rs for innovating novel antibiotics: sharing resources, risks, and rewards		
Song, et al., 2017 University, Research institutes, Consulting businesses		technological advancements, patient empowerment and the decline in pharmaceutical blockbuster R&D efficiency Maximising patient benefit		
Tambuyzer, et al., 2010	Regulators, payer, healthcare provider, patients	sustained engagement with the patient groups, treating physicians as well as other stakeholders. New players in the healthcare field will have become fully integrated partners and stakeholders in the healthcare systems.		
Tiriveedhi, et al., 2018	prescriber, the patient, and the payer	value analysis Innovative cost efficiency strategies novel healthcare economic models involving, hospitals, pharmaceutical industries, and reimbursement agencies		
Ulman, et al., 2013	healthcare manufacturers and administrator Customer Segment: POCT manufacturers realise that though patients are the beneficiaries of POCT, it is the Government and the Non-Governmental Organisations (NGO) that are the real customers especially in rural areas.	A business model can only be successful if customers are provided with a value proposition that is affordable and addresses a special need.		
Verhees, et al., 2018	The actors involved within the business model are (1) NHG, (2) health insurer, (3) diagnostic centre, (4) general practice, (5) ICT company, (6) POCT product, and (7) manufacturer.	only if the POCT diagnosis results lead to immediate therapeutic decisions, do they successful integration into the health system across organisations		
Wagner, et al., 2012	academic researchers, industrial developers, clinicians, investors, policy makers	collaborative arrangement between investigators involved in discovery research, clinicians, assay developers and statisticians, investigators have to willing to have their assays and biomarkers verified by an independent laboratory.		

Any fundamental and effective changes will need the involvement of all stakeholders to ensure that the changes made in the healthcare system are beneficial to all. Thus, achieving effectiveness in healthcare innovation requires the active involvement and collaboration of various stakeholders, including industry players, funding sources, public policy influencers, technology developers, customers, and accountability mechanisms. The healthcare sector's complexity, characterised by diverse stakeholders and cross-departmental interactions, requires a radical level of innovation to successfully address the multifaceted needs within the industry. (Rose, Jiang and Mangematin, 2017; Pundziene, Heaton and Teece, 2019; Terra, Rodrigues and Maia, 2019; Chen, Liu and Hu, 2020; Denoo, Yli-Renko and Clarysse, 2021; Palas and Bunduchi, 2021).

2.5.3.3 BM Value capture

One of the dimensions of successful BM design for healthcare technologies is the valuation and revenue model (Khuntia, Mithas and Agarwal, 2017; Nikou and Bouwman, 2017; Vimarlund and Mettler, 2017; Fidrich *et al.*, 2018). According to Chesbrough and Rosenbloom (2002), creating value for customers and capturing value for the organisation are key objectives of BMs. They suggest that revenue models should be designed to maximise customer value while ensuring the financial sustainability of the organisation. In healthcare technologies, aligning the revenue model with the value proposition is crucial to attract and retain customers, as well as to ensure long-term profitability and growth (Nguyen Dang Tuan, Nguyen Thanh and Le Tuan, 2019; Malm, Pikkarainen and Hyrkäs, 2020; Mueller, 2020; Bhattacharya, Wainwright and Whalley, 2021; Lehoux *et al.*, 2021; Nigam, Mbarek and Boughanmi, 2021).

The value capture dimension of the BM is usually discussed for its financial implications. Discussions of monetisation have often stopped with pricing ignoring important issues of timing and effectiveness which are paramount additional value capture dimensions for organisations (Teece, 2010; Harrington and Burge, 2018). Concerning pricing, there are many other possibilities, including negotiated prices, and price based on value delivered. Value capture should consider how the technology can be used to reduce costs, improve efficiency, and improve patient outcomes. A healthcare technology BM should also include a timeline of implementation, a strategy for market penetration, and a pricing model. Additionally, it should address the potential return on investment and any potential revenue streams that may be generated through the use of the technology (Yang *et al.*, 2016; Dupont *et al.*, 2017; Palas and Bunduchi, 2021; Schiavone *et al.*, 2021).

Furthermore, crucial considerations include the timing of revenue collection, whether it occurs before the sale, at the point of sale, or after the sale. A significant decision in the BM for durable goods involves choosing between renting a machine or selling it outright. Opting for a rental system entails a distinct form of customer engagement and offers flexibility in aligning income collection with value-based pricing (Khuntia, Mithas and Agarwal, 2017; Denicolai and Previtali, 2020).

2.6 Challenges and barriers in designing healthcare technology BM

Designing and implementing successful business models for healthcare technologies present several challenges. The literature also highlights various challenges and barriers in designing and implementing effective business models for healthcare technologies. These include an increasingly complex regulatory environment, pressure to demonstrate value and cost-effectiveness, the need for interdisciplinary collaboration, and the potential for disruptive innovation (Linner *et al.*, 2017; Terra, Rodrigues and Maia, 2019; Bhattacharya, Wainwright and Whalley, 2021; Lehoux *et al.*, 2021; Oderanti *et al.*, 2021; Vimarlund, Nikula and Nøhr, 2021; Chen, 2022). Moreover, the growing emphasis on patient-centred care and the integration of digital health technologies necessitates innovative and adaptive BMs that can address evolving healthcare needs (Fredriksson *et al.*, 2017; Rose, Jiang and Mangematin, 2017; Khatab and Yousef, 2021).

As some studies highlight, one of the primary challenges in designing healthcare BMs is the complex regulatory environment within the healthcare industry (Garmann-Johnsen and Eikebrokk, 2017; Kaštelan Mrak, Bodiroga Vukobrat and Sokolić, 2017; Nikou and Bouwman, 2017; Rose, Jiang and Mangematin, 2017; Terra, Rodrigues and Maia, 2019; Mueller, 2020; Thiebes *et al.*, 2020). Other challenges identified include the lack of financial resources, limited access to innovative technology, and a high degree of uncertainty with respect to reimbursement and pricing strategies (Oderanti and Li, 2016; Bhattacharya, Wainwright and Whalley, 2021; Nigam, Mbarek

and Boughanmi, 2021; Palas and Bunduchi, 2021; Vimarlund, Nikula and Nøhr, 2021). Further, O'Brien et al. (2015) underline the importance of addressing ethical issues, as well as concerns related to data privacy and security, while designing business models for healthcare technologies. Despite these challenges, the healthcare technology sector presents numerous opportunities for innovative BMI design (Chen, Liu and Hu, 2020). By harnessing advances in biomedical research, digital technology, and data analytics, healthcare organisations can create value propositions that address unmet medical needs, improve patient outcomes, and reduce healthcare costs (Kelley *et al.*, 2020; Malm, Pikkarainen and Hyrkäs, 2020; Bhattacharya, Wainwright and Whalley, 2021; Fürstenau *et al.*, 2021; Oderanti *et al.*, 2021; Chen, 2022). Furthermore, new partnerships and collaboration models can enable healthcare innovators to access resources, expertise, and markets more effectively, accelerating the development and diffusion of lifesaving technologies (Laya, Markendahl and Lundberg, 2018; García-Holgado, Marcos-Pablos and García-Peñalvo, 2019; Pundziene, Heaton and Teece, 2019; Malm, Pikkarainen and Hyrkäs, 2020; Vimarlund, Nikula and Nøhr, 2021).

2.7 Knowledge gaps

After conducting an extensive analysis of the existing literature, a number of research gaps have come to light:

1. There is an increasing need for an effective framework to guide the development of healthcare technologies. While there are many traditional BMs used in other industries, they may not be as applicable when it comes to medical technologies. This limitation arises from the unique nature of health technologies, where a BM successful for one technology may not suit another. Consequently, an empirical investigation is needed to develop a BM that encompasses the complete healthcare technology development cycle. This includes the

development, deployment, management and evaluation of the technology. With the lack of research into BM for healthcare technology developments there is still no overarching framework or guideline that provides healthtech researchers/ entrepreneurs the necessary direction to design their BM, particularly in the diagnostic field.

- 2. In terms of conceptual underpinnings, most studies define BM in terms of the Business Model Canvas (BMC) (Hajiheydari, Khakbaz and Farhadi, 2013; Ulman, Ray and Raikar, 2013; Meertens, Staring and Sikkel, 2016). However, there is still a limitation in the BMC (Osterwalder and Pigneur, 2010) because it faces a limitation in its applicability to the intricate landscape of healthcare technologies. BMC is often too broad to effectively address the specific developments in healthcare technology development (Terra, Rodrigues and Maia, 2019; Korsgaard, Hasenkam and Vesterby, 2021; Sibalija *et al.*, 2021).
- 3. A network-level perspective shall be used in BM design for solutions based on multidisciplinary collaborations in health, social care and wellbeing. Most studies have examined the BM on a single firm perspective and not from a network perspective (Chesbrough and Rosenbloom, 2002; Magretta, 2002; Teece, 2010; Verhees, van Kuijk and Simonse, 2017; Laya, Markendahl and Lundberg, 2018; Palas and Bunduchi, 2021; Schiavone *et al.*, 2021; Vimarlund, Nikula and Nøhr, 2021; Chen, 2022).
- 4. Another challenge is to take into account the various stakeholders' perspectives and their needs in developing effective BMs. This considers the different BM elements, such as customer segmentation, pricing, and operations. By taking a holistic view of the BM, the researcher can uncover opportunities for improvement and develop strategies that create value for all stakeholders involved.

2.8 Conceptualising business models for healthcare

In the extant literature, the definition of a BM and its dimensionality vary significantly. Zott and Amit (2008) emphasise the way through which the focal firm handles its relationships with suppliers, customers, and partners within its value network as a salient aspect of a BM. This study conceptualised the BM similar to Johnson, Christensen, and Kagermann (2008), who described a BM into four main elements: the customer value proposition (value offering), the main processes (value delivery), the primary resources (value network), and the profit equation (value capture). However, considering that healthcare businesses include a social aspect, the fourth dimension is enhanced with the social profit equation, which is exclusive to and an important cornerstone for organisations that are born with an important socially oriented mandate while aiming at being financially self-sustainable (Yunus, Moingeon and Lehmann-Ortega, 2010; Bhattacharya, Wainwright and Whalley, 2021; Vimarlund, Nikula and Nøhr, 2021).

Based on the SLR, the BM for healthcare innovations is centred on the value where the benefit being offered (value offering), activity systems (value delivery), stakeholder network (value network) and financial structures (value capturing) (Pundziene, Heaton and Teece, 2019; Denoo, Yli-Renko and Clarysse, 2021; Lehoux *et al.*, 2021; Oderanti *et al.*, 2021; Palas and Bunduchi, 2021; Schiavone *et al.*, 2021). The conceptualisation of a BM hinges on four dimensions of value:

- Value offering: how an organisation creates value for its customers through customer-based products or service offerings (Osterwalder, 2004; Khuntia, Mithas and Agarwal, 2017; Schiavone *et al.*, 2021; Sibalija *et al.*, 2021)
- 2. Value delivery: Physical resources, encompassing technology infrastructure and assets; organisational forms and practices; and human resources, including employee skills, constitute essential components. Additionally, a knowledge base necessitates configuration

and organisation in a manner that facilitates a competitive value proposition. (Hedman and Kalling, 2003; Oderanti *et al.*, 2021; Vimarlund, Nikula and Nøhr, 2021).

- Value network: those cross-organizational collaborations, partnerships, and relationships necessary to create and deliver value (Shafer, Smith and Linder, 2005; Teece, 2010; Acheampong and Vimarlund, 2015; Harrington and Burge, 2018; Bhattacharya, Wainwright and Whalley, 2021; Denoo, Yli-Renko and Clarysse, 2021; Viswanadham, 2021).
- 4. Value capture: the revenue-earning logic to be profitable (or sustainable) and the monetisation aspects of a BM enhanced with the social profit equation (Yunus, Moingeon and Lehmann-Ortega, 2010; Palas and Bunduchi, 2021; Vimarlund, Nikula and Nøhr, 2021).

On this foundation, a BM for healthtech is represented in Figure 2.9. This representation is inspired by the Business Model Canvas (BMC) by (Osterwalder and Pigneur, 2010), justified for several reasons:

- Widespread acceptance and familiarity: The BMC developed by Osterwalder and Pigneur is
 widely recognised and used in the business and entrepreneurship community. It has become
 a standard framework for describing, analysing, and innovating BMs. Many professionals,
 researchers, and practitioners are already familiar with the BMC, making it a convenient and
 common language for discussing BMs.
- Structured and comprehensive framework: The BMC provides a structured framework with defined building blocks that cover key aspects of a BM, such as customer segments, value propositions, channels, revenue streams, and cost structure. This structured approach helps ensure that critical elements are not overlooked when designing or analysing a BM.
- Interdisciplinary application: The BMC's simplicity and versatility make it applicable across various industries, including health technology. Health technology often requires collaboration between healthcare experts, technologists, and business professionals. Using a

framework like the BMC bridges disciplinary gaps and facilitates communication among these diverse stakeholders.

- Alignment with research and literature: As mentioned, many academic studies define and analyse BMs using the BMC as a foundational reference point. This alignment with existing research and literature allows for a more seamless integration of research findings and a common point of reference for academic discussions.
- Visual representation: The BMC is a visual tool, which makes it effective for summarising complex information and conveying it in a clear and concise manner. Visual representations are particularly useful when communicating complex concepts to diverse audiences, including practitioners, investors, and policymakers.
- Iterative design and innovation: The BMC's flexibility supports iterative design and innovation. Health technology is an evolving field, and BMs must adapt to changing market dynamics, technologies, and user needs. The BMC allows for continuous refinement and adjustment of the BM as new insights are gained.
- Empirical basis: Osterwalder and Pigneur developed the BMC based on empirical research and extensive case studies. It draws on real-world business practices and has been tested and refined over time.

Each value dimension is broken down into distinct components: product/service, target segments, value proposition, key activities, channel, key partners, key resources, revenue, cost and social value. Each component in turn contributes to a total of ten areas that make up a BM for healthcare. For enhanced clarity and visualisation of these dimensions, the border is thickened for compiling each group. Additionally, they've been colour coded where the value network is shaded in blue, value offering in pink, value delivery in green and value capture in yellow. Compiling the factors in each component based from the SLR, they are bulleted in each box.

Value Network Key Partners Key Resources - Network utilization - Securement of a professional workforce - Organisational culture - Patent retention - Funding capacity - Funding capacity		Value	Offering	g Value Delivery		
		Product/service - Technological innovativeness - Market analysis skills Value Proposition - Product competitiveness - Ease of use - Personalized platform	- Product's market size - R& infra Com adva - Effective communication Cleasuician		Key Activities - R&D facilities and infrastructure / Continuous advancement - customer-oriented approach - clinical standards	
- Available funds/ Cost - Poter		te streams ntial growth of profit capital/ Investment		Social value - social profit		

Figure 2.9 Conceptual business model for healthcare technologies

2.9 Summary

This literature review has presented a comprehensive overview of the method for empirical research on BM design for healthcare technologies. The existing research highlights the importance of understanding the key factors influencing business model design, as well as the diverse types of business models applicable to healthcare technologies. Furthermore, innovators in the healthcare technology sector must navigate the challenges and opportunities associated with this field to develop and implement successful and sustainable BMs. Future research should explore novel approaches to BM design in healthcare, considering the unique complexities and dynamics of the industry.

Chapter 3: Methodology

3.1 Introduction

The formulation of a suitable methodology to achieve research objectives and to answer the research questions is a critical aspect of the research process. This chapter comprehensively describes and justifies the methodological framework used for this study including the research philosophy, approach, design, strategy and methods. Adopted from Saunders et al. (2023), the research "onion" is exhibited in Figure 3.1, which illustrates the various components that have been taken into account when selecting the core data collection techniques and analysis procedures of this thesis. When examined from the outside, each layer of the onion describes a more detailed stage of the research process. It provides an effective progression through which a research methodology can be designed. For this study, each layer of the research onion has been mapped, giving an overview of the methodology adopted.

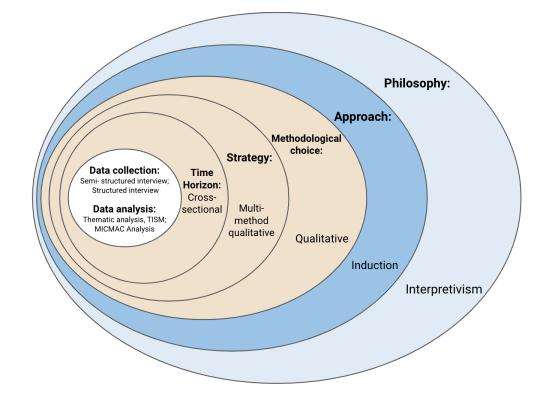


Figure 3.1 Research onion (adopted from (Saunders et al. 2023)

3.2 Research philosophy

The outermost layer of the research onion is the research philosophy, which refers to the underlying beliefs concerning the nature of the reality being investigated (Bryman, 2012). It is a field of inquiry that examines the development of knowledge and the nature of knowledge itself (Saunders, Lewis and Thornhill, 2023). It covers the theoretical foundations of research and assumptions made by researchers underpin all of the other research design choices and guide how data about a phenomenon should be gathered, analysed and used (Burrell and Morgan, 1982; Easterby-Smith, Thorpe and Jackson, 2012). This means recognising the researcher's interpretation of the reality they are studying (ontological assumptions); the researcher's views on how knowledge is acquired and how it should be interpreted (epistemological assumptions); and about the extent to which the researcher's values and beliefs influence the research process (Saunders, Lewis and Thornhill, 2023). This awareness is beneficial as it allows researchers to recognise any potential biases or limitations inherent in their work and to reflect upon philosophical choices with respect to the alternatives that could have been adopted.

According to Saunders et al. (2023), the five major philosophies in business and management are: positivism, critical realism, interpretivism, postmodernism and pragmatism. A brief comparison of those research philosophies, with respect to ontology, epistemology, axiology, and typical methods is provided in Table 3.1. In this study, the interpretivist research philosophy is focused as other research philosophies are beyond the scope of this thesis. Therefore, exclusion of alternative philosophies will be evident as the discussion shifts to interpretivism in the following paragraphs.

After reviewing and identifying research gaps in the previous chapter about BM development in the healthcare diagnostics ecosystem and applications in healthcare, the interpretivism approach is chosen. It has identified several factors which need to be taken into account such as managerial, social, economic, technological, and operational considerations. Due to the complex and interrelationships of these concepts, knowledge necessary for this research would be gained by participating in the subject of interest (Irani and Anandan, 2000).

Research philosophy	Ontology : nature of reality or being	Epistemology: what constitutes acceptable knowledge	Axiology: role of values	Typical methods
Real, external, independentPositivismOne true reality (universalism)Granular (things) Ordered		Scientific method Observable and measur- able facts Law-like generalisations Numbers Causal explanation and prediction as contribution	Value-free research Researcher is detached, neutral and independ- ent of what is researched Researcher maintains objective stance	Typically deductive, highly structured, large samples, measurement, typically quantitative methods of analysis, but a range of data can be analysed
Critical Realism	Stratified/layered (the empirical, the actual and the real) External, independent Intransient Objective structures Causal mechanisms	Epistemological relativism Knowledge historically situated and transient Facts are social constructions Historical causal expla- nation as contribution	Value-laden research Researcher acknowl- edges bias by world views, cultural experience and upbringing Researcher tries to mini- mise bias and errors Researcher is as objective as possible	Retroductive, in-depth historically situated analysis of pre-existing structures and emerging agency Range of methods and data types to fit subject matter
Interpretivism	meanings, interpretations, realities Flux of processes, experiences, practices understandings and worldviews as contribution Nominal Complex, rich Socially constructed through power relations What counts as 'truth' and 'knowledge' is decided by dominant ideologies Focus on absences, silences and oppressed/ repressed		Value-bound research Researchers are part of what is researched, subjective Researcher interpretations key to contribution Researcher reflexive	Typically inductive. Small samples, in-depth investigations, qualitative methods of analysis, but a range of data can be interpreted
Postmodernism			Value-constituted research Researcher and research embedded in power relations Some research narratives are repressed and silenced at the expense of others Researcher radically reflexive	Typically deconstructive – reading texts and reali- ties against themselves In-depth investigations of anomalies, silences and absences Range of data types, typically qualitative methods of analysis
Pragmatism	Complex, rich, external 'Reality' is the practical consequences of ideas Flux of processes, experiences and practices	Practical meaning of knowledge in specific contexts 'True' theories and knowledge are those that enable successful action Focus on problems, practices and relevance Problem solving and informed future practice as contribution	Value-driven research Research initiated and sustained by researcher's doubts and beliefs Researcher reflexive	Following research problem and research question Range of methods: mixed, multiple, qualitative, quantitative, action research Emphasis on practical solutions and outcomes

Table 3.1 Comparison of five research philosophies

Source: Saunders et al. (2023)

The purpose of interpretivist research is to generate new, richer understandings and interpretations of a particular context, and the nature of reality is socially constructed (Willis, 2007). Interpretivism emphasises that humans are different from physical phenomena because they create meanings (Creswell, 2014). Interpretivists argue that social phenomena cannot be measured or quantified like natural phenomena, and that the only way to understand them is through the lived experience of the actors involved. It is based on the belief that there is no single, objective truth to be discovered, but rather multiple subjective interpretations of reality that can be explored through the study of human experience and meaning. Typical research methods are done in an inductive way where data are collected through qualitative methods such as interviews, observations and document analysis.

Due to the subjective nature of interpretivism philosophy, bias is inevitable as participants' own interpretation and belief system affects the research outcome, and it is based on the researcher's own interpretation of the data. However, as emphasised by (Saunders, Lewis and Thornhill, 2023), a single phenomenon could be interpreted from different angles rather than a truth that could be determined by a process of measurement. It is also assumed that there are many possible interpretations of the same data, all of which are potentially meaningful. Thus, interpretivism, being explicitly subjective, provides a more holistic understanding of a particular context, as it looks at the various perspectives of those involved and accepts the multiple viewpoints of individuals from different groups (Saunders, Lewis and Thornhill, 2023).

Interpretivism is particularly relevant to this research on BM as it allows for real-world phenomena to be understood in detail within the healthcare context. Since healthcare value chains are complex, with different stakeholders playing different roles (Dijkman *et al.*, 2015; Talari, Rehman and Rehman, 2019; Van Velthoven and Cordon, 2019; Khatab and Yousef, 2021), taking an interpretive approach is recommended compared to other philosophies (Alvesson and Willmott, 2003; Creswell, 2014). An interpretivist position was adopted in this research to investigate complex business and management realities and explore the multiple perspectives of the stakeholders involved. Moreover,

this research aims to integrate concepts and themes derived from the empirical data collected through interviews, which demands the researcher's active participation in the subject. This perception is inconsistent with other approaches, but it aligns well with the interpretivist paradigm.

3.3 Research approach

Research approaches encompass the plans and procedures for conducting research across different phases from broad assumptions to detailed methods of data collection, analysis, and interpretation (Creswell and David Creswell, 2018). The three main research approaches are the deductive approach, inductive approach, and abductive approach (Saunders, Lewis and Thornhill, 2023). Each of these approaches has its own characteristics, as elaborated in Table 3.2.

	Deduction	Induction	Abduction
Logic	In a deductive inference, when the premises are true, the conclusion must also be true	known premises are used to premises are used to generate test-	
Generalisability	Generalising from the general to the specific	be general ficGeneralising from the specific to the generalGeneralising from the intera between the specific and generals used to tions or ed to an oryData collection is used to explore a phenome- non, 	Generalising from the interactions between the specific and the general
Use of data	Data collection is used to evaluate propositions or hypotheses related to an existing theory		Data collection is used to explore a phenomenon, identify themes and patterns, locate these in a conceptual framework and test this through subsequent data collec- tion and so forth
Theory	Theory falsification or verification	Theory generation and building	Theory generation or modification; incorporating existing theory where appropriate, to build new theory or modify existing theory

Table 3.2 Characteristics of deductive, inductive, and abductive research approach (adopted from Saunders et al. 2023)

In deciding whether to use a deductive or an inductive approach, (Creswell and David Creswell, 2018) recommends two practical criteria for evaluation. First, the nature of the research topic. If there is a wealth of literature that can help researchers to develop a theoretical framework, then a

deductive approach is suggested; otherwise, an inductive approach. Second, the available time for conducting research. Usually, deductive research can often be much quicker since a hypothesis is already known and the researcher can move quickly to the observation and experimentation stage. In comparison, inductive research can take longer to complete since a hypothesis is not yet known and the researcher involves more data collection, depending on the complexity of the research. In light of the preceding discussions on deductive and inductive approaches, this study adopts an inductive approach. Specific justifications are as follows:

- The conceptual framework (see Figure 2.9) in Chapter 2, was based on an inductive approach for investigating the literature as well as establishing BM dimensions and factors.
- Subsequently, an empirical phase utilising an inductive methodology would be implemented to allow new themes and connections to be formed from the gathered data, as there is scant literature that describes the relationships among the variables.
- Finally, the prioritisation of BM factors guide the effective use of the framework for designing BM in healthcare technological innovations.

3.4 Methodological choice

The methodological choice can be divided into three categories: qualitative research, quantitative research, and mixed methods research design. Table 3.3 outlines the primary differences between these choices.

Table 3.3 Differences an	nong quantitative,	qualitative, and	nd mixed met	thods research ((adopted from
Saunders et al. 2023)					

	Qualitative Quantitative		Mixed methods
Research philosophy	Generally associated with interpretivism	Generally associated with positivism	Generally associated with critical realism and pragmatism
Research approach	Usually associated with inductive approach	Usually associated with deductive approach	May use deductive, inductive, and abductive approach
Characteristics	Studies participants' meanings and the relationships between them	Usually examine relationships between variables numerically Usually associated with experimental and survey research strategy	Not specified
Research strategies	Usually associated with action research, case study research, ethnography, grounded theory and narrative research		Mixed research strategies

Since both interpretivism philosophy and inductive approach are adopted in this research, the study is best suited for a qualitative research design. Specifically, as interpretivist approaches focus on the deeper meaning of human perspectives, behaviour and interactions, qualitative research is a highly flexible type of research that uses naturalistic inquiry to gain insight into complex social phenomena (Silverman, 2013). Rather than a quantitative study, qualitative is particularly useful when gaining an in-depth understanding of a phenomena which cannot be easily measured or quantified, such as social behaviour, attitudes, beliefs, and motivations involving the collection and analysis of words, images, videos, and other non-numerical data (Maxwell, 2012; Creswell and David Creswell, 2018). Furthermore, this thesis aims to gain an in-depth understanding of the relationships between the factors of designing a BM based from insights of experienced stakeholders across the healthcare value chain, as well as to understand the relationships among these factors. The qualitative method

is necessary due to the complexity of healthcare value opinions and the difficulty of capturing such perspectives through quantitative research.

3.5 Research strategy

The research strategy defines how research is conducted and primarily focuses on the chosen research approach. This study utilised a qualitative approach to answer the research questions such as "what are the factors of a BM that exist in healthcare diagnostic technologies?", "What are the relationships among the BM factors?", and "What are the most important factors of designing a BM for healthcare diagnostic technologies?" A multi-method qualitative strategy was selected as a research strategy, as highlighted in Figure 3.1. In contrast to mixed methods, a multi-method approach in qualitative research is a combination of two or more qualitative methods to investigate a research question or phenomenon without the inclusion of quantitative methods (Saunders, Lewis and Thornhill, 2023). Using multiple qualitative approaches can be advantageous for achieving a more comprehensive and deeper understanding of the research questions than a single-method research design and gives more opportunity to discover new factors that may lead to future research (Flick, 2011; Denzin et al., 2023). In addition, this enables researchers to ask a broader set of questions (e.g., what, how, and why), expand the scope of the study, and enhance richness in data (Lambert and Loiselle, 2008). Based on the above discussions, this study adopts a multi-method qualitative research strategy to obtain answers to the research questions and meet the research objectives.

There are two time horizon strategies, namely, cross-sectional and longitudinal studies. Crosssectional studies involve the study of a particular phenomenon at a specific time, whereas longitudinal studies mainly focus on the change and development regards a specific phenomenon (Saunders, Lewis and Thornhill, 2023). Thus, this research adopts a cross-sectional strategy as it allows for a detailed analysis of the factors that influence people's attitudes towards the BM design. Moreover, it enables the researcher to capture data from a large and diverse population within the time consideration of the PhD study. Moreover, this can provide valuable insights to inform future research on how the study has changed over time, as well as any underlying factors that may be influencing the change.

3.6 Research design

Research design is a systematic process to choose different methods and techniques to combine them in a logical and reasonable manner in order to answer research questions efficiently and effectively (Saunders, Lewis and Thornhill, 2023). The research philosophy, approach, methodological choice, and strategy all contribute to a research design that tends to be quantitative, qualitative, or mixed (Creswell and David Creswell, 2018).

In this study, the research design has been developed to align with the research aim and objectives, as well as the multidisciplinary nature of the research topic. In adopting an interpretivist philosophy, this study acknowledges the complex and multifaceted nature of the healthcare BM domain (Russell Bernard, 2017; Creswell and Poth, 2023). Interpretivism recognizes that social phenomena, including BMs, are socially constructed through culture and language, giving rise to multiple meanings, interpretations, and realities. It emphasises the dynamic and evolving nature of social processes, experiences, and practices, rejecting overly simplistic theories and concepts in favour of narratives, stories, perceptions, and interpretations. The chosen design acknowledges the intersecting academic domains such as business management, health, and technology. By incorporating insights from these diverse fields, an understanding of the complexities involved in designing BMs for innovative healthcare technologies are explored.

As illustrated in Figure 3.2, the research design of this study consists of four stages: theoretical phase, empirical phase one (identifying key components and factors in designing BM of innovative healthcare technologies), empirical phase two (establishing relationships and prioritisation of factors in BM model), and conclusion phase. Having two distinct empirical phases has been designed in order to meet the research aim and objectives.

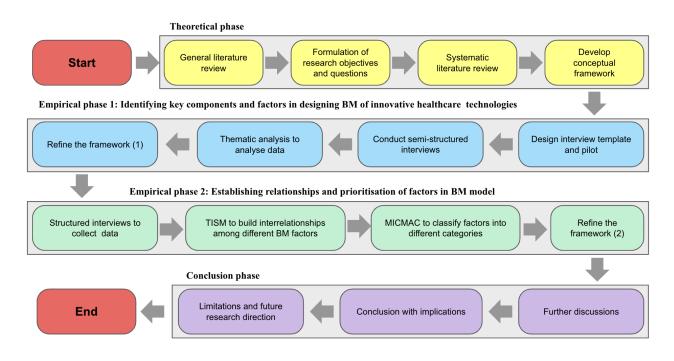


Figure 3.2 Overall research design

The first stage is the theoretical phase consisting of four components: a general literature review, the formulation of research questions and objectives, a systematic literature review, and the development of a conceptual framework. This phase is designed to establish a robust theoretical foundation to underpin the research. It commences with a broad literature review, followed by an introduction to the research context, research justification, research aim, research objectives, and research questions. Then, a systematic literature review (SLR) focused on business model (BM) in healthcare innovations was conducted to build a deep understanding of the topic and identify research gaps. This process results in the development of the conceptual framework.

Second stage is the first empirical phase, aimed at refining and validating the conceptual model by interviewing key stakeholders and knowledge experts from business and healthcare sectors. Next, thematic analysis will be used to identify the main themes generated by opinions across the different experts to be interviewed. After data analysis, the conceptual model will be reviewed to be able to refine it based on the empirical analysis.

After identifying and validating the BM factors in the previous phase, a structured interview has been done to prioritise and understand the interrelationships among the BM factors. The TISM methodology adopted in the study, which explicitly captures the causal thinking behind the interrelationship during data collection. Then, the MICMAC analysis, which stands for Matrice d'Impacts croises-multiplication appliqu'ean classment (cross-impact matrix multiplication applied to classification) was used to analyse the driving power and the dependence power of the factors in order to find the most important factors within the system. As a result, a validated BM framework is developed.

Stage 4 is the conclusion phase where a comparison of the research results of this study with that in literature is conducted. Conclusions across different stages are discussed. Finally, limitations and future research directions were proposed.

3.7 Research methods

Research methods include the set of tools used for data collection and analysis to explore a certain issue (Easterby-Smith, Thorpe and Jackson, 2012). The nature of the research questions and objectives guide the research methods for this study. Figure 3.5 illustrates the research methods adopted in this study divided into 2 phases. The following sections further explains the justification for using each method.

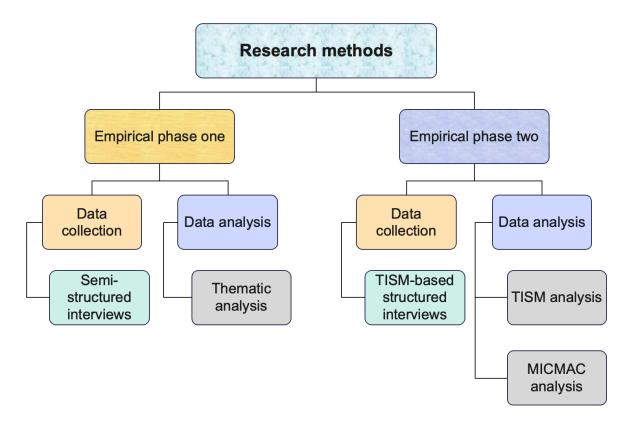


Figure 3.3 Research methods adopted

3.7.1 Research methods adopted for identifying key factors in designing business models of innovative healthcare technologies

The objective of the initial empirical phase is to identify key factors influencing the design of diagnostic healthcare technology BMs. Semi-structured interviews were used for data collection, which is then analysed with thematic analysis techniques.

A range of data collection methods has been considered in qualitative research such as focus groups, triads, interviews, and uninterrupted observations (Bryman, 2012; Saunders, Lewis and Thornhill, 2023). After a thorough evaluation, the most suitable choice was to employ semi-structured interviews, supported by several reasons. Firstly, as data is gathered both from the business and healthcare sector, interview is found to be most suitable and manageable taking into consideration the time and logistical constraints compared to other methods (ie. focus groups, triads and uninterrupted observations). Secondly, in contrast with structured interviews and in-depth interviews, this method allowed for a structured yet flexible approach, ensuring that the research

questions guiding the study could be explored comprehensively. It enabled the researcher to tailor questions to each participant's background and responses, ensuring that the interview was relevant to the individual being interviewed (Saunders, Lewis and Thornhill, 2023). Thirdly, these interviews were instrumental in not only confirming existing knowledge but also in unveiling novel themes. This was achieved by allowing interviewees the freedom to articulate their views in their own terms (Creswell and David Creswell, 2018; Saunders, Lewis and Thornhill, 2023). Fourthly, semi-structured interviews are a fundamental tool in qualitative research, providing a means to gather rich qualitative data that can be analysed thematically or through other qualitative methodologies.

While semi-structured interviews emerged as the most suitable data collection method for the first empirical phase, it's equally important to recognise their limitations in order to address potential factors that could undermine the validity of findings. Some notable limitations associated with semi-structured interviews include being time-consuming, sensitivity to interviewee responses, the requirement for interviewers to possess a thorough mastery of the research technique, and the potential for bias to emerge during the data collection process. To address these, the researcher planned the interviewes by creating a clear interview guide with well-structured questions. Trust has been built with the interviewees at the beginning of each interview to create a comfortable and trusting atmosphere. Assuring them that their responses will be treated with confidentiality and ethically was done.

Thematic analysis was used to analyse qualitative data collected through semi-structured interviews with experts and key stakeholders in the field of business and healthcare diagnostics. This method was the appropriate analysis method for the empirical stage of the study because thematic analysis is useful for identifying, extracting, analysing and reporting patterns (themes) within the collected textual materials and then organising and describing those themes in detail (Braun and Clarke, 2006; Denzin *et al.*, 2023). Thematic analysis represents a systematic approach to dissecting

qualitative data, defined as "a method for identifying, analysing, and reporting patterns (themes) within data" (Braun and Clarke, 2006). Its core essence lies in the methodical process of coding, examining meaning, and constructing a description of the social reality through the formulation of themes (Vaismoradi et al., 2016). Compared from other qualitative analysis methods, such as content analysis, narrative analysis, and discourse analysis, thematic analysis has the capacity to provide qualitative, intricate, and detailed account of data by scrutinising and identifying common threads spanning entire interviews or sets of interviews (DeSantis and Noel Ugarriza, 2000; Braun and Clarke, 2006). Moreover, thematic analysis helped to identify new themes emerging from coded data and also to confirm existing themes such as BM components (King and Horrocks, 2010).

3.7.2 Research methods adopted to establish relationships and prioritisation of BM factors

The objective of the final empirical phase is to establish relationships among key factors influencing the design of diagnostic healthcare technology BMs, and to prioritise them based on their driving and dependence power. A structured interview following the TISM method has been done to understand the interrelationships among the BM factors. The TISM methodology adopted in the study is an extension of interpretive structural modelling (ISM) (Sushil, 2012), which explicitly captures the causal thinking behind the interrelationship during data collection.

TISM is a qualitative modelling technique rooted in Interpretive Structural Modeling (ISM) that facilitates the transformation of intricate, poorly articulated mental models into visually explicit and well-defined structures, thereby supporting multiple interpretations (Sushil, 2012). Structural models are widely recognized and applied to analyse complex systems with numerous interacting factors (Watson, 1978). Interpretive Structural Modeling (ISM), initially proposed by (Warfield, 1974), offers a valuable methodology that facilitates an interactive learning process. ISM enables the structuring of various variables affecting the system under consideration into a systematic model, transforming weakly articulated mental models into visible, well-defined models. It serves as a tool for imposing order and direction on the complexity of relationships among elements within a system, offering an intuitive and visual representation of complex problems through graphics and words. While ISM provides a robust framework for modeling complex systems, it has certain limitations highlighted in the literature (Jena et al., 2016, 2017; Biswas, 2017; Lee et al., 2010; Rajesh, 2017):

- ISM does not interpret the links, failing to explain how factor A contributes to achieving factor B (Yadav and Sushil, 2013).
- ISM primarily identifies direct relationships among factors and does not focus on transitive or indirect relationships.
- ISM's diagraph requires further interpretation for decision-making and is best suited for domain experts.

To address the limitations inherent in traditional ISM, Total Interpretive Structural Modeling (TISM) was developed as an extension (Sushil, 2005; Dubey et al., 2016). TISM incorporates additional modelling constructs, with a key tool being the "interpretive matrix," which provides interpretations for relationships within structural models (Sushil, 2005). The interpretive matrix offers insights into the relationships between pairs of elements in matrix form, enhancing the depth of interpretation for structural models.

Unlike ISM, which primarily focuses on structural relationships, TISM provides rich interpretations for both links and nodes within the hierarchical structural model. This attribute enables researchers to delve deeper into the "what," "why," and "how" aspects of theory building (Jena *et al.*, 2017). As stated by Sushil (2012), the interpretation of each link and node, grounded in profound knowledge and supported by a panel of domain experts, not only enhances the comprehensibility of the hierarchical model but also contributes to the creation of a knowledge repository for interpretive logic pertaining to all interrelations.

While various modelling techniques exist for establishing relationships among constructs, several shortcomings that hinder their suitability for this study:

- DEMATEL: Decision-making Trial and Evaluation Laboratory (DEMATEL) is limited in its capacity to address issues of uncertainty and the biases associated with human judgement (Si *et al.*, 2018). Given the complexity and inherent uncertainties in the research context, DEMATEL is deemed less applicable.
- Graph Theory: Graph theory, although a valuable tool for modelling relationships, has limitations when it comes to determining the direction of relationships between factors (Deo, 2016). This limitation poses challenges in uncovering the causal mechanisms crucial to this study.
- ANP (Analytic Network Process): ANP, while robust, presents challenges due to its complex procedural requirements, making it less suitable for the current research's scope and objectives.
- SEM (Structural Equation Modelling): SEM demands a large sample size to be effective (Wolf *et al.*, 2013). Given the constraints of the available data, SEM was not a viable option.
 In light of the limitations associated with alternative modelling techniques and the unique advantages offered by TISM, it becomes evident that TISM aligns with the research objectives and constraints of this study. As such, TISM was chosen as the primary methodology for building relationships among the diverse constructs under investigation.

3.8 Sampling techniques

There are two main types of sampling techniques: probability and non-probability sampling, each used to address different research questions. Probability sampling ensures that every member of the population has an equal chance of being represented. On the other hand, non-probability sampling selects participants based on specific criteria, such as availability, accessibility, or the researcher's

judgement (Patton, 2014). Given the exploratory nature of this study, a non-probability sample is the most practical technique since using random sampling in qualitative research would not be suitable (Palys and Atchison, 2021). Furthermore, non-probability sampling allows to explore issues in-depth rather than to generalise findings to a larger population. This study utilised a combination of two non-probability sampling methods: purposive (or judgemental) sampling and snowball sampling.

Purposive sampling is a technique used in qualitative research for the identification and selection of information-rich cases for the most effective use of limited resources (Patton, 2014). This technique was applied to strategically select participants based on a predetermined criteria (Cresswell and Plano Clark, 2011). In addition, availability and willingness to participate, and the ability to communicate experiences and opinions in an articulate, expressive, and reflective manner are important (Russell Bernard, 2017). This purposive approach allowed the researcher to target individuals from both the business and biotech healthcare domains with extensive experience and expertise in their respective fields. Therefore, ensuring that the interviews would yield in-depth and contextually relevant insights to comprehensively explore the multifaceted aspects of BM within the healthcare industry.

Saturation serves as the predominant guiding principle for evaluating the sufficiency of purposive samples in qualitative research (Miles and Michael Huberman, 1994; Sandelowski, 1995). The concept of saturation was developed by (Glaser and Strauss, 2017) as 'theoretical saturation' and was part of their influential grounded theory approach to qualitative research. Although many qualitative research studies do not adhere to a grounded theory approach, the concept of saturation is commonly applied in various other qualitative research approaches, often referred to as "data saturation" or "thematic saturation" (Hennink, Kaiser and Marconi, 2017). In this broader sense, saturation is more concerned with evaluating sample size rather than the sufficiency of data for theory development (as in theoretical saturation). In this context, saturation indicates the stage in

data collection where no new issues or insights emerge, and data repetition occurs, suggesting that further data collection is unnecessary. This signifies that an adequate sample size has been achieved. Saturation is a crucial indicator that the sample is sufficient for studying the phenomenon, ensuring that the collected data have captured the diversity and depth of the subject under investigation, thereby establishing content validity (Francis *et al.*, 2010). Achieving saturation has emerged as a crucial element in qualitative research, enhancing the robustness and validity of data collection (O'Reilly and Parker, 2013). Moreover, saturation is "the most frequently touted guarantee of qualitative rigour offered by authors to reviewers and readers" (Morse, 2015).

In non-probability sampling techniques, the determination of sample size lacks specific rules, unlike probability sampling. Instead, the emphasis is on establishing a logical relationship between the sample selection technique and the purpose, objectives, and focus of the research. Qualitative methods prioritise saturation, aiming to achieve a comprehensive understanding by continuing the sampling process until no new substantive information is obtained. (Miles and Michael Huberman, 1994). Accordingly, sample size in qualitative research depends on various factors, including research questions, objectives, resource availability, confidence in findings, required accuracy, and anticipated categories for analysis (Patton, 2014). Purposive sample size depended on the time and resources available, as well as the objective of the study. Most datasets reached saturation between 9 and 17 interviews, with a mean of 12-13 interviews, which aimed to understand the commonalities of a rather homogenous population (Guest, Bunce and Johnson, 2006; Hennink and Kaiser, 2022). propose a continuous collection of qualitative data through additional interviews until data saturation is achieved. They emphasise that there's no need to predefine the sampling size in qualitative studies, as it can be determined during fieldwork. Saturation, in this context, is reached when no relevant new codes or categories emerge, and issues begin to repeat without contributing further understanding or insight into the study phenomenon, its dimensions, or variability (Hennink and Kaiser, 2022).

Specific criteria for recruiting suitable participants are:

- Participants should have relevant experience in the biomedical/ healthcare industry, particularly in the area of business models. This could include healthcare executives, business development professionals, or entrepreneurs who have experience in developing or implementing healthcare business models.
- 2. The participants must have more than three years of working experience in healthcare research or entrepreneurship, to ensure that the participants have a high level of knowledge, experience and expertise.
- The selected company can be a startup, research organisation, or healthcare provider because these companies have rich experience and a deep understanding of managing healthcare technologies.
- 4. Participants should be available and willing to participate in the study. Gave an informed consent to participate in the study, including a clear understanding of the purpose of the study, the nature of the interview, and the confidentiality of their responses.

3.9 Research ethics

It is crucial that ethical considerations are taken into account when conducting research particularly to the rights of people who are, or may be affected by, the research in question (Saunders, Lewis and Thornhill, 2023). This study followed the required standards of the ethical guidelines published by University of Plymouth. During the data collection, participants were made aware of the purpose of the research and any potential implications of their involvement beforehand. Additionally, they were given the consent form including stating their right to withdraw from the research at any point without suffering any negative consequences. Participants were treated with respect and their privacy was maintained. All data collected were handled securely and with confidentiality. Research

ethics were obtained and approved by the University of Plymouth research ethics committee through the AiPBAND Project in accordance with the highest ethical standards. All participants were fully informed of the aims and procedures of the research, and gave their informed consent to participate.

Chapter 4 Identifying key factors in designing business models of innovative healthcare technologies

4.1 Introduction

This chapter presents the empirical data collection, data analysis, and empirical findings in the first phase of the empirical study. This phase aims to validate the conceptual framework developed in Chapter 2 and to understand and identify key factors of each value dimension for the BM development of medical technology for diagnosis and healthcare. While the previous chapter has justified the what and why specific data collection and analysis methods were selected, this chapter explains how these methods were applied to answer the research questions. Section 4.2 describes the use of semi-structured interview methods to collect data in this study, which includes the development of interview questions and the process of conducting interviews. Section 4.3 and Section 4.4 explains the data analysis approach and presents the results of thematic analysis, respectively. Then, the conceptual BM is refined in Section 4.5. Finally, the chapter is summarised in Section 4.6.

4.2 Data collection using semi-structured interviews

4.2.1 Designing the interview questions

Semi-structured interview technique was chosen as the primary data collection method in this phase due to its flexibility in allowing participants to express their insights and experiences. Prior to conducting the interviews, an interview guide was developed (see Appendix B), and questions focused on obtaining the participants' opinion on how to design BM for healthcare diagnostic technologies. Furthermore, there was freedom for participants to express ideas with respect to the context being discussed, and the interview guide was used as guidance to keep the focus of the discussion on the subject.

The interview template design comprises three distinct sections, each meticulously crafted to fulfil a specific research objective. It starts with general information asking about the interviewee and the place they work in, followed by specific questions about the BM concept and probing questions to get participants to clarify their answers where necessary. The first section, referred to as "General questions," is tasked with initiating the interview process. In this section, the interviewer seeks to gather essential background information regarding the interviewee, including their professional scope, experience, and their role within the healthcare industry. These initial questions lay the foundation for subsequent discussions. The second section, "Business model specific questions," is central to the research and encompasses a series of inquiries aimed at exploring critical facets of healthcare BMs. The questions within this section delve into the definition of a successful BM, factors influencing success, key stakeholders in the context of health diagnostics, current challenges and their resolutions, strategies for innovation adoption, and the social and economic values inherent in healthcare diagnostic BMs. These questions directly address the research inquiries pertaining to the development and implementation of healthcare BMs. The third section, labelled "Validating the conceptual framework," extends the inquiry to validate the underlying conceptual BM. Within this section, various components of the framework are probed, including the value proposition, technology system, customer segments, value network, and financial aspects. These questions collectively contribute to the validation of the research framework. In total, the interview template consists of 21 thoughtfully constructed questions. Each question plays a specific role in the comprehensive exploration of healthcare BMs, facilitating the collection of rich and pertinent data for the research.

Prior to the implementation of the interview template, a comprehensive review process by a panel of three academics with expertise in BM and healthcare technologies. Subsequently, a pilot testing phase involved the engagement of two industry practitioners specialising in biomedical innovations. The feedback obtained from both the academic experts and industry practitioners did not necessitate significant alterations to the template's structure and content. However, the valuable insights garnered from these reviewers led to minor adjustments, primarily focused on refining the wording of sentences and rephrasing certain elements within the questions. These refinements were made to enhance the overall clarity and accessibility of the template, with the goal of ensuring that participants would readily comprehend the questions and content, thereby minimising the potential for misunderstanding or confusion during the interview process.

4.2.2 Conducting the interview

To begin, the researcher identified suitable interview participants through various channels, including professional social media platforms such as LinkedIn and industry contacts. Initial contact was established with the AiPBAND Project (see Appendix I) consortium partners where the researcher has done secondments to gather data. Following the initial identification of potential participants, contact was established through email correspondences. In these communications, participants were presented with a comprehensive overview of the research's focus, objectives, and the intended purpose of the interviews. The consent form was provided to the interview participant in advance, and they signed it before the interview commenced. The consent form, refer to Appendix C, explicitly sought permission for audio recording during the interview. The audio files proved invaluable for transcribing all interviews verbatim, minimising biases, and enhancing the reliability and validity of the research. To ensure accuracy, confirmations for each transcription were obtained from the respective interview participants.

The semi-structured interviews were conducted either face-to-face or via Zoom, depending on the participant's preference and availability. A total of 30 one-to-one semi-structured interviews were conducted, with 6 interviews taking place on-site and 24 interviews conducted online via Zoom. All

interviews were audio recorded with the consent of the participants, in order to facilitate word-for-word transcribing purposes. One interview was on average one and a half hours in duration.

An interview guide was used, consisting of open-ended questions related to the factors influencing BMs. The guide served as a framework, allowing flexibility for the researcher to probe further into specific areas based on the participant's responses. At the conclusion of the interview, each respondent was asked to obtain further information on the topic as well as to ascertain if the respondent was able to provide recommendations for further study. This was beneficial in producing a better understanding of the issues discussed, as well as helping to identify further potential interviewees for future studies (Creswell and David Creswell, 2018).

The interviews were conducted over a period of 10 months from November to December 2019 and Nov 2020 to June 2021. For reference, there was a gap in the data collection process due to the Covid-19 pandemic which affected the availability of respondents.

4.2.3 Interview participants

The participants are summarised in Table 4.1. During the purposive sampling phase, participants were selected based on predefined criteria, as set in Section 3.8 Sampling techniques, which enabled the researcher to answer the research questions. The selected interviewees represented diverse roles involved within the development process, spanning research, invention, early-concept definition, actual development, regulatory approval, and postmarket feedback. To enhance the validity and generalisability of the results, interviewees were deliberately selected from different backgrounds, technology areas, companies, and regions.

To ensure a well-rounded perspective, interviewees were selected from different management levels within their respective organisations. This included:

- Top-Level Executives (12 participants): CEOs, Founders, Cofounders, and a Professor, individuals who play pivotal roles in steering the strategic direction of their organisations.
- Middle-Level Managers (8 participants): Project managers and team leads responsible for project execution and team coordination.
- Lower Management Level (10 participants): Comprising researchers and staff contributing to the day-to-day functioning of the organisations.

The participants were drawn from various geographic regions, with 26 participants based in Europe and four located in Asia. This diverse geographic representation underlined the global perspective of the research, enriching the study with different cultural and regional viewpoints.

ID	Nature of business	Technology focus	Interviewee's Position	Level of management	Years of experience	Country
1	Medical device	Diagnosis/analysis equipment manufacturer	CEO	Top level strategic	10-15 years	India
2	Medical device	Diagnosis/analysis equipment manufacturer	CEO	Top level strategic	5-10 years	India
3	Medical device	Diagnosis/analysis equipment manufacturer	CEO	Top level strategic	5-10 years	Turkey
4	Medical device	Diagnosis/analysis equipment manufacturer	CEO	Top level strategic	3-5 years	UK
5	IT service provider	Biomedical informatics solutions	Founder	Top level strategic	5-10 years	Netherlands
6	IT service provider	Biomedical informatics solutions	CFO	Top level strategic	3-5 years	Netherlands
7	IT service provider	Biomedical informatics solutions	Sales	Top level strategic	5-10 years	Netherlands
8	IT service provider	Biomedical informatics solutions	CEO	Top level strategic	5-10 years	Netherlands
9	IT service provider	Biomedical informatics solutions	Office manager	Top level strategic	5-10 years	Netherlands
10	Legal and policy	Various, for clinical standards and regulations	Co founder	Top level strategic	5-10 years	Germany
11	Medical device	Diagnosis/analysis equipment developer	CEO, professor	Top level strategic	10-15 years	Italy
12	Medical device	Diagnosis/analysis equipment developer	CEO	Top level strategic	15-20 years	Italy
13	Medical device	Diagnosis platform	Project manager	Middle level tactical	10-15 years	Slovenia
14	Medical service provider	Diagnosis platform	Engineer	Middle level tactical	5-10 years	Slovenia
15	Healthcare recruitment agency	Various	Manager	Middle level tactical	3-5 years	UK
16	IT service provider	Biomedical informatics solutions	Project manager	Middle level tactical	3-5 years	Netherlands
17	IT service provider	Biomedical informatics solutions	Team lead	Middle level tactical	3-5 years	Netherlands
18	IT service provider	Biomedical informatics solutions	Project manager	Middle level tactical	10-15 years	Netherlands
19	IT service provider	Biomedical informatics solutions	Project manager	Middle level tactical	3-5 years	Netherlands

Table 4	4.1 Background informat	tion of the o	companies a	nd interviewees.

20	IT service provider	Biomedical informatics solutions	Team lead	Middle level tactical	5-10 years	Netherlands
21	University	R&D healthcare	Medical doctor, researcher	Low level operational	3-5 years	Philippines
22	Medical device	Diagnosis platform	Researcher	Low level operational	3-5 years	Switzerland
23	IT service provider	Biomedical informatics solutions	Marketing executive	Low level operational	3-5 years	Netherlands
24	IT service provider	Biomedical informatics solutions	Office manager	Low level operational	5-10 years	Netherlands
25	University	R&D diagnostic solutions	Researcher	Low level operational	3-5 years	UK
26	University	R&D diagnostic solutions	Researcher	Low level operational	3-5 years	Italy
27	Research institute	R&D diagnostic solutions	Researcher	Low level operational	3-5 years	Italy
28	Medical device	R&D diagnostic solutions	Research staff, PhD student	Low level operational	3-5 years	Italy
29	Contract Research Organisation	R&D diagnostic solutions	Research staff, PhD student	Low level operational	10-15 years	Italy
30	Research institute	R&D diagnostic solutions	Research staff, PhD student	Low level operational	10-15 years	Italy

4.3 Data analysis process

Thematic analysis was employed to analyse the collected data. This method involves identifying, analysing, and reporting patterns or themes within the data. The analysis was carried out using the following steps, illustrated in Figure 4.1:

- Familiarisation with the data: The researcher thoroughly read and re-read the interview transcripts to become familiar with the content.
- 2. Generating initial codes: The data was systematically coded, with codes representing the most basic elements of the raw data that were relevant to the research question.
- 3. Searching for themes: The codes were collated into potential themes, which represented patterns or relationships between the codes.
- 4. Reviewing themes: The themes were reviewed and refined to ensure their relevance to the research question and consistency across the data.
- Defining and naming themes: The final themes were clearly defined and named, providing a detailed analysis of each theme.
- 6. Producing the report: The findings were written up, providing a detailed account of the identified themes and their relevance to the research question.

This approach allows the researcher to systematically organise and interpret the data, highlighting the underlying factors that contribute to successful BMs.

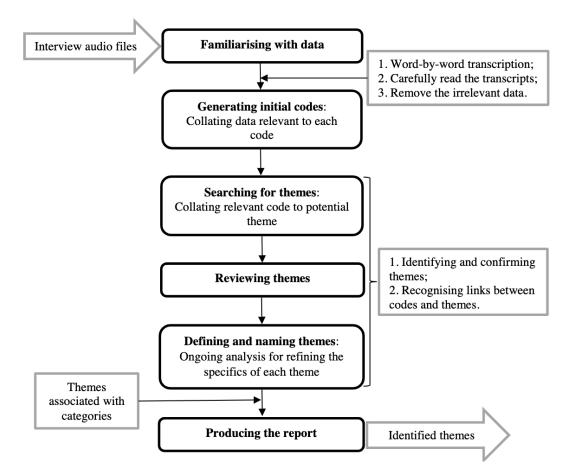


Figure 4.1 Thematic analysis (adopted from Zhao et al., 2020)

The interviews were transcribed verbatim and returned to the participants for comments or correction. The transcripts were analysed in random order using the qualitative data analysis tool NVivo QSR International Software (Version-12.6). At the commencement of open coding, the interview outline was utilised as the preliminary coding frame for the semi-structured interview data. The coding focused on BM components such as product/ service, target segment, value proposition, key activities, channel, key partners, key resources, revenue, cost, and social value associated with healthtech. The initial codes as BM factors based on the recurring ideas or concepts from the transcripts. New codes can be given if initial codes are insufficient. Saturation was reached when no additional codes were found (IJntema *et al.*, 2022).

Throughout the analysis, a number of themes were identified by considering the three stages proposed by King and Horrocks (2010):

- Descriptive coding (first-order codes): the transcript data from interviews were assigned to appropriate descriptive codes aimed at addressing the research questions.
- Interpretive coding (second-order themes): the descriptive codes sharing common meanings were grouped together, and interpretive codes were established to capture them.
- Defining overarching themes (aggregate dimensions): a number overarching themes were identified to represent the fundamental concepts in the analysis.

4.4 Thematic analysis results

The thematic analysis results are discussed in this section, based on the data collected from 30 perspectives of professionals engaged in the development of medical diagnostic technologies across different countries – UK, Italy, Turkey, Netherlands, Germany, India, Slovenia, and Philippines. In consistency with the conceptual framework (refer to Figure 2.2), the empirical findings are categorised into four key themes, namely, value offering, value delivery, value network and value capture. In the following sections, the thematic analysis results are discussed to support the inclusion of the variables.

4.4.1 Identifying key factors affecting BM value offering

In the development of health diagnostic innovations, the value offering addresses the unmet needs in disease detection, considering the economic and political considerations, innovativeness, and identified market based on health focus. Furthermore in the value proposition component, experts highlighted five factors, namely, the importance of early detection, ease of use, cost-effectiveness, platform for collaboration, and portability in the diagnostic process. Table 4.2 shows the different BM value offering factors identified based on the data collected from biomedical/ healthcare industry experts. The empirical findings reveal the 9 BM factors. The first-order codes are the direct quotes from the interview transcript (see column one), while the second-order themes are the The BM factors represent the first-order codes, as shown in the second column. The third column indicates the presence or absence of evidence obtained from the interview cases. Higher numbers indicate stronger evidence for the finding in the corresponding factor. Triple ticks $(\sqrt[4]{v})$ represent strong evidence and double ticks $(\sqrt[4]{v})$ represent moderate evidence. Single tick $(\sqrt[4]{v})$ represents weak evidence and a blank represents no evidence. The final column is the aggregate dimensions which are the BM components.

Table 4.2 Empirical evidence in discovering BM value offering

	Second-order								Su	pp	ort				ase f 30							off	eri	ng								Aggregate
First-order codes	themes (BM factors)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	5 27	28	8 29	30	dimensions (BM components)
"we find out the problems shortcomings or any limitations in the healthcare industry. And once we found find those out, we find a technological solution to that"	Meeting the needs of current standard of care	222	222	222	とここ	222	222	222	222	222	222	ンンン	222	222	222	ンンン	222	222	222	222	>	22	とと	222	222	222	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~					
"of course, is that it should be able to access it, I've seen those remote locations where there is not even a hospital not even a Primary Health Care Center, and people really need it desperately. So, to start with having that access, second value be and this will save lives, their devices there and people doing that." "So in terms of the national economic value is that because you extend the screening to the whole population, and you cover all the cases that exist, and you have a lot of prevention. Either guidelines in terms of so the gynecologist have guidelines, how they treat specific women based on the results of the specimen exams. And this way, you can prevent worse disease occurrence or later stages of the cancer of the cervix, thus avoiding treatment	Navigating economic and political considerations	222	~ ~	222	222	222	22	55	222		222	222	222	222	222	222	5 C C C	222	222	222	22	22	~	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	22	22	5				222	Product/ service

costs over book appointments for removal of cancer oncology therapies. So all this then decreases the cost of treatment on a national level So there's the economic benefit on a national and also psychological level with the population."																											
giving more of a personalised healthcare to the people. So we are catering not only to the bottom of the pyramid, but also the super rich, because health requirements are same for a poor person or a super rich person, but the only ways of delivering it change. So we are catering to the needs of each and every sector of the society, which we are serving, and being a technology company that has a strength in developing medical devices.	Fostering technological innovation	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	22	v	 	, u , u , u	22	2	~	r	v	<i></i>	- 0	~ ~			v	222	~	~	~	~	222	~	· •		
"we have actually two market segments, the primary one being, you know, the the organisations that treat the injured people, which is like hospital, trauma centres, ambulances, emergency helicopters, so on and so forth, where people once they are injured, and the secondary market as the places like schools, defence where people are not yet injured, but they're likely I'm in heaven forbid, but they're likely to get injured in a school to old age homes, people are likely to fail and hurt themselves. So those are secondary	Identified market based on health focus	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	222	~~~~		/ v / v / v	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	222	222	222	222						v	222	222	222	222	22	222	222		Target segme	ent

market." "we have focused on these two segments, small and medium pathology labs in India, we have around 350,000 of them and rural semi urban and urban clinicians offices, which we have	
segments, small and medium pathology labs in India, we have around 350,000 of them and rural semi urban and	
labs in India, we have around 350,000 of them and rural semi urban and	
of them and rural semi urban and	
urban clinicians offices, which we have	
around a million centres. So our target	
market becomes 1.3 million centres	
where we can base our machine so how	
to get to them. ancillary social	
healthcare workers. And there's	
something called something like that.	
So they are the main work force of the	
healthcare at the bottom of the	
pyramid."	
"I think prevention is also extremely	
important. Because you can save a lot	
of trouble if you actually diagnose, but	
also prevent correctly, like, you know,	
and then treatments."	
"And this way, you can prevent disease	
occurrence or later stages of the cancer	
of the cervix, plus avoiding treatment	
costs overbooked appointments for removal of cancer oncology therapies detection	ition
removal of cancer oncology therapies. detection	
So all this then decreases the cost of	
treatment on a national level."	
"what we do is to make, we invented	
the chemical reagents that boost DNA	
reaction that are used for detect DNA	
alteration, cancer, that this this	
separation are used for prognostic	
purposes, or diagnostic purposes as	

well. And we make possible to do that test in two hours instead of three working days. That is the actual standard."																										
"what we do is to make, we invented the chemical reagents that boost DNA reaction that are used for detect DNA alteration, cancer, that this this separation are used for prognostic purposes, or diagnostic purposes as well. And we make possible to do that test in two hours instead of three working days. That is the actual standard." "So we made more of a robust device that is strong enough that can bear the high temperatures of the Indian summers, and can be even sustained the fall if it falls down."	Ensuring ease of use	222	222	~ ~ ~	~ ~ ~	222	2	222	222	222	222	222	222	222	222	~ ~ ~	222		- 0	, 	· · · · · · · · · · · · · · · · · · ·		222	555	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
"Efficient treatment, reduce hospitalisation, cost effective for hospital budget" "The important solutions cannot be tailor made for our needs. And any anything that comes from the US or Europe, it's always overpriced and is beyond the reach of affordability. For anyone say for example, any product that comes from the US or UK or any to any other country, it has a lot of costs added to that. So that is why it becomes costlier. So it's always that indigenous products would have a better say what	Maintaining cost-effectiveness	222	222	222	222	222	2	222	~	222	22	22	22	22	22	~ ~	22	~ •	/ .		, u , u			22		

you call it as a better fulfilling the needs better in a better way and more targeted approach. And there is a special trust to medical device startups"																								
"So it's collaborative. So typically, the client, of course, has a question, right? We try to answer the question. And in many cases, the answer is relatively straightforward. They just want to use, and they want to have the data in there. Often, when they want to have new functionality, it's a bit more involved. So you have to describe the functionality, really try to understand what they want to do with it, etc. And then there's also the community as a whole, every time something new was built."	Providing a platform for collaboration	~			v	222	r	~~~~					222	v	v	v	v	r	r	~	v		v	
"lab on chip biosensors Like the other glucose by sensors. This can be also integrated or like a lab on chip by sensor, and this is really, really good. I could say, a simple bio sensing system, which can also be an implantable device as well" "The device we developed is battery operated, so it can be carried on. And in gives results in two minutes. So anybody, like any lay man who's not from medical background can be trained to use that machine, within 10 minutes, it's just 10 years of training	Offering portability	222	222	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	v		222	~		~	 	 	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	~	v	v	~ ~ ~ ~	r			~ ~ ~ ~	~	· •	

 ence - √√, wea	ence - J J weak evide	onco - J J work ovidence - J					ence - √√, weak evidence - √, no evidence – [blank].		

Meeting the needs of current standard of care

This subtheme focuses on identifying gaps or limitations in current diagnostic approaches and developing innovative solutions to meet those needs. One of the interviewees highlighted the importance of understanding the existing challenges and gaps in disease detection by conducting thorough research and analysis, the company aims to pinpoint these issues. Once identified, their focus is on developing technological solutions that address these unmet needs. This approach demonstrates a commitment to bridging the gaps and improving the healthcare landscape by leveraging technology and innovation in designing BMs.

"we find out the problems shortcomings or any limitations in the healthcare industry. And once we found find those out, we find a technological solution to that"

Irrespective of their social or economic background, the company aims to leverage technology and medical device innovation to ensure healthcare services for all individuals .

"giving more of a personalised healthcare to the people. So we are catering not only to the bottom of the pyramid, but also the super rich, because health requirements are same for a poor person or a super rich person, but the only ways of delivering it change. So we are catering to the needs of each and every sector of the society, which we are serving, and being a technology company that has a strength in developing medical devices."

Navigating economic and political considerations

Furthermore, the value proposition should align with economic and political considerations to ensure feasibility and support from healthcare systems. This subtheme recognizes the importance of aligning the innovations with economic and political considerations to foster acceptance and integration within healthcare systems. By catering to the needs of both the wealthy and the economically disadvantaged, the company aims to create a BM that incorporates a cross-subsidisation approach. This approach involves leveraging the support and resources from the wealthier individuals to help offset the costs associated with providing healthcare services to those who may be less financially privileged.

"Because if we are into healthcare providing for the people in the bottom of the pyramid, the business model should not be only for the rich ones. It could be serving the rich ones helping cross subsidise the costs for the poor ones."

"...of course, is that it should be able to access it, I've seen those remote locations where there is not even a hospital not even a Primary Health Care Center, and people really need it desperately. So, to start with having that access, second value be and this will save lives, their devices there and people doing that."

The economic value of implementing widespread screening programs, as it enables the identification and coverage of all existing cases, leading to increased prevention efforts. By providing guidelines for healthcare professionals based on diagnostic results, such as in the case of gynecologists treating women with specimen exam results, the innovations facilitate early interventions and reduce the occurrence of more severe stages of diseases like cervical cancer.

"So in terms of the national economic value is that because you extend the screening to the whole population, and you cover all the cases that exist, and you have a lot of prevention. Either guidelines in terms of so the gynecologist have guidelines, how they treat specific women based on the results of the specimen exams. And this way, you can prevent worse disease occurrence or later stages of the cancer of the cervix, thus avoiding treatment costs over book appointments for removal of cancer oncology therapies. So all this then decreases the cost of treatment on a national level... So there's the economic benefit on a national and also psychological level with the population."

"Economically, the business model contributes to the healthcare system by reducing healthcare costs associated with late-stage glioma diagnosis, optimising resource allocation, attracting research funding, and potentially creating commercial opportunities through the developed biomarker technology."

This proactive approach not only improves patient outcomes but also significantly decreases treatment costs, avoiding the need for extensive oncology therapies and related appointments. The economic benefits extend on a national scale, as the overall cost of treatment decreases. Additionally, there is a psychological benefit to the population, as the availability of comprehensive screening and prevention strategies alleviates concerns and promotes a sense of well-being among individuals.

Fostering technological innovation

Innovativeness of a value offering of health technology can be defined as the capacity of a product, service or solution to create new value and deliver something new that is of benefit to customers or other stakeholders. It involves the identification of new opportunities, the development of new products, services, or processes, and the implementation of creative solutions. This innovation can be in the form of technology, products, services, or processes and should result in tangible value for the customer. generate an improvement in existing value offerings within the field of healthcare.

The innovativeness of the biomarker technology plays a crucial role in attracting stakeholders' interest and fostering market adoption. By recognizing the challenges in disease detection, such as limitations in accuracy, invasiveness, or accessibility, healthcare diagnostic innovations aim to provide improved and more effective diagnostic tools and technologies. These innovations may include advancements in imaging techniques, biomarker-based tests, or point-of-care devices that offer faster and more accurate diagnoses.

"These biomarkers represent a novel approach to glioma detection, utilising advancements in molecular biology, genomics, and other technologies, we are able to push the boundaries of medical science in glioma diagnosis. Their innovative nature captures the interest and attention of stakeholders, including researchers, clinicians, and patients. Developing these biomarkers demonstrates our commitment to finding better ways to detect and diagnose gliomas, and our determination to make a positive impact on the lives of those affected by this disease."

Identified market based on health focus

The identification of the market based on health focus is a key factor in designing the BM for healthcare diagnostic innovations. By understanding the specific segments within the healthcare industry that would benefit from the innovations, the BM can be tailored to meet their needs effectively.

For example, in the case of an organisation that provides care for injured individuals, such as hospitals and trauma centres, the BM may focus on providing rapid and accurate diagnostics to support immediate medical interventions. This could involve streamlining workflows, ensuring quick turnaround times for test results, and establishing strong partnerships with emergency medical services to facilitate seamless integration. In the secondary market, which includes places like schools, defence establishments, and old age homes, the BM may emphasise preventive care and early detection. This could involve developing diagnostic solutions that can be easily implemented in these settings, such as point-of-care devices or screening programs. The BM may also involve collaboration with educational institutions, government agencies, and healthcare providers to raise awareness, implement guidelines, and facilitate regular screening or risk assessment.

"we have actually two market segments, the primary one being, you know, the the organisations that treat the injured people, which is like hospital, trauma centres, ambulances, emergency helicopters, so on and so forth, where people once they are injured, and the secondary market as the places like schools, defence where people are not yet injured, but they're likely I'm in heaven forbid, but they're likely to get injured in a school to old age homes, people are likely to fail and hurt themselves. So those are secondary market."

Early detection

Early detection is a key value proposition of diagnostic solutions that enable timely and accurate detection of diseases or conditions, shaping the overall strategy and operations of the BM.

"what we do is to make, we invented the chemical reagents that boost DNA reaction that are used for detect DNA alteration, cancer, that this this separation are used for prognostic purposes, or diagnostic purposes as well. And we make possible to do that test in two hours instead of three working days. That is the actual standard."

In addition, an interviewee emphasised that "early detection is crucial for improving patient outcomes and survival rates." and "I think prevention is also extremely important. Because you can save a lot of trouble if you actually diagnose, but also prevent correctly, like, you know, and then treatments." The value offering lies in the potential to provide early interventions, enable personalised treatment strategies, and ultimately improve patient outcomes. This aligns with the growing recognition that early detection can lead to more effective treatment options and improved quality of life for patients, especially with gliomas.

Ease of use

Incorporating a user-oriented approach, can enhance usability for healthcare professionals and also providing a more positive experience for patients, as highlighted by the following transcripts. "what we do is to make, we invented the chemical reagents that boost DNA reaction that are used for detect DNA alteration, cancer, that this this separation are used for prognostic purposes, or diagnostic purposes as well. And we make possible to do that test in two hours instead of three working days. That is the actual standard." This emphasis on ease of use and efficiency allows for faster results, enabling healthcare professionals to make timely clinical decisions and potentially expedite patient treatment plans. The shortened turnaround time reduces waiting periods and the anxiety associated with prolonged diagnostic processes, improving the overall patient experience.

Biomarkers that are simple to administer, interpret, and integrate into existing clinical workflows are more likely to be embraced by healthcare providers. Minimising the need for specialised equipment or extensive training ensures the broad accessibility and usability of the biomarker technology across different healthcare settings

By ensuring the durability and reliability of the device, healthcare professionals can rely on its performance without concerns about damage or malfunctions. This reliability contributes to ease of use by eliminating potential disruptions in workflow and ensuring that the device can consistently deliver accurate results.

"So we made more of a robust device that is strong enough that can bear the high temperatures of the Indian summers, and can be even sustained the fall if it falls down."

Cost effective

In the BM of diagnostic solutions, cost effectiveness is a key factor so that providers can develop pricing strategies that align with the economic capabilities of the target market.

By using diagnostic solutions that streamline the diagnostic process and enable timely interventions, healthcare providers can potentially reduce the duration and intensity of treatment required. This can lead to a decrease in hospitalisation rates, shorter hospital stays, and a lower burden on healthcare facilities, ultimately resulting in cost savings for both the hospital budget and patients.

"Efficient treatment, reduce hospitalisation, cost effective for hospital budget"

Particularly in contexts where imported products from the US, Europe, or other countries may be overpriced and unaffordable. An interviewee suggests that local products have the potential to meet the specific needs of the healthcare system in a more targeted and cost-efficient manner. This supports the notion that locally developed diagnostic solutions can be tailored to the economic realities of the region, ensuring affordability and accessibility for healthcare providers and patients. "The important solutions cannot be tailor made for our needs. And anything that comes from the US or Europe, it's always overpriced and is beyond the reach of affordability. For anyone say for example, any product that comes from the US or UK or any to any other country, it has a lot of costs added to that. So that is why it becomes costlier. So it's always that indigenous products would have a better say what you call it as a better fulfilling the needs better in a better way and more targeted approach. And there is a special trust to medical device startups"

Platform for collaboration

A platform for collaboration emerges as a key BM factor in the context of diagnostic solutions, as indicated by the following transcript.

"So it's collaborative. So typically, the client, of course, has a question, right? We try to answer the question. And in many cases, the answer is relatively straightforward. They just want to use, and they want to have the data in there. Often, when they want to have new functionality, it's a bit more involved. So you have to describe the functionality, really try to understand what they want to do with it, etc. And then there's also the community as a whole, every time something new was built." By providing a collaborative environment, the BM facilitates community. This collaborative approach involves active engagement with clients to gather feedback, understand desired functionalities, and ensure that the diagnostic solutions effectively meet their needs. By fostering this collaboration, the BM promotes a sense of partnership and mutual understanding between the diagnostic provider and the clients.

Furthermore, the value offering of diagnostic technologies includes acting as a platform for collaboration among stakeholders. These solutions can serve as a catalyst for interdisciplinary collaboration, bringing together researchers, clinicians, industry partners, and patient advocacy

groups. Collaboration fosters knowledge exchange, accelerates research and development efforts, and facilitates the translation of biomarker innovations into clinical practice.

Portability

The portability of blood-based biomarkers is an essential aspect of their value offering. Portable biomarker testing devices or methodologies that can be easily transported and deployed in various healthcare settings offer flexibility and accessibility as expressed by an interviewee. He mentions the portability of lab-on-chip biosensors allows for on-the-go testing and monitoring, enhancing convenience for both healthcare professionals and patients. Additionally, the mention of implantable devices highlights the potential for portable diagnostic solutions that can be carried within the body, providing continuous monitoring and real-time data."

lab on chip biosensors Like the other glucose by sensors. This can be also integrated or like a lab on chip by sensor, and this is really, really good. I could say, a simple bio sensing system, which can also be an implantable device as well"

In another transcript, the portability of a specific device that is battery-operated and provides results in just two minutes. The mobility of this device enables it to be easily carried and used in various settings, including remote or resource-limited environments. The simplicity of operation, requiring minimal training, further enhances its accessibility and usability by a wide range of individuals, including those without a medical background. The immediate display of objective results in real-time adds to the device's value proposition, providing actionable information for prompt decision-making.

"The device we developed is battery operated, so it can be carried on. And it gives results in two minutes. So anybody, like any lay man who's not from medical background can be trained to use that machine, within 10 minutes, it's just 10 years of training that is needed. Once a person knows how to use it. The person can scan the patient's head. And if there's a haemorrhage what is the location of the haemorrhage that screen displays in green or red in real time. So it's like very

objective."

Furthermore, the mention of upcoming devices in the third transcript underscores the commitment to portability. The future devices are described as portable, smart, and capable of diagnostics, with some even having therapeutic functionalities. This highlights the BM's focus on developing a range of portable solutions that can cater to diverse diagnostic needs.

"right now we have six more devices, already into the various phases of development, almost, the hardware development and the firmware development has been done only the clinical validation for those devices as required. So in the next six to eight months, or a year or so if we have some good funding, we would be able to bring those six to eight devices into the market, all our portable, all our smart, all are capable of diagnostics, and some are even therapeutic, specifically for the respiratory care devices, then what we have is all the devices work with the smartphone, the personalised home healthcare versions also worked with a smartphone, giving more of a personalised healthcare to the people."

4.4.2 Identifying key factors affecting BM value delivery

Value delivery in the context of health diagnostic innovations involves several subthemes, including regulatory approval, satisfying customer requirements, managing collaborations, training support, sustaining research and development (R&D) innovations, onboarding customers, effective sales channels, earning trust of stakeholders, adoption of innovation, clear customer needs, satisfied regulatory clearance, training and support provided, timely delivery of value, and awareness initiatives. Table 4.3 shows the different BM value delivery factors identified based on the data collected from biomedical/ healthcare industry experts. The empirical findings reveal the 14 BM factors.

The BM factors represent the first-order codes, as shown in the second column. The third column indicates the presence or absence of evidence obtained from the interview cases. Higher numbers indicate stronger evidence for the finding in the corresponding factor. Triple ticks $(\sqrt[4]{v})$ represent strong evidence and double ticks $(\sqrt[4]{v})$ represent moderate evidence. Single tick $(\sqrt[4]{v})$ represents weak evidence and a blank represents no evidence. The final column is the aggregate dimensions which are the BM components.

Table 4.3 Empirical evidence in discovering BM value delivery

	Second-order							S	Sup	po									aluo nts)		ffer	ing	g							Aggregate
First-order codes	themes (BM factors)	1	2	3	4	5	6	7	8 9	9 1	0 1	1 12	13	14	15	16	17	18	19 2	20 2	21 2	2 23	3 24	25	26	27	28	29	30	dimensions (BM components)
"So the product lifecycle, especially in the EU context will be R&D, regulatory approval, market distribution, and post market surveillance and build the product lifecycle."	Securing regulatory approval	~ ~ ~ ~	222	222	222	222	~ ~ ~	~ .					22	22	22	22	~ ~	22	~ .					222	222	22	222	~	222	
"so the way that we build software's, especially services, especially software oriented, is really started to gather requirements are the early stage." "Map customer journey, understanding the needs of the end user dissemination/ showcasing success stories in the website collaboration, story mapping, engaging people"	Satisfying customer requirements	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	222	222	222				/		/ v / v		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	~ ~ ~	222	222	222	~ ~ ~	~ · ·					~ ~ ~	222	222	222	~ ~ ~ ~	222	Key activities
"key activities, well, managing relationships with our customers on a regular basis. That would be a different discovery workshops that we have our sessions."	Effectively managing collaborations	~ ~ ~ ~	222	ンンン	222	222							222	222	222	222	ンンン	222	~ ~ ~	/.				222	222	222	~ ~ ~ ~	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	2 2 2 2	

"Internal training support is necessary in helping healthcare professionals and laboratory staff adopt and utilise blood-based biomarkers in clinical practice. By providing comprehensive training, we ensure that they have the necessary skills and knowledge to use the biomarker technology effectively and accurately interpret the results."	Training support (internal)	222	222	~ ~ ~	~ ~ ~	~ ~ ~	~~~~	~ ~	222	222	~ ~ ~ ~	~ ~ ~	222	555	222	~ ~ ~	222		/ . / .			/ 0	•	•			v v v		
"So I would say 70% of our cost, little over 70% maybe goes into r&d and that is because So, this is not the only device in the process of developing this device. We have to develop certain expertise in deep tissue investigation. So all r&d is done in house. But mainly 90% of r&d is done in house, I would say."	R&D for sustaining innovations	222			~ ~ ~	r	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	v	222	~	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	222	222	222	222	~ ~ ~	222		, u , u , u		 / 1	· · ·		•			~ ~ ~		
"Even major upgrades, we do events with individual customers." "So value beneficiaries there, there are many. So, of course, we have paying customers, the majority there is basically from, from pharma companies who would like to use the (our solution) to, to analyse their own proprietary data. So that could be datasets that they acquired, or that they generate in house, you know, from clinical trials or tumour profiling studies. And of course, they	Onboarding of customers	222	r	~ ~ ~	~ ~ ~	~~~~	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	r	v	2	~ ~ ~ ~	222	222	222	222	~ ~ ~	222		~ •	 • 	 < •		 • 	-	~ •	/ .	222		

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don't want to share the data. So they																												
can just go and send it into the public																												
cBioportal. So they want to have																												
their own installation. So we set it up																												
for them. And then we also do do																												
development. Then there's also																												
hospitals who also want to analyse																												
their own data that's a smaller group																												
for us. And then we're also involved																												
in Horizon 2020 grants, where to																												
cBioportal is really like the central																												
repository for the data coming from																												
different different partners. Then, you																												
know, for these pharmaceutical																												
companies, we do quite some																												
development of new, new																												
functionality. And since it's open																												
source, that will all go back into the																												
open source, open source code base.																												
So the value beneficiaries for that are																												
basically everybody who uses (our																												
solution), everybody who goes to																												
(our solution) org to analyse public																												
data to anybody who has like in a																												
private installation, whether we																												
manage it or not, would benefit from																												
that, from that work."																												
So we have two incoming channels			T	\square	╈	T	\square	\uparrow	╈	Τ		Γ		╈	╈	╈		Π										
one is the customer feedback. So																												
based on our current customers and	Establishing effective	~ ~		レ レ	٢.	//			~ •	//	1	1	~	~ •	//	//	1			~	~	~	~		~	~	~	
their wishes for further	distribution channels			~	<u> </u>			1	<u> </u>	//			ン ン ン	<u> </u>	//		~	~	~	~	~	~	~	~	~	~	~	Channel
enhancements of the products, we		 		[-				~ '			ľ	 	"	" "													
collect those through either our																												
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support desk or our business development. We're our product managers which are in constant contact with them. So that's one. And with these existing customers, we do product discoveries, which are hands on workshops, where we have a set of interviews "Transparent and trustworthy	5																		
practices build strong relationships with stakeholders, enabling the company to communicate openly and honestly with its customers. As the reputation for accuracy and ethical behaviour spreads, word-of-mouth becomes a powerful channel for reaching new customers. Satisfied stakeholders are more likely to share their positive experiences with others, contributing to the growth of the customer base." "Because you know, when the real money starts coming in, things start to change. And specially investors, private investors who invested, they want more and more money out of the money that they have invested. And further to explain that we are sharing the benefits with no external parties who's not really under your rights, that becomes difficult to sustain. But what we have done is, we have already signed contracts	Earning the trust of stakeholders	~ ~ ~			222	222	222	222	222	222	22		22	22	r	22	~ · ·		

and maintain, what should I call an extreme level of transparency. So any new contract that I signed, of course, there'll be some parts that are not for everybody, but everybody, all the stakeholders, including investors, or bankers, or employees, our advisors everybody's aware of, and, of course, the legal structure, which is that Chartered Accountants that the company secretaries, everybody is aware of all the things that we do, I mean, all the deals that we make, all the elements of those contracts that we made, but either distributors or hospitals, or anyone, so it's very transparent and very clear to everybody beforehand."																									_	
look at have good personal	Driving adoption of innovation	~ .	222	222	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	222	222	222	222		222	222	22	22	22	22	22	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		22	22	22				

ost-effectiveness of our diagnostic levices through rigorous scientific tudies and partnerships with key pinion leaders in the field." 'we want to really scale up fast, we're focused on the more on the product development, not so much on project specific deliveries. Therefore, tacking out our product offering from the database layer, to the intermediate governance player up to the front end application level, we eally want to make sure that the pustomer can get the whole stack"																																		
"First of all, we put a lot of emphasis on the customer requirements or expectations." "So it's basically driven also from, from the community itself, we do the questions that we get from users tell us in which direction they would like to move, what they are missing in the system as it is now. So it's basically driven also from, from the community itself, we do the questions that we get from users tell us in which direction they would like to move, what they are missing in the system as it is now."	Having clear customer needs	v	v	~ ~	222	222	22	v	222	r	222	222	222	222	222		222	ンンン	222	r	7	ととと		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	· · · · · · · · · · · · · · · · · · ·		222	レンン						
"And then, from the side of regulation, of course, because it's the healthcare and it's heavily regulated, especially in UK as we experienced.	Satisfied regulatory clearance	222	~	V	222	~	222	~		~	~	~	r	~	~		v	~	~		2 2 2	~	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	' 	1.	/	~	レンレ	~	1				

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The whole process of making sure							
that the patient safety is assured that							
we need the NHS standards."							
"Because when I go to the investors,							
they are asking for the certification,							
otherwise, we become very early							
stage, even if we have a working							
prototype; even I spent seven years							
for the product they see it as an early							
stage company, because we just set							
up in 2017. So they won't just							
because of the health care aspects,							
they want to see the certification at							
least FDA approval, or at least CE							
marking and then they want to take							
this risk, and invest to the company."							
"we have to get FDA approval,							
because FDA probably shows that							
your diagnostic is accurate. Your							
diagnostic is working. And also CE							
marking CE marking shows that your							
device is safe, safe. We just need to							
this certification for the value							
proposition. If we have enough							
funding right now, is a line process							
because we know what we should do							
for the next step. But to get the							
certifications and finalize the final							
product, we need funding, we need							
investment. And right now we don't							
have this type of investment. We are							
just using government r&d grants."							

"The team is also very much involved in collaborating in the community, making this kind of a joint effort. And they're also now involved in training end users, and people would want to load data So you know, training people is also a good way to get more sustainability. Because the more users you have, the more people eventually are willing to invest in the thing that you're building."	Training and support provided	v	2	~ ~				v	222	~~~~		· · · · · · · · · · · · · · · · · · ·	222	222	222	~	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			· · · ·	
"We've sent out our research team went out, and we found out that it is mainly because there is a delay in detection of the haemorrhage. So there's a golden period within which if damage is detected, it's easier to be freed in the haemorrhage is not detected within that tiny stipulated time, it becomes very difficult for doctors to contain the damage. The device we developed is battery operated, so it can be carried on. And it gives results in two minutes. So anybody, like any lay man who's not from medical background can be trained to use that machine, within 10 minutes, it's just 10 years of training that is needed. Once a person knows how to use it. The person can scan the patient's head. And if there's a haemorrhage what is	Timely delivery of value	22	2	er.	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	. v	2		222	222		 	222	222	222					· · ·	

the location of the haemorrhage that screen displays in green or red in real time. So it's like very objective.'																
"Even major upgrades, we do events with individual customers." "So we have two incoming channels, one is the customer feedback. So based on our current customers and their wishes for further enhancements of the products, we collect those through either our support desk or our business development. We're our product managers which are in constant contact with them. So that's one. And with these existing customers, we do product discoveries, which are hands on workshops, where we have a set of interviews" "Promoting awareness, education, and training programs to familiarise healthcare providers with the benefits and applications of the biomarker technology increases its acceptance and integration into clinical practice."	Implementing awareness initiatives		 222		222		222	222	222					222		

Regulatory approval

BMs must navigate complex ethical and regulatory frameworks related to healthcare technology development, patient privacy, data sharing, and compliance with healthcare regulations, as emphasised by the transcripts. Obtaining regulatory approval is a critical step in the product lifecycle, ensuring that the diagnostic solutions meet the necessary quality, safety, and efficacy standards before they can be distributed in the market and used by healthcare professionals. After research and development (R&D), the diagnostic solution must undergo rigorous regulatory assessment to demonstrate its compliance with established regulations and guidelines. This process ensures that the diagnostic solution meets the required performance and safety standards, providing confidence to healthcare providers and patients about its effectiveness and reliability.

"So the product lifecycle, especially in the EU context will be R&D, regulatory approval, market distribution, and post market surveillance and build the product lifecycle."

Compliance with regulations demonstrates a commitment to quality and patient safety, positioning the company as a reliable partner in the healthcare sector. This reputation can lead to strengthened collaborations with key stakeholders, such as academic researchers and oncologists, as mentioned in the following transcript, fostering a network of trusted relationships that drive innovation and value creation.

"Developing a successful business model in the healthcare environment, particularly in brain cancer diagnostics, requires considering factors such as innovation in technology, adherence to ethical standards, regulatory compliance, collaboration with key stakeholders (e.g., academic

researchers, oncologists)"

Satisfying customer requirement

The process of gathering and understanding customer requirements plays a crucial role in designing and developing diagnostic solutions that effectively meet the needs of end users. An interviewee Gathering requirements at an early stage of the software development process. This customer-centric approach ensures that the diagnostic solutions are built with a clear understanding of the specific needs and preferences of the target users. By involving customers from the outset, the BM can align its efforts with the actual demands of the end users, leading to the creation of more relevant, useful, and user-friendly diagnostic solutions.

"so the way that we build software's, especially services, especially software oriented, is really started to gather requirements at the early stage."

"Map customer journey, understanding the needs of the end user dissemination/ showcasing success stories in the website collaboration, story mapping, engaging people"

Managing collaborations

Effective management collaborations of key stakeholders such as diagnostic companies, research institutions, healthcare professionals, researchers, regulatory bodies, and industry partners, play a significant role in advancing technology development, clinical validation, and commercialisation efforts. Managing these collaborations involves establishing clear communication channels, building and maintaining strong and productive relationships with customers. Regular communication with customers allows businesses to address concerns, provide timely support, and demonstrate a commitment to delivering value. This ongoing interaction helps businesses stay attuned to customer needs, expectations, and feedback, enabling them to continuously improve their products or services to better meet customer demands.

"key activities, well, managing relationships with our customers on a regular basis. That would be a different discovery workshops that we have our sessions."

"Developing a successful business model in the healthcare environment, particularly in brain cancer diagnostics, requires considering factors such as ... collaboration with key stakeholders

(e.g., academic researchers, oncologists)"

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Training support (internal)

Providing comprehensive training to healthcare professionals and laboratory staff ensures their competence in using the biomarker technology effectively and interpreting the results accurately. This support may include training programs, workshops, and ongoing educational initiatives to keep the users updated on the latest developments and best practices.

"Internal training support is necessary in helping healthcare professionals and laboratory staff adopt and utilise blood-based biomarkers in clinical practice. By providing comprehensive training, we ensure that they have the necessary skills and knowledge to use the biomarker technology effectively and accurately interpret the results."

R&D sustaining innovation

Continued research and development (R&D) to sustain innovation is crucial for delivering value. This activity involves dedicating significant resources and effort to R&D, with a focus on continuous improvement and innovation to sustain the growth and competitiveness of the diagnostic solutions. As shared by one of the cases, over 70%, of the company's costs are allocated to R&D. This investment is justified by the need to continually develop and enhance the diagnostic solutions to meet the evolving demands of the healthcare industry. The commitment to in-house R&D showcases the company's dedication to maintaining control over the innovation process, allowing for greater flexibility and agility in responding to market needs.

"So I would say 70% of our cost, little over 70% maybe goes into r&d and that is because So, this is not the only device in the process of developing this device. We have to develop certain expertise in deep tissue investigation. So all r&d is done in house. But mainly 90% of r&d is done in house, I would say."

Onboarding customers

This activity involves the process of welcoming and integrating new customers into the business ecosystem, providing them with necessary resources, support, and guidance to ensure a smooth and successful adoption of the diagnostic solutions. By providing dedicated onboarding sessions, the BM enables customers to quickly familiarise themselves with the diagnostic solutions, reducing the learning curve and enhancing their overall experience. Efficient onboarding ensures that customers can start using the diagnostic solutions effectively, enabling them to derive value from the solutions early on and accelerating the realisation of benefits.

"Even major upgrades, we do events with individual customers."

As expressed by an interviewee engaged in Horizon 2020 projects, various value beneficiaries, including pharma companies, hospitals, and partners involved in Horizon 2020 grants. For pharma companies, the BM sets up customised installations of the solution, allowing them to analyse their proprietary data without sharing it publicly. This tailored approach ensures that customers can harness the full potential of the solution while maintaining data privacy and security.

"So value beneficiaries there, there are many. So, of course, we have paying customers, the majority there is basically from, from pharma companies who would like to use the (our solution) to, to analyse their own proprietary data. So that could be datasets that they acquired, or that they generate in house, you know, from clinical trials or tumour profiling studies. And of course, they don't want to share the data. So they can just go and send it into the public (company solution). So

they want to have their own installation. So we set it up for them. And then we also do

development."

Effective sales channel

Satisfying customer requirements and managing collaborations involve understanding the needs and expectations of end-users, healthcare providers, and other stakeholders to ensure that the developed

biomarker aligns with their specific requirements. Providing training support and onboarding assistance to customers facilitates the smooth integration and utilisation of the biomarker technology in their clinical practices. Effective sales channels, awareness initiatives, and earning trust from stakeholders contribute to successful adoption and utilisation of the innovation (Johnson et al., 2023).

"The success factors for the business model as basically the model is successful there, we see it as that when we meet the targets, i.e we are setting targets every year, year over year that that you should be able to sell so many devices, and around which you should be able to sell so many m disposables, so many subscriptions. And if you are able to achieve that the sales target, we say that, okay, this successful now, because again, as I said to be our r&d companies, we are also looking for investors, any periods investments, as we need and on the term stand, we call it successful. first

challenge is to make people know that our device is a very unique device"

Furthermore, the value proposition should align with economic and political considerations to ensure feasibility and support from healthcare systems.

"So this could be a more of a feasible model or a viable model. But it should not be totally against the ethos of the company. That's what I think could be profitable. Yeah, should be a win win situation for all. I'm not going to go into partners who are key stakeholders are integrating these are the basic things, that what I think for a business model to succeed have to be my business model canvases are just to what we call it as to refine your model, how you can do that what your strategy is, and how is this strategy gonna work for you? But these are the basic things what I believe, are, are very important for a business model to be practical."

Earning trust of stakeholders

Earning the trust of stakeholders is paramount for the successful delivery of value in healthcare technologies. The importance of building a deep trust relationship is highlighted as a crucial factor

for the BM's success. The trust earned from stakeholders, including healthcare providers, patients, and regulatory bodies, serves as the foundation for cultivating strong and enduring customer relationships.

"you have to build a very deep trust relationship. The trust earned from stakeholders serves as the foundation for a strong and enduring customer relationship. It encourages customers to remain

loyal and repeat business with us."

This includes building a reputation for reliability, accuracy, and ethical conduct. When stakeholders perceive the company's commitment to accuracy and ethical behaviour, their positive experiences become a powerful channel for reaching new customers through word-of-mouth recommendations. This organic form of promotion contributes to the expansion of the customer base and the wider acceptance of the biomarker technology in the healthcare market.

"Transparent and trustworthy practices build strong relationships with stakeholders, enabling the company to communicate openly and honestly with its customers. As the reputation for accuracy and ethical behaviour spreads, word-of-mouth becomes a powerful channel for reaching new customers. Satisfied stakeholders are more likely to share their positive experiences with others, contributing to the growth of the customer base."

"Because you know, when the real money starts coming in, things start to change. And specially investors, private investors who invested, they want more and more money out of the money that they have invested. And further to explain that we are sharing the benefits with no external parties who's not really under your rights, that becomes difficult to sustain. But what we have done is, we have already signed contracts and maintain, what should I call an extreme level of transparency. So any new contract that I signed, of course, there'll be some parts that are not for everybody, but

everybody, all the stakeholders, including investors, or bankers, or employees, our advisors everybody's aware of, and, of course, the legal structure, which is that Chartered Accountants that the company secretaries, everybody is aware of all the things that we do, I mean, all the deals that we make, all the elements of those contracts that we made, but either distributors or hospitals, or anyone, so it's very transparent and very clear to everybody beforehand."

Adoption of innovation

Evident from the transcripts, to ensure successful adoption, the BM employs several strategies to make its healthcare innovation widely accepted and utilised. One key approach is creating awareness and accessibility. By making the platform open source and publicly available, the BM enables users to explore the technology and access hundreds of public datasets. This approach fosters familiarity with the platform and encourages potential users to engage with the innovation, thus increasing the likelihood of adoption.

"The other part in helping adoption is obviously, you know, just getting users to know the platform. And you know, (our solution), it's it's, it's open source, it's also publicly available. It has their like hundreds of public datasets that people can look at. have good personal, personal relation with them. So an understanding of what they need, and what we need to make that relationship a

success "

Moreover, demonstrating the clinical utility and cost-effectiveness of diagnostic devices through rigorous scientific studies and partnerships with key opinion leaders in the field.

"To ensure adoption of healthcare innovation, we focus on demonstrating the clinical utility and cost-effectiveness of our diagnostic devices through rigorous scientific studies and partnerships with key opinion leaders in the field."

Furthermore, as mentioned by an interviewee, the BM's commitment to product development and scaling up rapidly is a driving force for adoption.

"we want to really scale up fast, we're focused on the more on the product development, not so much on project specific deliveries. Therefore, stacking out our product offering from the database layer, to the intermediate governance player up to the front end application level, we really want to make sure that the customer can get the whole stack"

Clear customer needs

Understanding and addressing clear customer needs has been emphasised in delivering a more effective and impactful solution.

"First of all, we put a lot of emphasis on the customer requirements or expectations." By actively engaging with the community and listening to the questions and feedback from users, the BM gains valuable insights into the direction in which they want the technology to evolve. This direct feedback from the community serves as a guiding force in shaping the development and improvement of the innovation. It helps the model identify any gaps or areas where the system can be enhanced to better meet the users' needs and expectations.

"So it's basically driven also from, from the community itself, we do the questions that we get from users tell us in which direction they would like to move, what they are missing in the system as it is now. So it's basically driven also from, from the community itself, we do the questions that we get from users tell us in which direction they would like to move, what they are missing in the system as

it is now."

Satisfied regulatory clearance

The healthcare industry is heavily regulated, especially in regions like the UK, where patient safety is of utmost importance. Therefore, obtaining regulatory approvals, such as FDA approval and CE marking, is essential to validate the accuracy and safety of the diagnostic device.

"And then, from the side of regulation, of course, because it's the healthcare and it's heavily regulated, especially in UK as we experienced. The whole process of making sure that the patient safety is assured that we need the NHS standards." For the BM to deliver its value proposition effectively, it must adhere to the stringent regulations set by health authorities. FDA approval confirms that the diagnostic device is accurate and reliable, while CE marking ensures that the device meets the safety standards required for use in the European market. Furthermore, satisfying regulatory clearance is not only necessary for the value proposition but also for securing funding and investment.

"we have to get FDA approval, because FDA probably shows that your diagnostic is accurate. Your diagnostic is working. And also CE marking CE marking shows that your device is safe, safe. We just need to this certification for the value proposition. If we have enough funding right now, is a line process because we know what we should do for the next step. But to get the certifications and finalise the final product, we need funding, we need investment. And right now we don't have this type of investment. We are just using government r&d grants."

Training and support provided

By providing training and support to end-users, the BM aims to enhance the sustainability of its innovation. When users are well-trained and proficient in utilising the technology, they become more confident and willing to invest in the solution. The BM recognizes the importance of collaborating with the community and ensuring that end-users receive proper training and support to effectively use the technology.

"The team is also very much involved in collaborating in the community, making this kind of a joint effort. And they're also now involved in training end users, and people would want to load data... So you know, training people is also a good way to get more sustainability. Because the more users

you have, the more people eventually are willing to invest in the thing that you're building."

Timely delivery of value

Timely delivery of value is critical particularly in detecting medical conditions promptly. Timely delivery ensures that healthcare providers can make informed decisions promptly, leading to timely interventions, treatment planning, and improved patient outcomes. In a case highlighted by an interviewee, especially in cases like haemorrhage, timely intervention can significantly impact patient outcomes. Their battery-operated device is an innovation capable of delivering results in just two minutes. This rapid response time allows healthcare professionals to quickly detect haemorrhage and take necessary actions within the crucial golden period when damage can be effectively contained.

"We've sent out our research team went out, and we found out that it is mainly because there is a delay in detection of the haemorrhage. So there's a golden period within which if damage is

detected, it's easier to be freed if the haemorrhage is not detected within that tiny stipulated time, it

becomes very difficult for doctors to contain the damage. The device we developed is battery operated, so it can be carried on. And it gives results in two minutes. So anybody, like any lay man who's not from medical background can be trained to use that machine, within 10 minutes, it's just 10 years of training that is needed. Once a person knows how to use it. The person can scan the patient's head. And if there's a haemorrhage what is the location of the haemorrhage that screen displays in green or red in real time. So it's like very objective."

Awareness initiatives

Conducting awareness initiatives plays a significant role in the successful delivery of value. These initiatives aim to educate healthcare providers, patients, and the public about the benefits and potential of the biomarker technology. Awareness programs can include educational campaigns, conferences, workshops, and collaborations with patient advocacy groups.

"Promoting awareness, education, and training programs to familiarise healthcare providers with the benefits and applications of the biomarker technology increases its acceptance and integration into clinical practice."

Customer feedback serves as another crucial channel for raising awareness and delivering value. The BM actively seeks input from current customers, collecting their suggestions and requirements for further product enhancements. This iterative feedback process allows the model to continuously improve its offerings, ensuring that the solutions align closely with customer expectations and demands.

"Even major upgrades, we do events with individual customers."

"So we have two incoming channels, one is the customer feedback. So based on our current customers and their wishes for further enhancements of the products, we collect those through either our support desk or our business development. We're our product managers which are in constant contact with them. So that's one. And with these existing customers, we do product discoveries, which are hands on workshops, where we have a set of interviews"

4.4.3 Identifying key factors affecting BM value network

The value network in the development of health diagnostic innovations encompasses subthemes such as health champions for technology adoption, outsourcing value creation, sustaining value ecosystem, team expertise, culture and values, intellectual property, and funding. Table 4.4 shows the different BM value offering factors identified based on the data collected from biomedical/ healthcare industry experts. The empirical findings reveal the 7 BM factors.

The BM factors represent the first-order codes, as shown in the second column. The third column indicates the presence or absence of evidence obtained from the interview cases. Higher numbers indicate stronger evidence for the finding in the corresponding factor. Triple ticks $(\sqrt[4]{\sqrt{3}})$ represent

strong evidence and double ticks $(\sqrt{\sqrt{}})$ represent moderate evidence. Single tick $(\sqrt{})$ represents weak evidence and a blank represents no evidence. The final column is the aggregate dimensions which are the BM components.

Table 4.4 Empirical evidence in discovering BM value network

								S	Sup	po	ort									alu nts		off	eri	ng								
First-order codes	Second-order themes (BM factors)	1	2	3	4	5	6	7	8 9	9 1	10	Ì				-			-		,	21	22	23	24	25	26	27	28	29	30	Aggregate dimensions (BM components)
"network is everything We have to create our network because it will very helpful it is very helpful to reach the investors reach the right customer reach them, manufacturing companies is all about network actually, when I when I start this journey, my first duty was that creating a network because without a network, we can't reach each other" "One of the primary reasons health champions are crucial to our business model's success is their ability to bridge the gap between technological advancements and real-world implementation. Their firsthand experience and credibility in the healthcare sector allow them to effectively communicate the benefits and value of our biotech solutions to their colleagues and decision-makers. By doing so, they build trust and confidence in our technologies, which is vital for gaining acceptance in the healthcare industry, where adopting new innovations can often be met with		555	5 S	~			•••••••••••••••••••••••••••••••••••••••				222	222	222	222	555	5 5 5 2 2	111	555	5 5 5 2 5	555	٢	۲	٢	٢	7	7	٢	7	٢	2	222	Key partners

skepticism." "And community is really what made open source tools powerful. if you are in an open source community, and you would have a similar software, you may have like an OHDSI, for instance, you would meet medical doctors that are epidemiologists, data scientists, and clouds professionals, or this whole spectrum of people that is involved."																								
"key partners are really very, very key to our operations to our existence actually, because the device that we are making, it involves a lot of components that are very, very specific to us, and they are customised in a way we have caused a lot of people to do this for us. And then we went out of the network that we had been in this startup ecosystem in India and abroad." "But as I said, we take some support from various labs and various consultants across the world. Some specialists that we need, we take consultancies and guidance from them and some access to certain labs."	Outsourcing value creation	v	~ ~	r l		~ ~ ~	. v v	r	222	222	222		· · · · · ·	222	222	222			~	222			v	
"Now we are connected to at least 20 defended startup ecosystems across the globe, including London, to the UK. So we are very connected, and we use our connections to reach out to different partners who are capable of	Sustaining the value ecosystem	22	222	~	~ ~ ~			~	222	222	222			222	222	~ ~ ~	-			 222	~	~	~ ~	

mentors."		\prod	Τ					Γ						Τ	Τ																
"I would imagine starting from the PIs, that are working in this project, networking from them, because I think already to start to think about it. People that are everybody in this project and are building biosensor for investigating cancer, they must already within the network of brain cancer community" "So if you see also in our company, all our background comes from university or some researching, and either is a deep software developer, software, computer science, or research	Securing team expertise				222	222			222	222	222	222					~	222	222	222	222	22	~ ~ ~		222	K	eyı	reso	urce	s	
"Secondly, it is the disposable of this biological waste actually creating this biogas that we create. So, in our case, although it is a silicone composite	Organisational culture	2 2 4 2 2	/	r	222	~~~~			222	ンンン	ンンン	~	~ . ~ . ~ .						22					22	~ ~ ~						

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pocket, we have ensured, although it							
was a cost to us, but we ensured that it							
is naturally biodegradable, so you just							
throw it away and bacteria that will							
become soil and then you can grow							
grow flowers and that kind of"							
"what is our vision? Everyone in life							
science works together towards better							
health. But what does this mean? All							
the companies in our field are looking							
for better health. So all the companies							
are doing the same. What's our unique							
position? Our unique position is							
working towards better health for Life							
Sciences, with Life Sciences, the							
researchers/ scientists. So that's							
important and what's important for							
them, that they collaborate, they work							
together. And our role is helping them,							
enabling them to collaborate. And so							
that it's our vision: everyone in Life							
Science works together towards better							
health. And what are we doing? Our							
mission: enabling Open Science by							
developing and implementing open							
source solutions and fairifying data in							
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"As a company, we what we do is we, we sell consultancy hours. So we don't sell licenses, we don't sell the product itself, we sell services around. So for us that's, you know, deployment, training, building new functionality is data loading those types of activities, we can just judge that by by the hour, then, a big part of sustainability is of course, grant money. Then we started working on it about five years ago. And, yeah, basically, we have a steady stream of income, which is used to finance the team and for us to work on on cbioportal. So as long as people are using it, and you know, willing to pay for that, then that will just continue. I think visualization platform like cBioportal will be needed for the coming, I don't know. 10-20 years. And as long as there's a need, I think there's going to be company funding for it." "It should encompass collaborations with industry partners, intellectual property protection strategies, engagement with healthcare providers, and the potential for commercialisation of the developed biomarker technology."	Protecting intellectual property	222	r													r		r	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	r	22		v	222	
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Health champions for technology adoption

Health champions for technology adoption are a key component of a BM's value network towards the success and widespread implementation of healthcare diagnostic innovations, as highlighted in the following transcripts. These individuals or entities act as advocates, influencers, and key stakeholders who passionately support the adoption of innovative technologies and solutions within the healthcare industry.

"network is everything.. We have to create our network because it will very helpful it is very helpful to reach the investors reach the right customer reach them, manufacturing companies is all about network actually, when I when I start this journey, my first duty was that creating a network because without a network, we can't reach each other"

Building and nurturing a strong network is essential for reaching investors, potential customers, and manufacturing partners. Health champions play a pivotal role in driving the adoption and integration of blood-based biomarkers into clinical practice. These individuals, such as influential clinicians or patient advocates, champion the benefits and value of the biomarker technology within their professional networks and patient communities. Their endorsement and advocacy enhance the credibility and acceptance of the biomarkers, fostering their integration into standard care pathways and clinical guidelines.

"One of the primary reasons health champions are crucial to our business model's success is their ability to bridge the gap between technological advancements and real-world implementation.

Their firsthand experience and credibility in the healthcare sector allow them to effectively

communicate the benefits and value of our biotech solutions to their colleagues and decision-makers. By doing so, they build trust and confidence in our technologies, which is vital for gaining acceptance in the healthcare industry, where adopting new innovations can often be met with scepticism."

Furthermore, fostering a community around our open-source tools amplifies their impact and power.

"And community is really what made open source tools powerful. if you are in an open source community, and you would have a similar software, you may have like an OHDSI, for instance, you would meet medical doctors that are epidemiologists, data scientists, and clouds professionals, or this whole spectrum of people that is involved."

Outsourcing value creation

Healthcare diagnostic innovations often require substantial investments in research, development, and manufacturing. By outsourcing certain aspects of the value creation process, companies can reduce operational costs and allocate their resources more efficiently. Thus, outsourcing value creation is a factor relevant in the BM value network.

"key partners are really very, very key to our operations to our existence actually, because the device that we are making, it involves a lot of components that are very, very specific to us, and they are customised in a way... we have caused a lot of people to do this for us. And then we went out of

the network that we had been in this startup ecosystem in India and abroad."

Outsourcing provides several advantages, including cost-efficiency, access to specialised knowledge, and accelerated development timelines. By outsourcing certain aspects of the value creation process, companies can reduce operational costs and allocate their resources more efficiently. Additionally, outsourcing enables companies to tap into specialised knowledge and expertise that may not be readily available in-house. Healthcare diagnostic innovations are multidisciplinary endeavours that require expertise in various fields, including medicine, biotechnology, engineering, and data science. By partnering with external vendors or collaborating with research institutions, businesses can access cutting-edge knowledge and technology, driving innovation and ensuring the development of high-quality solutions.

"But as I said, we take some support from various labs and various consultants across the world. Some specialists that we need, we take consultancies and guidance from them and some access to

certain labs."

Sustaining value ecosystem

This factor encompasses strategies and actions aimed at nurturing a supportive and interconnected ecosystem that enhances the long-term value of the diagnostic solutions. A sustainable value ecosystem ensures the continued success of the innovations, fosters collaboration among stakeholders, and creates a positive impact on patient outcomes and healthcare practices. As highlighted by an interviewee, the significance of building and nurturing connections with various stakeholders in the healthcare and biotech industries.

"Now we are connected to at least 20 defended startup ecosystems across the globe, including London, to the UK. So we are very connected, and we use our connections to reach out to different partners who are capable of mentors."

An interviewee, coming from an EU funded collaborative project, highlighted the significance of networking with principal investigators (PIs) and experts working on cancer investigation projects, emphasising the value of building connections within the brain cancer community. This collaboration fosters knowledge exchange, access to specialised insights, and facilitates the alignment of goals and resources within the value network.

"I would imagine starting from the PIs, that are working in this project, networking from them, because I think already to start to think about it. People that are everybody in this project and are building biosensor for investigating cancer, they must already within the network of brain cancer

community"

Team expertise

The presence of highly skilled and experienced professionals within the team creates a strong foundation for the network's success. Coming from an interviewee, they have a diverse team with backgrounds rooted in academia and research that enables the company to design and develop innovative diagnostic solutions that address critical needs in the healthcare industry. The team's

expertise in areas such as computer science, software development, and research brings valuable perspectives and technical capabilities to the value network.

"So if you see also in our company, all our background comes from university or some researching, and either is a deep software developer, software, computer science, or research oriented."

Additionally, in another company, an interviewee shares the incorporation of clinical safety officers within their team ensures that the developed diagnostic solutions align with the highest standards of safety, efficacy, and clinical relevance. By having diverse professionals, including paediatric doctors and pharmacists, the company can benefit from a multidisciplinary approach, enriching the value network's expertise and potential for success.

"what we have internally is clinical safety officers. So these are experts, or they are practitioners, which decided to go to the business side and love to stay in the healthcare institutions. So we have paediatrics doctors, who still have their own practice, but collaborate with us on a part time basis, we have pharmacist, which are working in the pharmacy, hospital settings for many years. So we tried to onboard as many of these people as we can."

Culture and values

The culture and values of the company play a key role in shaping its BM value network. For instance, interviewee's mention of ensuring that their silicone composite pocket is naturally biodegradable highlights the conscious effort to reduce the environmental impact of their products. This exemplifies a culture that values sustainability and demonstrates the company aligns its actions with a broader goal of contributing positively to both the environment and society. By aligning with ethical practices and societal values, the company builds a positive reputation within the industry and among stakeholders. Such engagement fosters a sense of purpose and shared values, creating a cohesive and motivated network that works towards common goals.

"Secondly, it is the disposable of this biological waste actually creating this biogas that we create. So, in our case, although it is a silicone composite pocket, we have ensured, although it was a cost to us, but we ensured that it is naturally biodegradable, so you just throw it away and bacteria that

will become soil and then you can grow grow flowers and that kind of"

According to an interviewee, their company's core values, include continuity, happiness, and job satisfaction, underscore its dedication to creating a positive work environment that encourages employees to excel in their roles. Their mission statement further reinforces the company's commitment to open science, as it develops and implements open-source solutions and facilitates fair data sharing in the life sciences domain. By adopting an open and collaborative approach, the company fosters a culture that promotes knowledge sharing and collective progress, rather than focusing solely on individual gains.

"corporate identity.. what is our vision? Everyone in life science works together towards better health. But what does this mean? All the companies in our field are looking for better health. So all the companies are doing the same. What's our unique position? Our unique position is working towards better health for Life Sciences, with Life Sciences, the researchers/ scientists. So that's important and what's important for them, that they collaborate, they work together. And our role is helping them, enabling them to collaborate. And so that it's our vision: everyone in Life Science works together towards better health. And what are we doing? Our mission: enabling Open Science by developing and implementing open source solutions and fairifying data in life sciences. That's the message. We are enabling scientists, we are helping them. So we are not finding things. But we are helping people to find things. And that's completely different with what some people think. So I need also a team around that, I need to manage that from the customer until the end. So the most important values money for continuity, happy, nice work that makes people happy."

Intellectual property

Intellectual property (IP) plays a crucial role in the BM resources of the company. In a company that sells consultancy services, its underlying IP includes proprietary technologies, know-how, and data processing methodologies, forming the foundation for these services. The ownership and protection of its IP provide the company with a competitive advantage, allowing it to offer unique and specialised solutions to its customers. By safeguarding its IP, the company ensures that its expertise and innovative approaches remain exclusive, preventing competitors from replicating its offerings and maintaining its position as a leader in the market. Furthermore, the company's IP serves as a key driver for sustainability and revenue generation. As it continues to build and expand its IP portfolio, the company can explore licensing opportunities or enter strategic partnerships that leverage its proprietary assets. This diversification of income sources complements the revenue from consultancy services and enhances the company's financial stability and long-term sustainability. The existence of robust IP protections also instills confidence in investors and funding agencies, leading to increased opportunities for securing grants and funding. This financial support aids the company's R&D efforts, facilitating the development of new functionalities and expanding the capabilities of its services.

"As a company, we what we do is we, we sell consultancy hours. So we don't sell licenses, we don't sell the product itself, we sell services around. So for us that's, you know, deployment, training, building new functionality is data loading those types of activities, we can just judge that by by the hour, then, a big part of sustainability is of course, grant money. Then we started working on it about five years ago. And, yeah, basically, we have a steady stream of income, which is used to finance the team and for us to work on on (our solution). So as long as people are using it, and you

know, willing to pay for that, then that will just continue. I think visualisation platform like cBioportal will be needed for the coming, I don't know. 10-20 years. And as long as there's a need, I think there's going to be company funding for it."

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Funding capacity

Funding emerges as a critical resource in the BM, as highlighted in the interview transcripts. Adequate funding is essential for the successful development and commercialisation of the company's products and services. It is necessary to facilitate the necessary steps in the product development process, ensuring compliance with regulatory requirements and achieving market readiness. Government R&D grants serve as an initial funding source, providing crucial support during the early stages of the company's journey.

"If we have enough funding right now, is a line process because we know what we should do for the next step. But to get the certifications and finalise the final product, we need funding, we need investment. And right now we don't have this type of investment. We are just using government r&d

grants."

In the context of an open-source tool, funding assumes an equally vital role in sustaining its development and growth. As the tool gains traction within the community, there arises a demand for further enhancements and improvements. Users actively engage with the platform, contributing valuable insights and expressing their needs. Securing funding becomes instrumental in implementing these user-driven improvements and expanding the tool's functionalities, addressing gaps in the current system. This reciprocal relationship between user feedback and funding ensures the continuous evolution and sustainability of the open-source tool.

"So it's basically driven also from, from the community itself, we do the questions that we get from users tell us in which direction they would like to move, what they are missing in the system as it is now. And we just try to, you know, try to find the funding to actually actually implement those. if you if you have an open source tool, and if you have enough users, then there will always be users that are willing to invest either their time or money into the tool. And that's how you sustain it."

4.4.4 Identifying key factors affecting BM value capture

Value capture in the context of health diagnostic innovations encompasses subthemes such as adaptive revenue streams, investor support, managing costs, and knowledge exchanges. Table 4.5 shows the different BM value offering factors identified based on the data collected from biomedical/ healthcare industry experts. The empirical findings reveal the 4 BM factors.

The BM factors represent the first-order codes, as shown in the second column. The third column indicates the presence or absence of evidence obtained from the interview cases. Higher numbers indicate stronger evidence for the finding in the corresponding factor. Triple ticks $(\sqrt[4]{v})$ represent strong evidence and double ticks $(\sqrt[4]{v})$ represent moderate evidence. Single tick $(\sqrt[4]{v})$ represents weak evidence and a blank represents no evidence. The final column is the aggregate dimensions which are the BM components.

Table 4.5 Empirical evidence in discovering BM value capture

	Second-order							Sı	ıpp	or									alu (ts)		ffeı	ing	5							Aggregate
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that you have to take that you can have access to but all that is if you ask me, that is a challenge for us. And again, we have to do what we have to do to make it happen." "So if there is if there is some people that they know, they know you if there is some network between you and the investor, it's much more easier to take to get investment or to reach the people you need. You need network or you have to create network is all about network."																									
"for the distributor, say, for example, I want to sell something for \$1. So equal it to my cost, I'll have to pay to the distributors, this becomes an inefficient way, because unnecessarily cost of our devices being increased. And this very high cost reduces our sales and margins. What we did was we worked, we started we changed our strategy. Yeah, we have sales as a model. But what we have done is we have also started as device as a service." "product development is a massive one. So actually just getting the money in place to start creating a product to actually research the product. A lot of the time you test a product doesn't work. You've got to keep going back and doing it again. But you're also paying people for their time to do that. People obviously need to be able to give the opportunity to do the job and test it out properly. So you've got to invest in the actual infrastructure to test your product,	Managing costs	~ ~ ~ ~	222	~ .		 222	222		~ ~ ~ ~	222	~~~~		 v	222	222	222	222	222	222	222			Co	st	

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from less expenses, can actually go into				
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are sick, or you that you have access in a				
better healthcare system, but that's I think,				
where it also helps."				
"Knowledge exchanges among stakeholders				
contribute to value capture in blood-based				
biomarkers. Collaborative initiatives, such				
as scientific conferences, symposiums, or				
industry forums, enable the exchange of				
expertise, insights, and best practices.				
These exchanges enhance the				
understanding of the biomarker technology,				
foster innovation, and drive improvements				
in research, development, and				
commercialisation efforts. The knowledge				
gained from these exchanges helps capture				
value by refining the biomarker technology				

Adaptive revenue stream

A company's approach to flexible revenue generation is a key factor in the BM value capture. tailoring the pricing model to meet the diverse needs of its customers. By offering various pricing options, such as hourly rates, fixed prices, and recurring revenue models, the company ensures that its solutions are accessible to a wide range of customers with varying budget constraints and preferences.

"So it depends really also on what's the pricing model that I that I choose that I'm like to choose for my for my deals, I don't always sell on an hourly basis on a on a on a rate basis. I also sell on fixed price very often, when you have the capacity to influence budget from the very beginning, that's actually quite a successful quite a successful model because you can ensure to sell for for an established amount of money you can ensure to sell only what you're really confident that you can deliver. And that doesn't, doesn't doesn't bring me through the hassle of agreeing on specific rates per person per specialist. So we have to make an effort to spell the requirements as clear as

possible."

Another case is rather than relying solely on upfront device sales, the company has strategically structured agreements with customers, providing the device for free and charging them based on the number of tests performed. This model not only reduces the customers' capital expenditure but also establishes a sustainable and recurring revenue source for the company.

"I found out that consumables for the test are gonna be the main source of recurring revenue. So, now, what we do is say for example, you are a pathology lab owner, and are interested to use this

device... So we sign an agreement with you and we give the device for free the device is our property, but placed at your blood centre for every test you do will charge you at the end of the month. So that whatever business you do, you have to pay only for that. So you are not you do not have overhead the very large capital expenditure made. So this is an it becomes a recurring source of revenue for us. our focus is on the sale of the device. Although we have two more sources of revenues, as I mentioned, but not optimal state of the device, we went on to find out that there are different kinds of potential customers, and some of them are not able to afford the upfront charges of the device. So they're not able to buy the device in one go. So for such customers, we have come up with three different in total, there are three different models."

Furthermore, the reliance on grant money as a part of the revenue stream showcases the company's adaptability and resourcefulness in securing funding. Grants serve as an additional source of support, contributing to the company's financial sustainability and enabling it to focus on its core services and offerings.

"And we just try to, you know, try to find the funding to actually actually implement those. So we don't sell licences, we don't sell the product itself, we sell services around. So for us that's, you know, deployment, training, building new functionality is data loading those types of activities, we can just judge that by the hour, then, a big part of sustainability is of course, grant money."

Investors support

As an R&D company seeking to advance its innovative solutions, securing investments becomes essential for driving growth and successful implementation of projects. Investors play a crucial role in providing the necessary financial backing and resources to fuel the company's research endeavours and bring its cutting-edge technologies to fruition.

"as I said, we are an r&d company so we are also looking for investors, any periods investments, as we need and on the term stand, we call it successful."

"So now we have to talk to investors for that, again, investors have to be convinced, they should be convinced, so a lot of things have to go on. And there are some grants that you have to take that you can have access to but all that is if you ask me, that is a challenge for us. And again, we have to do what we have to do to make it happen." Building a strong network is also emphasised as a critical element in accessing investor support. A well-established network provides valuable connections and referrals, making it easier to reach potential investors and stakeholders. Leveraging existing relationships and fostering new connections in the industry can enhance the company's credibility and visibility, ultimately increasing its chances of attracting investor interest.

"So if there is if there is some people that they know, they know you if there is some network between you and the investor, it's much more easier to take to get investment or to reach the people

you need. You need network or you have to create network is all about network."

Managing costs

As an R&D company seeking to advance its innovative solutions, securing investments becomes essential for driving growth and successful implementation of projects. Investors play a crucial role in providing the necessary financial backing and resources to fuel the company's research endeavours and bring its cutting-edge technologies to fruition.

The process of developing and commercialising innovative products involves substantial financial investments at various stages. The initial phase of product development necessitates significant funding for research, testing, and infrastructure. Since product development can be iterative, additional resources may be required for repeated testing and refinement.

"product development is a massive one. So actually just getting the money in place to start creating a product to actually research the product. A lot of the time you test a product doesn't work. You've got to keep going back and doing it again. But you're also paying people for their time to do that.

People obviously need to be able to give the opportunity to do the job and test it out properly..." Regulatory compliance and clinical trials represent substantial cost factors in the commercialisation process. Conducting clinical trials, especially on a large scale with hundreds or thousands of patients, demands considerable financial resources to cover facility expenses, equipment, data processing, and personnel costs.

"So you've got to invest in the actual infrastructure to test your product, you've also got to pay for the regulatory process, you've also got to pay for clinical trials, and that's gonna be a massive one is that if you're recruiting 100, or 1000, patients, you need to pay for the facility and the time to actually go out and do the research, you need to pay for all the equipment you're going to be using. And you also need to have people you're paying for to process that data and collect it as well. And then it's building.."

Moreover, after successful product development, building an effective sales team and establishing market presence incurs additional expenses, such as hiring and providing necessary resources for networking events.

"if once you go through the commercialisation process, you've then got to build out your sales team, you've got to hire people, you know, a few people at a time, and you've also got to pay for them to have things like their phone, their car, just little things to go out there paying for networking events, as well... So all that costs really add up until you can even actually start selling your product. And then once you sell it, you still got to wait, you got to invoice for the product, you've got to wait for it to actually pay. And that can be weeks from the client actually using the product to actually paying

for it. So it takes a long time. So a lot of investment before you get anything back in returns." To address cost challenges and enhance efficiency, an interviewee shared that their company has adopted an innovative approach, offering the device as a service. This alternative pricing model aims to optimise costs for distributors and customers, ensuring a more streamlined and cost-effective distribution process. By exploring alternative revenue models, the company can strike a balance between pricing its products competitively and maintaining healthy margins while mitigating excessive costs that might hamper sales. "for the distributor, say, for example, I want to sell something for \$1. So equal it to my cost, I'll have to pay to the distributors, this becomes an inefficient way, because unnecessarily cost of our devices being increased. And this very high cost reduces our sales and margins. What we did was we worked, we started we changed our strategy. Yeah, we have sales as a model. But what we have done is we have also started as device as a service."

Knowledge exchanges

Knowledge exchanges, driven by collaboration and partnership, further enhance value capture, as insights and expertise enrich the development and utilisation of diagnostic technologies.

"Knowledge exchanges among stakeholders contribute to value capture in blood-based biomarkers. Collaborative initiatives, such as scientific conferences, symposiums, or industry forums, enable the exchange of expertise, insights, and best practices. These exchanges enhance the understanding of the biomarker technology, foster innovation, and drive improvements in research, development, and commercialization efforts. The knowledge gained from these exchanges helps capture value by

refining the biomarker technology and expanding its applications"

The process of sharing and reusing information in a purposeful manner leads to substantial reductions in redundant efforts and resources. As shared by an interviewee, while this does not imply the complete elimination of necessary procedures, such as patient X-rays, it holds great potential for optimising research endeavours. The concept of knowledge exchange aligns harmoniously with the overarching mission of improving healthcare and patient outcomes. By strategically leveraging existing information, organisations can drive down costs and allocate resources more efficiently. The resulting savings can then be reinvested into enhancing the quality of healthcare services, ultimately translating to improved patient care.

"If this information can be reused in a in a constructive way, then you reduce a lot, of course, of making more and more, right, of course, that doesn't mean that when a patient goes, you will not take an X ray. But when it comes to research, I think researchers can benefit a lot from the information that is already available. And yeah, I think in at least in the experience that I have, that would be the the benefit in any economy. benefit or profit that you get from less expenses, can actually go into better healthcare. So if let's say, okay, you are sick, or you that you have access in a better healthcare system, but that's I think, where it also helps."

4.5 Modelling the factors on the BM for healthcare technologies

This section presents how the BM for healthcare technologies has been modelled based on empirical findings. Following the thematic analysis, a total 34 distinct factors were identified in order to design a successful BM for healthcare innovations. Each of the four BM dimensions: value offering, value delivery, value capture and value network dimensions of the BM, were populated with the factors represented in Figure 4.2. These factors encompass a wide range of considerations in the healthcare technology sector and provide valuable insights for developing effective BMs. Table 4.6 provides all the factors and descriptions complementing the full value circle of healthcare technology BM.

Value N	letwork		Value	Offering		Value Delivery
Key Partners 24 Cultivating health champions for technology adoption 25 Outsourcing value creation 26 Sustaining value ecosystem	Key Resources 27 Securing team expertise 28 Organisational cu 29 Protecting intelled property 30 Funding capacity	ctual	Product/service 1 Meeting the needs of current standard of care 2 Navigating economic and political consideration 3 Technological innovativeness Value Proposition 5 Enabling early detection 6 Ensuring ease of use 7 Maintaining cost-effectiveness 8 Providing a platform for collaboration 9 Offering portability	health foo Channe 16 Establ distributio 17 Earnin 18 Driving 19 Having 20 Satisfi 21 Trainir 22 Timely	ed market based on cus	Key Activities 10 Securing regulatory approval 11 Satisfying customer requirement 12 Effectively managing collaborations 13 Providing training support (internal) 14 R&D for sustaining innovations 15 Onboarding of customers
			Value Capture			
Cost structure 33 Managing costs		31 Ada	te streams otive revenue stream stors support		Social value 34 Promoting knowle	edge exchanges

Figure 4.2 Refined BM for healthcare technologies with key factors

Table 4.6 BM	Factor	descriptions
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BM value dimension	Component	No.	BM Factor	Description
Product/ service Target segment Value offering Value proposition		1	Meeting the needs of current standard of care	Refers to the process of identifying and addressing gaps in the current standards of care regarding the utilisation of health technology.
		2	Navigating economic and political consideration	Involves considering the ethical, economic, and legal implications of introducing new health technologies and their potential impact on individuals and communities.
		3	Technological innovativeness	Describes the capacity of a product, service, or solution to create new value and deliver innovative benefits to customers and stakeholders in the health technology domain.
	4	Identified market based on health focus	Requires understanding and catering to the needs of various customer-user groups, including individuals, healthcare providers, employers, insurance companies, and other organisations, to establish a compelling value proposition.	
	I I	5	Enabling early detection	Relates to the concept of using technology to identify health issues at an early stage, potentially leading to improved patient outcomes through tailored treatments.
		6	Ensuring ease of use	Concerns the usability and user-centric approach in the context of health technology.
		7	Maintaining cost-effectiveness	Signifies a health technology's ability to achieve desired outcomes at a cost lower than alternatives within a specific context.
		8	Providing a platform for collaboration	Encompasses the creation of a collaborative environment for healthcare providers, technology companies, and industry stakeholders to share ideas, best practices, and resources related to health technology.
		9	Offering portability	Refers to a health technology's capability to be easily transported or deployed in different locations without compromising its effectiveness or usability.
Value	Var	10	Securing regulatory approval	This process involves the evaluation, approval, and compliance with regulatory requirements for medical devices and health technologies.
Value	Key activities			······································

delivery

activities

BM value dimension	Component	No.	BM Factor	Description
		11	Satisfying customer requirement	Involves meeting the needs and expectations of customers in the realm of health technology, including delivering products and services that align with customer specifications and providing a high level of customer service.
		12	Effectively managing collaborations	Encompasses working collaboratively with partners to coordinate the development, implementation, and assessment of health technologies and associated services.
		13	Providing training support (internal)	Includes providing access to educational materials, resources, and tools to empower staff in gaining the knowledge and skills necessary for effectively utilising the company's health technology products and services.
		14	R&D for sustaining innovations	Involves continuously improving existing products and services to enhance their effectiveness, efficiency, and convenience in the health technology sector.
		15	Onboarding of customers	Encompasses introducing customers to health technology products or services, delivering necessary training and resources for effective usage, and ensuring customer satisfaction.
		16	Establishing effective distribution channel	May comprise a combination of in-person sales, online sales, and direct-to-consumer sales for health technology distribution.
		17	Earning trust of stakeholders	Involves building strong relationships with stakeholders by demonstrating the value of health technology, providing transparent communication to facilitate an understanding of its benefits, limitations, and impacts.
		18	Driving adoption of innovation	Entails the process of integrating and utilising new health-related technologies within clinical practice, patient care, and healthcare delivery.
		19	Having clear customer needs	Addresses the channels used to gather input from customers, staff, volunteers, and community partners regarding customer needs in the context of health technology.
		20	Satisfied regulatory clearance	Involves compliance with regulatory requirements related to product distribution, which may vary by industry and location.

BM value dimension	Component	No.	BM Factor	Description
		21	Training and support provided	Involves providing comprehensive support to customers for health technology use, including software, hardware, and services.
		22	Timely delivery of value	The ability to swiftly and accurately deliver cost-effective solutions to the target market within the health technology sector.
		23	Implementing awareness initiatives	To reach consumers and promote health technology, building relationships with potential customers and industry stakeholders.
Value network Key	Key partners	24	Cultivating health champions for technology adoption	Describes individuals who actively promote and facilitate the adoption of health-related technologies to enhance health outcomes.
		25	Outsourcing value creation	The strategic practice of utilising external resources, services, or expertise to enhance the overall value proposition and competitiveness of a health technology-focused business or organisation.
		26	Sustaining value ecosystem	Consists of key partners such as healthcare providers, payers, technology developers, and users, all working together to ensure the continued success and integration of health technologies.
		27	Securing team expertise	Signifies the importance of a team of experts knowledgeable in health technology to assist organisations in designing, implementing, and maintaining tailored technological solutions.
	Key resources	28	Organisational culture	Shapes the way employees think, act, and interact with each other and with customers within the context of health technology.
		29	Protecting intellectual property	Encompasses the safeguarding of intellectual property through measures like patents, trademarks, copyrights, trade secrets, and other protections to preserve innovative ideas and products.
		30	Funding capacity	Signifies the capital required to develop, market, and launch health technology products.

BM value dimension	Component	No.	BM Factor	Description
Value capture	Revenue	31	Adaptive revenue stream	Concerns pricing strategies, including negotiated prices and value-based pricing, within the health technology sector.
		32	Investors support	Entails identifying individuals willing to finance business growth within the health technology domain.
	Cost	33	Managing costs	Involves cost control, monitoring, and reduction strategies to efficiently deliver value-based products and services to health technology customers.
	Social value	34	Promoting knowledge exchanges	Involves collaborative networks of healthcare institutions, industry stakeholders, and others to share best practices, evidence, and knowledge resources to enhance healthcare delivery, reduce costs, and improve outcomes.

4.6 Summary

This chapter presented an in-depth exploration of the first phase of the empirical study and its findings. In the initial phase of the investigation, purposive sampling and snowball sampling techniques were employed to identify suitable participants to participate in this research. Then, semi-structured interviews were conducted as the chosen method for data collection. To analyse the data, thematic analysis was utilised to generate themes among the data gathered. These interviews were instrumental in achieving the research objective to identify and validate the key factors in designing a BM for healthcare diagnostic technologies. Finally, the conceptual BM was refined to incorporate the findings of this phase.

Chapter 5 Establishing relationships and prioritisation of BM factors

5.1 Introduction

The objective of this chapter is to establish interrelationships and prioritisation of BM factors identified during the initial phase of the empirical study. Section 5.2 explains how the Total interpretive structural modelling (TISM) and MICMAC methods were adopted for this study. The TISM result determining the hierarchical interrelationships among BM factors is then explained in Section 5.3. Afterwards, MICMAC analysis was used to classify them based on their driving power and dependence power in Section 5.4. Finally, the BM for healthcare technologies with key factors is further refined in Section 5.5 integrating the results in the final empirical phase of the study.

5.2 Total interpretive structural modelling (TISM) method

An approach integrating TISM methodology with MICMAC analysis has been adopted for this study. The TISM analysis process applied to this study conforms to the nine steps developed by (Sushil, 2012). This structured approach systematically explores and understands the intricate interrelationships among various factors within the BM. Figure 5.1 provides a visual representation of these nine steps, which are navigated through in the following subsections.

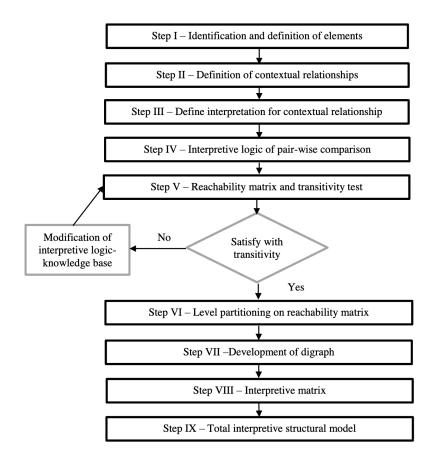


Figure 5.1 TISM analysis process (Source: Sushil. 2012)

5.2.1 Defining elements of BM factors

In this first step, the key factors that constitute the BM were identified from extensive literature review in Chapter 2 and discussion with experts through semi-structured interviews in Chapter 4. The thirty four factors (refer to Table 4.7) serve as the building blocks of the analysis and provide the foundation upon which the subsequent steps of TISM are constructed. Despite the difficulty in using the TISM process when the number of variables increases, all of the 34 BM factors were considered to ensure a more solid foundation of the study. This will also have implications on better understanding the key BM value dimensions, namely value delivery, value proposition, value network and value capture.

5.2.2 Defining the contextual relationships among the BM factors

In order to develop the TISM model, it is essential to state the contextual relationship among the elements. This involves specifying the nature of the structure under consideration, whether it pertains to purpose, significance, attribute enhancement, process, or mathematical interdependence (Sushil, 2012). Here, the contextual relationships between two BM factors is defined as "BM factor A influences/enhances BM factor BM" to build the relationship among BM factors.

5.2.3 Interpretation of contextual relationships among the BM factors

Further to indicating whether 'elements A will influence/enhance element B' or not, this step extracts the explanation 'in what way will they influence/enhance each other?' Thus, clarification from five business and biotech healthcare experts, illustrated in Table 5.1, were asked for the interpretation/logic behind the expressed relationship. Business experts, possessing a deep understanding of strategy, innovation, and market dynamics, offered insights into the economic and strategic aspects of healthcare BM. While biotech healthcare experts, with their specialised knowledge of medical technologies, treatments, and patient care, contributed valuable insights into the clinical and patient-centric dimensions of healthcare value models. The interpretation of the relationship would be specific for each pair of objectives by answering the above interpretive query in order to make the deep rooted knowledge explicit as shown in <u>Appendix D</u>.

Experts	Country	Working	Job specialisation	Management
		experience		level
1	Italy	More than	Company owner and key	CEO
		16 years	business decision maker	
2	India	More than	Company owner and key	CEO
		15 years	business decision maker	
3	Turkey	More than	Company owner and key	CEO
	-	7 years	business decision maker	
4	Philippines	More than 5 years	Healthcare professional specialising in	Medical Doctor
		-	clinical practice, research, and patient care.	
5	United Kingdom	More than	Researcher on scientific advancements, and	Research fellow
	-	15 years	collaborating with multidisciplinary teams	

Table 5.1 Detailed information of five experts

5.2.4 Interpretive logic of pairwise comparisons

Each BM factor has been compared against the other BM factors, the *ith* element is compared individually to all the elements from (i + 1)th to the *nth* element (Sushil, 2012). From the 34 identified BM factors, a total of 1,122 comparisons were made to generate for the logic knowledge base table. It is calculated by $[n\times(n - 1)] = (34 \times 33 = 1,122)$. Each pairwise comparison was discussed with the experts. If sixty percent of experts approved the influential relationship between two BM factors, then it is taken as 'Y' otherwise 'N'. All the responses for 'Y' were further analysed regarding the interpretations integrating all responses was developed in the form of an 'Interpretive Logic–Knowledge Base', see <u>Appendix D</u>.

5.2.5 Reachability matrix and transitivity check

The initial reachability matrix, as illustrated in Table 5.2, was constructed using the interpretive logic–knowledge base (see <u>Appendix</u> D) where a value of '1' represents "Y," while '0' indicates "N." The reachability matrix serves as a foundational tool for capturing relationships between various BM factors in the healthcare system. This matrix, represented as a square grid of binary values, offers insights into the direct and indirect influences that factors exert on each other. A "1" in a matrix cell indicates the presence of an influence, while a "0" signifies its absence.

Then, a further transitivity check is done for ensuring the logical consistency of these relationships. The transitivity rule is that if factor A relates to factor B and factor B relates to factor C, then this implies factor A necessarily relates to factor C. As a result, the final reachability matrix is created as shown in Table 5.3, where "1*" is used to denote a transitive relationship.

Additionally, whenever a new transitive link has been established, the Interpretive Logic-Knowledge Base (see Appendix D) was updated accordingly. The 'No' entry is modified to 'Yes,' and in the interpretation column, 'Transitive' is recorded. If the transitive relationship can be meaningfully explained, the logic behind it is documented along with the 'Transitive' entry.

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Table 5.2. Initial reachability matrix

Factor Name		F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13	F14	F15	F16	F17	F18	F19	F20	F21	F22	F23	F24	F25	F26	F27	F28	F29	F30	F31	F32	F33	F34
Meeting the needs of current standard of care	F1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	1	0	1	1	1	1	1	1	1	1	0	1	1	1	0	1
Navigating economic and political considerations	F2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1
Fostering technological innovation	F3	0	0	1	0	1	0	1	1	1	0	0	0	0	1	0	0	0	1	0	0	1	1	1	0	1	1	0	1	0	0	0	0	0	1
Identified market based on health focus	F4	0	0	1	1	1	1	1	1	1	0	0	1	0	1	0	0	0	1	0	0	0	0	1	1	0	1	0	1	0	0	1	0	0	0
Enabling early detection	F5	0	0	1	0	1	0	1	1	1	0	0	0	0	1	0	0	0	1	0	0	0	0	1	0	0	1	0	1	0	0	0	0	0	1
Ensuring ease of use	F6	0	0	1	1	1	1	0	0	1	0	0	1	1	1	0	0	0	1	0	0	1	1	1	1	0	1	0	1	0	0	0	0	0	0
Maintaining cost-effectiveness	F7	0	0	1	0	1	0	1	1	0	0	0	0	1	1	0	0	0	1	0	0	1	0	0	0	1	1	0	1	0	0	1	0	0	1
Providing a platform for collaboration	F8	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Offering portability	F9	0	0	0	0	0	0	0	1	1	0	0	1	1	1	0	0	0	1	0	0	1	1	0	0	1	1	0	0	0	0	1	0	0	0
Securing regulatory approval	F10	1	1	1	0	1	1	1	0	0	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	1	1	1	1
Satisfying customer requirements	F11	0	0	1	1	1	1	1	1	1	0	1	1	1	1	1	0	0	1	0	0	1	1	1	1	1	1	0	0	0	1	1	1	0	1
Effectively managing collaborations	F12	0	0	0	0	0	0	0	1	0	0	0	1	1	1	0	0	0	0	0	0	1	1	1	0	1	1	0	1	0	0	1	0	0	1
Training support (internal)	F13	0	0	0	0	0	0	0	1	0	0	0	0	1	1	0	0	0	1	0	0	1	0	1	0	0	1	0	0	0	0	0	0	0	1
R&D for sustaining innovations	F14	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	1	0	0	0	0	1	0	1	1	0	0	0	0	1	0	0	1
Onboarding of customers	F15	0	0	0	0	0	0	1	1	0	0	1	1	0	1	1	0	0	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	0	1
Establishing effective distribution channels	F16	1	1	1	1	0	0	1	1	1	1	1	1	0	1	1	1	1	1	1	0	0	1	1	1	1	1	0	0	0	1	1	1	1	1
Earning the trust of stakeholders	F17	0	1	0	0	0	0	0	1	0	1	1	1	0	1	1	1	1	1	0	0	0	0	1	1	1	1	0	1	0	1	1	1	0	1
Driving adoption of innovation	F18	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	1	0	0	1	0	0	0	0	1	0	0	1
Having clear customer needs	F19	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Satisfied regulatory clearance	F20	0	0	0	0	0	1	0	0	0	1	1	0	0	1	1	0	1	1	0	1	1	0	1	1	0	1	0	0	0	1	1	1	1	1
Training and support provided	F21	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	1	0	0	1	0	1	0	0	1	0	0	0	0	0	0	0	0
Timely delivery of value	F22	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	1	0	0	0	1	0	0	1	1	0	0	0	0	1	0	0	1
Implementing awareness initiatives	F23	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Cultivating health champions for technology adoption	F24	0	0	1	1	1	1	1	1	1	0	0	0	0	1	0	0	0	1	0	0	0	0	1	1	0	1	0	1	0	0	1	0	0	1
Outsourcing value creation	F25	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	0	0	1
Sustaining the value ecosystem	F26	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	1	0	0	1
Securing team expertise	F27	0	0	1	1	1	1	1	1	1	0	1	1	1	1	1	0	0	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	0	1
Organizational culture	F28	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	1	0	0	0	1	1	0	0	0	0	1	0	0	0	0	0	1
Protecting intellectual property	F29	0	0	1	0	0	0	1	1	0	0	1	1	0	1	1	0	0	1	0	0	0	0	0	0	1	0	1	0	1	1	1	1	0	0
Funding capacity	F30	0	0	1	1	1	1	1	1	1	0	0	0	1	1	1	0	0	1	0	0	1	1	1	1	0	1	0	1	1	1	1	1	0	1
Adaptive revenue stream	F31	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	1	0	0	1
Investors support	F32	0	0	1	0	0	0	1	1	1	0	0	1	1	1	1	0	0	1	0	0	1	0	1	1	0	1	1	0	0	1	0	1	0	1
Managing costs	F33	1	0	0	0	0	0	1	0	1	1	1	1	0	1	0	0	1	1	0	0	0	0	0	0	1	1	1	0	0	1	1	1	1	0
Promoting knowledge exchanges	F34	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	1	0	0	1

Table 5.3. Final reachability matrix

Factor Name		F1	F2	F3	F4	F5	F6	F7	F8	F9	F1	0 F11	F12	2 F13	F1	4 F15	F16	F17	F18	F19	F20	F21	F22	F23	F24	F25	F26	F27	F28	F29	F30	F31	F32	F33	F34
Meeting the needs of current standard of care	F1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1*	1*	1*	1	1*	1	1	1	1	1	1	1	1	1*	1	1	1	1*	1
Navigating economic and political considerations	F2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1*	1	1	1	1	1	1	1
Fostering technological innovation	F3	0	0	1	0	1	0	1	1	1	0	0	1*	1*	1	0	0	0	1	0	0	1	1	1	0	1	1	0	1	0	0	1*	0	0	1
Identified market based on health focus	F4	0	0	1	1	1	1	1	1	1	0	0	1	1*	1	0	0	0	1	0	0	1*	1*	1	1	1*	1	0	1	0	0	1	0	0	1*
Enabling early detection	F5	0	0	1	0	1	0	1	1	1	0	0	1*	1*	1	0	0	0	1	0	0	1*	1*	1	0	1*	1	0	1	0	0	1*	0	0	1
Ensuring ease of use	F6	0	0	1	1	1	1	1*	1*	1	0	0	1	1	1	0	0	0	1	0	0	1	1	1	1	1*	1	0	1	0	0	1*	0	0	1*
Maintaining cost-effectiveness	F7	0	0	1	0	1	0	1	1	1*	0	0	1*	1	1	0	0	0	1	0	0	1	1*	1*	0	1	1	0	1	0	0	1	0	0	1
Providing a platform for collaboration	F8	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Offering portability	F9	0	0	0	0	0	0	0	1	1	0	0	1	1	1	0	0	0	1	0	0	1	1	1*	0	1	1	0	1*	0	0	1	0	0	1*
Securing regulatory approval	F10	1	1	1	1*	1	1	1	1*	1*	1	1	1*	1	1	1	1	1	1	1	1	1	1	1	1	1*	1	1*	1	1	1	1	1	1	1
Satisfying customer requirements	F11	0	0	1	1	1	1	1	1	1	0	1	1	1	1	1	0	0	1	0	0	1	1	1	1	1	1	1*	1*	1*	1	1	1	0	1
Effectively managing collaborations	F12	0	0	0	0	0	0	0	1	1*	0	0	1	1	1	0	0	0	1*	0	0	1	1	1	0	1	1	0	1	0	0	1	0	0	1
Training support (internal)	F13	0	0	0	0	0	0	0	1	0	0	0	0	1	1	0	0	0	1	0	0	1	0	1	0	1*	1	0	0	0	0	1*	0	0	1
R&D for sustaining innovations	F14	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	1	0	0	0	0	1	0	1	1	0	0	0	0	1	0	0	1
Onboarding of customers	F15	0	0	1*	1*	1*	1*	1	1	1*	0	1	1	1*	1	1	0	0	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	0	1
Establishing effective distribution channels	F16	1	1	1	1	1*	1*	1	1	1	1	1	1	1*	1	1	1	1	1	1	1*	1*	1	1	1	1	1	1*	1*	1*	1	1	1	1	1
Earning the trust of stakeholders	F17	1*	1	1*	1*	1*	1*	1*	1	1*	1	1	1	1*	1	1	1	1	1	1*	1*	1*	1*	1	1	1	1	1*	1	1*	1	1	1	1*	1
Driving adoption of innovation	F18	0	0	0	0	0	0	0	1*	0	0	0	0	0	1	0	0	0	1	0	0	0	0	1	0	1*	1	0	0	0	0	1	0	0	1
Having clear customer needs	F19	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Satisfied regulatory clearance	F20	1*	1*	1*	1*	1*	1	1*	1*	1*	1	1	1*	1*	1	1	1*	1	1	1*	1	1	1*	1	1	1*	1	1*	1*	1*	1	1	1	1	1
Training and support provided	F21	0	0	0	0	0	0	0	1*	0	0	0	0	1	1	0	0	0	1	0	0	1	0	1	0	1*	1	0	0	0	0	1*	0	0	1*
Timely delivery of value	F22	0	0	0	0	0	0	0	1*	0	0	0	0	1	1	0	0	0	1	0	0	1*	1	1*	0	1	1	0	1*	0	0	1	0	0	1
Implementing awareness initiatives	F23	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Cultivating health champions for technology adoption	F24	0	0	1	1	1	1	1	1	1	0	0	1*	1*	1	0	0	0	1	0	0	1*	1*	1	1	1*	1	0	1	0	0	1	0	0	1
Outsourcing value creation	F25	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	1*	0	0	0	0	1*	0	1	1	0	0	0	0	1	0	0	1
Sustaining the value ecosystem	F26	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	1	0	0	1
Securing team expertise	F27	0	0	1	1	1	1	1	1	1	0	1	1	1	1	1	0	0	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	0	1
Organizational culture	F28	0	0	0	0	0	0	0	1	0	0	0	0	1*	1	0	0	0	1	0	0	1*	1	1	0	1*	1*	0	1	0	0	1*	0	0	1
Protecting intellectual property	F29	0	0	1	1*	1*	1*	1	1	1*	0	1	1	1*	1	1	0	0	1	0	0	1*	1*	1*	1*	1	1*	1	1*	1	1	1	1	0	1*
Funding capacity	F30	0	0	1	1	1	1	1	1	1	0	1*	1*	1	1	1	0	0	1	0	0	1	1	1	1	1*	1	1*	1	1	1	1	1	0	1
Adaptive revenue stream	F31	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	1	0	0	1
Investors support	F32	0	0	1	1*	1*	1*	1	1	1	0	1*	1	1	1	1	0	0	1	0	0	1	1*	1	1	1*	1	1	1*	1*	1	1*	1	0	1
Managing costs	F33	1	1*	1*	1*	1*	1*	1	1*	1	1	1	1	1*	1	1*	1*	1	1	1*	1*	1*	1*	1*	1*	1	1	1	1*	1*	1	1	1	1	1*
Promoting knowledge exchanges	F34	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	1	0	0	1

Note: "1*" means transitivity

5.2.6 Level partitioning

The level partitioning is performed until the level of each BM factor is determined as shown in Table 5.4. To achieve this, reachability and antecedent sets for all the BM factors were determined from the reachability matrix. The reachability set for a top-level factor includes the factor itself and any others within the same level that it can reach, such as components of a strongly connected subset. On the other hand, the antecedent set for a top-level factor comprises the factor itself, factors reaching it from lower levels, and any factor from a strongly connected subset within the top level. When both the intersection set and the antecedent set are similar (meaning BM factor does not drive any factor without being driven by it), BM factor is assigned a level and excluded from analysis. This process is iterated until all BM factors are assigned a level. If a factor is in the top level, the intersection of its reachability set and antecedent set remains the same as the reachability set. Therefore, top-level factors meeting this condition are removed from the set and repeat this process iteratively until all levels are determined. The complete version of the level partitioning process of the 34 BM factors is found in <u>Appendix E</u>, while the simplified version is shown in Table 5.4.

Factors	Reachability Set (RS)	Antecedent Set (AS)	Intersection set (RS ∩ AS)	Level
F1	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	XI
F2	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	XI
F3	3, 5, 7, 8, 9, 12, 13, 14, 18, 21, 22, 23, 25, 26, 28, 31, 34	1, 2, 3, 4, 5, 6, 7, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	3, 5, 7	VIII
F4	3, 4, 5, 6, 7, 8, 9, 12, 13, 14, 18, 21, 22, 23, 24, 25, 26, 28, 31, 34	1, 2, 4, 6, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	4, 6, 24	IX
F5	3, 5, 7, 8, 9, 12, 13, 14, 18, 21, 22, 23, 25, 26, 28, 31, 34	1, 2, 3, 4, 5, 6, 7, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	3, 5, 7	VIII
F6	3, 4, 5, 6, 7, 8, 9, 12, 13, 14, 18, 21, 22, 23, 24, 25, 26, 28, 31, 34	1, 2, 4, 6, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	4, 6, 24	IX
F7	3, 5, 7, 8, 9, 12, 13, 14, 18, 21, 22, 23, 25, 26, 28, 31, 34	1, 2, 3, 4, 5, 6, 7, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	3, 5, 7	VIII

Table 5.4. Simplified partitioning the final reachability matrix into different levels (iteration 1-11)

F8	8, 23	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	8	II
F9	8, 9, 12, 13, 14, 18, 21, 22, 23, 25, 26, 28, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	9, 12	VII
F10	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	XI
F11	3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 18, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 34	1, 2, 10, 11, 15, 16, 17, 19, 20, 27, 29, 30, 32, 33	11, 15, 27, 29, 30, 32	X
F12	8, 9, 12, 13, 14, 18, 21, 22, 23, 25, 26, 28, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	9, 12	VII
F13	8, 13, 14, 18, 21, 23, 25, 26, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 15, 16, 17, 19, 20, 21, 22, 24, 27, 28, 29, 30, 32, 33	13, 21	V
F14	8, 14, 18, 23, 25, 26, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 24, 25, 27, 28, 29, 30, 32, 33	14, 18, 25	IV
F15	3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 18, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 34	1, 2, 10, 11, 15, 16, 17, 19, 20, 27, 29, 30, 32, 33	11, 15, 27, 29, 30, 32	X
F16	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	XI
F17	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	XI
F18	8, 14, 18, 23, 25, 26, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 24, 25, 27, 28, 29, 30, 32, 33	14, 18, 25	IV
F19	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	XI
F20	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	XI
F21	8, 13, 14, 18, 21, 23, 25, 26, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 15, 16, 17, 19, 20, 21, 22, 24, 27, 28, 29, 30, 32, 33	13, 21	V
F22	8, 13, 14, 18, 21, 22, 23, 25, 26, 28, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 15, 16, 17, 19, 20, 22, 24, 27, 28, 29, 30, 32, 33	22, 28	VI
F23	23	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	23	I

F24	3, 4, 5, 6, 7, 8, 9, 12, 13, 14, 18, 21, 22, 23, 24, 25, 26, 28, 31, 34	1, 2, 4, 6, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	4, 6, 24	IX
F25	8, 14, 18, 23, 25, 26, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 24, 25, 27, 28, 29, 30, 32, 33	14, 18, 25	IV
F26	8, 23, 26, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	26, 31, 34	ш
F27	3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 18, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 34	1, 2, 10, 11, 15, 16, 17, 19, 20, 27, 29, 30, 32, 33	11, 15, 27, 29, 30, 32	x
F28	8, 13, 14, 18, 21, 22, 23, 25, 26, 28, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 15, 16, 17, 19, 20, 22, 24, 27, 28, 29, 30, 32, 33	22, 28	VI
F29	3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 18, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 34	1, 2, 10, 11, 15, 16, 17, 19, 20, 27, 29, 30, 32, 33	11, 15, 27, 29, 30, 32	X
F30	3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 18, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 34	1, 2, 10, 11, 15, 16, 17, 19, 20, 27, 29, 30, 32, 33	11, 15, 27, 29, 30, 32	X
F31	8, 23, 26, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	26, 31, 35	III
F32	3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 18, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 34	1, 2, 10, 11, 15, 16, 17, 19, 20, 27, 29, 30, 32, 33	11, 15, 27, 29, 30, 32	X
F33	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	XI
F34	8, 23, 26, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	26, 31, 36	Ш

5.2.7 Development of diagraph

A diagraph consists of nodes and directed links. Each node represents BM factors, and each link represents the direction of relationships between two factors based on the final reachability matrix. The initial diagraph is found in Appendix F. Afterwards, an enhanced version of the initial diagraph is obtained by eliminating the transitive relationships step-by-step by examining their interpretation from the knowledge base. Only those direct and transitive relationships may be retained whose interpretation is crucial. Each factor is arranged graphically in the diagraph, see Figure 5.2, as per the level obtained during level partitioning.

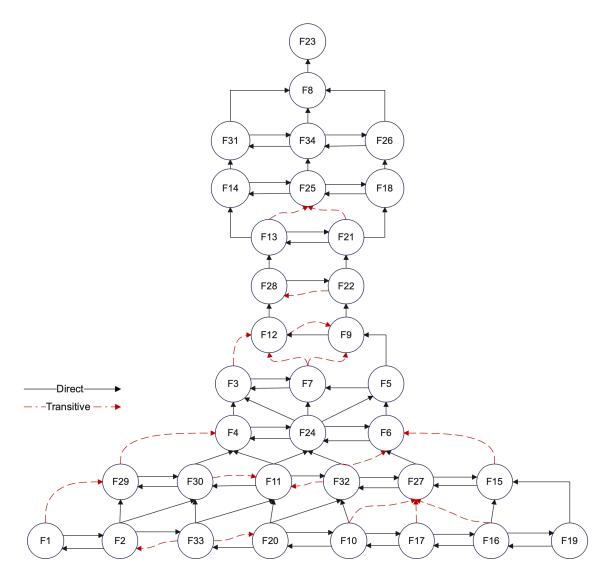


Figure 5.2 Diagraph with significant links

5.2.8 Develop interpretive matrix

For this step, the final diagraph is translated into a binary interaction matrix form and interpreted by selecting the relevant interpretation from the knowledge base in the form of an interpretive matrix. The binary interaction matrix is developed based on the diagraph Figure 5.2, by translating all interactions to "1" indicating both direct and transitive links between factors resulting in <u>Table 5.5</u>. With a total of 90 interactions identified, it became apparent that representing these links in a conventional interpretive matrix would be both unwieldy and impractical, given the constraints of

page space. Therefore, an interpretive table is created instead in Table 5.6. An interpretive table serves the same fundamental purpose as an interpretive matrix, which is to capture and represent the relationships and interactions between various factors within a complex system. This approach also ensures that the analysis remains accessible and comprehensible.

Table 5.5 Binary interaction matrix

Factor Name		F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13	F14	F15	F16	F17	F18	F19	F20	F21	F22	F23	F24	F25	F26	F27	F28	F29	F30	F31	F32	F33	F34
Meeting the needs of current standard of care	F1	-	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1*	0	0	0	0	0
Navigating economic and political considerations	F2	1	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	1	0
Fostering technological innovation	F3	0	0	-	0	0	0	1	0	0	0	0	1*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Identified market based on health focus	F4	0	0	1	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Enabling early detection	F5	0	0	0	0	-	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Ensuring ease of use	F6	0	0	0	0	1	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Maintaining cost-effectiveness	F7	0	0	1	0	1	0	-	0	1*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Providing a platform for collaboration	F8	0	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Offering portability	F9	0	0	0	0	0	0	0	0	-	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Securing regulatory approval	F10	0	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	1*	0	0	0	0	1	0	0
Satisfying customer requirements	F11	0	0	0	1	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	1	0	0
Effectively managing collaborations	F12	0	0	0	0	0	0	0	0	1*	0	0	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Training support (internal)	F13	0	0	0	0	0	0	0	0	0	0	0	0	-	0	0	0	0	1	0	0	1	0	0	0	1*	0	0	0	0	0	0	0	0	0
R&D for sustaining innovations	F14	0	0	0	0	0	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0
Onboarding of customers	F15	0	0	0	0	0	1*	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Establishing effective distribution channels	F16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-	1	0	1	0	0	0	0	0	0	0	1*	0	0	0	0	0	0	0
Earning the trust of stakeholders	F17	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	-	0	0	0	0	0	0	0	0	0	1*	0	0	0	0	0	0	0
Driving adoption of innovation	F18	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0
Having clear customer needs	F19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	-	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Satisfied regulatory clearance	F20	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	0	0	0	1	1	0
Training and support provided	F21	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	-	0	0	0	1*	0	0	0	0	0	0	0	0	0
Timely delivery of value	F22	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-	0	0	0	0	0	1*	0	0	0	0	0	0
Implementing awareness initiatives	F23	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	0	0	0
Cultivating health champions for technology adoption	F24	0	0	1	1	1	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	0	0
Outsourcing value creation	F25	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	-	0	0	0	0	0	0	0	0	1
Sustaining the value ecosystem	F26	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-	0	0	0	0	0	0	0	1
Securing team expertise	F27	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	-	0	0	0	0	1	0	0
Organizational culture	F28	0	0	0	0	0	0	0	0	0	0	0	0	1*	0	0	0	0	0	0	0	0	1	0	0	0	0	0	-	0	0	0	0	0	0
Protecting intellectual property	F29	0	0	0	1*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-	1	0	0	0	0
Funding capacity	F30	0	0	0	1	0	0	0	0	0	0	1*	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	-	0	0	0	0
Adaptive revenue stream	F31	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-	0	0	1
Investors support	F32	0	0	0	0	0	1*	0	0	0	0	1*	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	-	0	0
Managing costs	F33	0	1*	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1*	0	0	0	0	0	0	0	0	0	1	0	0	-	0
Promoting knowledge exchanges	F34	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	-

Note: 1* is transitive

Table 5.6 Interpretive table

No.	Pairwise	Paired comparison of factors	Interpretation
1	F1-F2	Meeting the needs of current standard of care will influence/enhance Navigating economic and political consideration	positive social and economic impact
2	F2-F1	Navigating economic and political consideration will influence/enhance Meeting the needs of current standard of care	receive support from both the public and policymakers
3	F1-F29	Meeting the needs of current standard of care will influence/enhance Protecting intellectual property	transitive: secure competitive advantages
4	F2-F29	Navigating economic and political consideration will influence/enhance Protecting intellectual property	adapt its strategies
5	F2-F30	Navigating economic and political consideration will influence/enhance Funding capacity	influenced by economic and political factors
6	F2-F33	Navigating economic and political consideration will influence/enhance Managing costs	impact the cost structure
7	F33-F2	Managing costs will influence/enhance Navigating economic and political consideration	Transitive: stronger position in economic and political discussions
8	F4-F3	Identified market based on health focus will influence/enhance Technological innovativeness	enhance
9	F3-F7	Technological innovativeness will influence/enhance Maintaining cost-effectiveness	reduced resource consumption
10	F7-F3	Maintaining cost-effectiveness will influence/enhance Technological innovativeness	strategic resource allocations
11	F3-F12	Technological innovativeness will influence/enhance Effectively managing collaborations	transitive: providing tools and platforms
12	F24-F3	Cultivating health champions for technology adoption will influence/enhance Technological innovativeness	foster
13	F11-F4	Satisfying customer requirement will influence/enhance Identified market based on health focus	positive feedback
14	F4-F24	Identified market based on health focus will influence/enhance Cultivating health champions for technology adoption	Promote technology adoption
15	F24-F4	Cultivating health champions for technology adoption will influence/enhance Identified market based on health focus	Tailored health focus
16	F29-F4	Protecting intellectual property will influence/enhance Identified market based on health focus	transitive: identify growth opportunities
17	F30-F4	Funding capacity will influence/enhance Identified market based on health focus	Strengthen the investment for target segment
18	F5-F7	Enabling early detection will influence/enhance Maintaining cost-effectiveness	lead
19	F7-F5	Maintaining cost-effectiveness will influence/enhance Enabling early detection	Develop cost effective diagnostic tool
20	F5-F9	Enabling early detection will influence/enhance Offering portability	Enhance value proposition
21	F24-F5	Cultivating health champions for technology adoption will influence/enhance Enabling early detection	drives

			transitive: Generate feedback to
22	F15-F6	Onboarding of customers will influence/enhance Ensuring ease of use	improve ease of use
23	F6-F24	Ensuring ease of use will influence/enhance Cultivating health champions for technology adoption	Strengthen
24	F24-F6	Cultivating health champions for technology adoption will influence/enhance Ensuring ease of use	advocate
25	F27-F6	Securing team expertise will influence/enhance Ensuring ease of use	improve value offering
26	F32-F6	Investors support will influence/enhance Ensuring ease of use	transitive: support value offering
27	F7-F9	Maintaining cost-effectiveness will influence/enhance Offering portability	transitive: enhance value offering
28	F7-F12	Maintaining cost-effectiveness will influence/enhance Effectively managing collaborations	transitive: strategic resource allocation
29	F24-F7	Cultivating health champions for technology adoption will influence/enhance Maintaining cost-effectiveness	influence
30	F8-F23	Providing a platform for collaboration will influence/enhance Implementing awareness initiatives	Collaboration supports the implementation of awareness initiatives.
31	F26-F8	Sustaining value ecosystem will influence/enhance Providing a platform for collaboration	Integration of key stakeholders for meaningful collaboration
32	F31-F8	Adaptive revenue stream will influence/enhance Providing a platform for collaboration	Diverse revenue can support collaboration platforms
33	F34-F8	Promoting knowledge exchanges will influence/enhance Providing a platform for collaboration	improve collaboration platforms
34	F9-F12	Offering portability will influence/enhance Effectively managing collaborations	increase accessibility
35	F12-F9	Effectively managing collaborations will influence/enhance Offering portability	transitive: contribute to development
36	F9-F22	Offering portability will influence/enhance Timely delivery of value	Strengthen value delivery
37	F10-F17	Securing regulatory approval will influence/enhance Earning trust of stakeholders	provides validation and assurance
38	F17-F10	Earning trust of stakeholders will influence/enhance Securing regulatory approval	positively influences its reputation
39	F10-F20	Securing regulatory approval will influence/enhance Satisfied regulatory clearance	expedite the clearance process to enter the market
40	F20-F10	Satisfied regulatory clearance will influence/enhance Securing regulatory approval	prevent unauthorised distribution
41	F10-F27	Securing regulatory approval will influence/enhance Securing team expertise	transitive: improve the development
42	F10-F32	Securing regulatory approval will influence/enhance Investors support	enhance
43	F20-F11	Satisfied regulatory clearance will influence/enhance Satisfying customer requirement	enhance
44	F11-F24	Satisfying customer requirement will influence/enhance Cultivating health champions for technology adoption	Increase adoption

45	F11-F30	Satisfying customer requirement will influence/enhance Funding capacity	increase business growth
46	F30-F11	Funding capacity will influence/enhance Satisfying customer requirement	transitive: further satisfy customer
47	F11-F32	Satisfying customer requirement will influence/enhance Investors support	Added value to investors
48	F32-F11	Investors support will influence/enhance Satisfying customer requirement	transitive: invest in meeting customer needs
49	F33-F11	Managing costs will influence/enhance Satisfying customer requirement	enhance
50	F12-F28	Effectively managing collaborations will influence/enhance Organisational culture	transitive: influence
51	F13-F14	Providing training support (internal) will influence/enhance R&D for sustaining innovations	Enhance value offering
52	F13-F21	Providing training support (internal) will influence/enhance Training and support provided	enhance comprehensive training provided
53	F21-F13	Training and support provided will influence/enhance Providing training support (internal)	improves
54	F13-F25	Providing training support (internal) will influence/enhance Outsourcing value creation	transitive: capacity to further develop value
55	F28-F13	Organisational culture will influence/enhance Providing training support (internal)	encourages
56	F14-F25	R&D for sustaining innovations will influence/enhance Outsourcing value creation	strengthens
57	F25-F14	Outsourcing value creation will influence/enhance R&D for sustaining innovations	optimise operations
58	F14-F31	R&D for sustaining innovations will influence/enhance Adaptive revenue stream	support adaptive revenue strategies.
59	F16-F15	Establishing effective distribution channel will influence/enhance Onboarding of customers	Efficient flow of transactions
60	F19-F15	Having clear customer needs will influence/enhance Onboarding of customers	tailor the onboarding process effectively.
61	F15-F27	Onboarding of customers will influence/enhance Securing team expertise	sustain human resources
62	F27-F15	Securing team expertise will influence/enhance Onboarding of customers	increase customer retention
63	F16-F17	Establishing effective distribution channel will influence/enhance Earning trust of stakeholders	builds confidence and reliability
64	F17-F16	Earning trust of stakeholders will influence/enhance Establishing effective distribution channel	fosters positive relationships
65	F16-F19	Establishing effective distribution channel will influence/enhance Having clear customer needs	efficient delivery of value
66	F19-F16	Having clear customer needs will influence/enhance Establishing effective distribution channel	aligned distribution channel
67	F16-F27	Establishing effective distribution channel will influence/enhance Securing team expertise	transitive: enhances value delivery

		Earning trust of stakeholders will influence/enhance Securing team	transitive: benefit the team's
68	F17-F27	expertise	development of expertise
69	F21-F18	Training and support provided will influence/enhance Driving adoption of innovation	drive innovation adoption
70	F18-F25	Driving adoption of innovation will influence/enhance Outsourcing value creation	enhance value network
71	F25-F18	Outsourcing value creation will influence/enhance Driving adoption of innovation	enhance value offering
72	F18-F26	Driving adoption of innovation will influence/enhance Sustaining value ecosystem	contributes to a robust value ecosystem
73	F20-F33	Satisfied regulatory clearance will influence/enhance Investors support	Increase investor support
74	F20-F33	Satisfied regulatory clearance will influence/enhance Managing costs	reduce costs linked with prolonged regulatory processes
75	F33-F20	Managing costs will influence/enhance Satisfied regulatory clearance	Transitive: invest in compliance measures
76	F22-F21	Timely delivery of value will influence/enhance Training and support provided	Sustain end users
77	F21-F25	Training and support provided will influence/enhance Outsourcing value creation	transitive: engage value networks
78	F27-F22	Securing team expertise will influence/enhance Timely delivery of value	contribute
79	F22-F28	Timely delivery of value will influence/enhance Organisational culture	transitive: positively influence
80	F32-F24	Investors support will influence/enhance Cultivating health champions for technology adoption	Enhance market adoption
81	F25-F34	Outsourcing value creation will influence/enhance Promoting knowledge exchanges	lead to knowledge exchanges
82	F26-F34	Sustaining value ecosystem will influence/enhance Promoting knowledge exchanges	Enhance value network activity
83	F34-F26	Promoting knowledge exchanges will influence/enhance Sustaining value ecosystem	Promote knowledge value capture
84	F27-F32	Securing team expertise will influence/enhance Investors support	enhance value delivery
85	F32-F27	Investors support will influence/enhance Securing team expertise	positive influence
86	F29-F30	Protecting intellectual property will influence/enhance Funding capacity	Enhances funding success
87	F30-F29	Funding capacity will influence/enhance Protecting intellectual property	Sustain IP
88	F33-F30	Managing costs will influence/enhance Funding capacity	Increase ROI
89	F31-F34	Adaptive revenue stream will influence/enhance Promoting knowledge exchanges	invest in knowledge-sharing
90	F34-F31	Promoting knowledge exchanges will influence/enhance Adaptive revenue stream	enhance revenue-generating opportunities

5.2.9 TISM model

In the final step, total interpretation of the structural model (TISM) is developed using the diagraph (Figure 5.2) and information obtained from the interpretive table (Table 5.6). The TISM of 34 BM factors is developed as illustrated in Figure 5.3 with eleven levels.

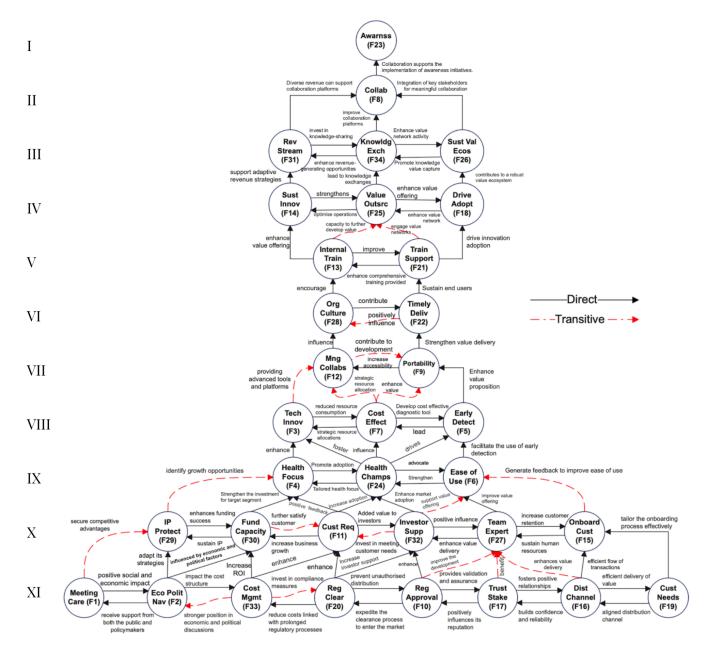


Figure 5.3 TISM of 34 BM factors

Here, the factor names have been abbreviated to fit the diagram where abbreviations and their corresponding full factor names are presented in a dedicated legend in Appendix G. The links are based on Table 4.6 interpretive table, explained further in Appendix H, based on the structured

interview conducted. These link explanations illustrate the complex web of interactions and influences among various factors in the context of this study. Each connection represents a significant relationship that contributes to the overall dynamics of the system analysed with TISM.

5.3 TISM Results

The TISM model provides valuable insights into the interplay of various factors within the BM and classifies these factors into different levels. It is not just a static representation; it is a dynamic tool for comprehending the intricate relationships among BM factors that shape the organisation's strategic decisions. Within the TISM hierarchy, BM factors are organised into levels, with each level signifying a different degree of influence and dependence.

5.3.1 Lowest level

Factors located at the lowest level of the TISM hierarchy represent the core drivers of the BM, which possess the highest driving power and the lowest dependence power. At the foundation of the TISM hierarchy, the following exert the most substantial influence on the entire system. These factors are characterised by having the highest driving power. In essence, they can shape and steer the entire BM according to their characteristics and attributes.

In the model (Figure 5.3), seven factors are located on Level XI:

- (F1) Meeting the Needs of Current Standard of Care: This holds a pivotal role in the BM. It signifies providing diagnostic products and services that align with the current healthcare standards. By meeting these needs effectively, the BM is well supported.
- (F2) Navigating Economic and Political Considerations: Factor two is equally crucial as it highlights the ability to adapt to the ever-changing economic and political landscape in the healthcare sector. This factor is vital for the resilience of the diagnostic technology business amid external challenges.

- (F33) Managing Costs: signifies the importance of cost-effective operations. Efficient cost management is essential for sustaining profitability and ensuring resource allocation aligns with the business goals.
- (F20) Satisfied Regulatory Clearance: this factor focuses on the successful clearance regulatory of innovative diagnostic technology solutions. This factor safeguards the business against potential obstacles and paves the way for smooth operations.
- (F10) Securing Regulatory Approval: This underscores the importance of compliance with regulatory requirements specific to diagnostic technology. It means adhering to industry standards and ensuring our diagnostic solutions meet the necessary approvals.
- (F17) Earning the trust of stakeholders: Building and maintaining trust with healthcare providers, institutions, and patients is crucial. Trust is the cornerstone of successful adoption of diagnostic technology, and this factor shall be prioritised.
- (F16) Establishing Effective Distribution Channels: This factor is fundamental for ensuring the products reach the intended markets such as healthcare professionals and facilities efficiently. This factor streamlines the distribution strategies, enabling us to deliver value seamlessly.
- (F19) Having Clear Customer Needs: This reinforces understanding customers' requirements comprehensively. By doing so, the diagnostic solutions precisely meet their expectations.

At Level X in the TISM hierarchy, six factors were identified:

- (F11) Satisfying Customer Requirements: This factor stands as a vital component for the business by comprehensively addressing the needs and demands of the customers. Customer's satisfaction also lay the groundwork for sustainable growth and customer loyalty.
- (F15) Onboarding of Customers: Factor fifteen is a critical component in the BM. It emphasises the importance of a seamless and efficient onboarding process for healthcare

providers and institutions. An effective onboarding experience enhances customer relationships and facilitates the successful adoption of diagnostic solutions.

- (F27) Securing Team Expertise: This underscores building and nurturing a talented and knowledgeable workforce within the diagnostic technology business. A skilled team contributes to innovation, quality, and overall excellence in the business operations.
- (F29) Protecting Intellectual Property: This factor highlights the significance of safeguarding innovations, technologies, and proprietary assets within the diagnostic technology field. Further contributing towards competitive advantages and the ability to capitalise on intellectual capital.
- (F30) Funding Capacity: Funding is pivotal for sustaining and expanding the diagnostic technology business. Adequate financial resources enable businesses to invest in research, development, and growth initiatives.
- (F32) Investors Support: This signifies the importance of cultivating and maintaining positive relationships with investors of the business. Investor support provides the financial backing and resources necessary for executing strategic initiatives and realising business goals.

At the on Level IX of the TISM, three factors are positioned which are still considered as core drivers for BM:

- (F4) Identified Market Based on Health Focus: This factor is crucial as it allows the business to define its target audience within the healthcare sector. Identifying specific health-focused markets enables the company to tailor its diagnostic technology solutions to meet the unique needs and demands of those markets.
- (F6) Ease of Use: This plays a pivotal role in the success of the BM. Diagnostic technology solutions that are intuitive and user-friendly are more likely to be adopted by healthcare

professionals. When end-users find the technology easy to use, it leads to quicker adoption rates, higher user satisfaction, and ultimately, improved patient care.

• (F24) Health Champions for Technology Adoption: Cultivating "health champions" within the healthcare ecosystem is essential for successful BM development. These advocates promote the adoption of diagnostic technology solutions among their peers and organisations. They create enthusiasm for technological advancements, overcome resistance to change, and drive the adoption curve upward.

5.3.2 Intermediate level

Ascending through the hierarchy, intermediate level factors are located in the middle, which are progressively influenced by those at lower levels. These intermediate level factors have a degree of driving power but are also dependent on factors below them. They serve as conduits for the influence of lower-level factors.

At on Level VIII of the TISM, three factors are positioned which are:

- (F3) Fostering technology innovation: This factor drives the creation of cutting-edge solutions and sets the business apart from competitors. Continuous innovation ensures that the technology remains relevant, competitive, and aligned with emerging healthcare trends. Innovativeness fuels the development of new diagnostic tools and methods, which can lead to improved patient outcomes and increased market demand.
- (F5) Enabling early detection: This factor is pivotal for diagnostic technology, as it directly impacts patient care and treatment outcomes. Diagnostic tools that enable early detection of diseases or health issues contribute significantly to the success of the BM. This factor can lead to increased market adoption and positive outcomes for both patients and healthcare providers.

 (F7) Cost Effectiveness: Cost-effective solutions are essential for widespread adoption in the healthcare industry. Developing diagnostic technologies that are not only accurate but also cost-effective is crucial for market penetration. Cost-effective solutions make it more feasible for healthcare institutions to invest in and integrate the technology into their practices. This factor can lead to increased market share and revenue generation while ensuring affordability and accessibility for patients.

On Level VII:

- (F9) Portability: Portability is a key factor in the success of diagnostic technology BMs. The ability to offer portable solutions enhances the value proposition by increasing accessibility and convenience for end-users. Portable diagnostic tools can be deployed in various healthcare settings, enabling healthcare professionals to reach patients in diverse environments, including remote or resource-constrained areas.
- (F12) Managing Collaborations: Effective management of collaborations is essential for a diagnostic technology BM success. Collaboration with other healthcare stakeholders, such as hospitals, research institutions, or regulatory bodies, can lead to synergistic benefits. It ensures the exchange of knowledge, resources, and expertise, ultimately contributing to innovation, cost-effectiveness, and regulatory compliance. Managing collaborations fosters a culture of cooperation and strengthens the business's ability to adapt to changing market dynamics. It also facilitates the development of strategic alliances, which can be instrumental in achieving shared goals.

On Level VI:

• (F22)Timely Delivery of Value: Ensuring that the benefits and results of diagnostic tools are delivered promptly to healthcare providers and patients is essential. Timely delivery enhances the overall user experience and patient care by reducing waiting times for test

results and treatment decisions. It also contributes to customer satisfaction and trust in the technology, ultimately driving adoption and market success.

• (F28) Culture and values: The culture and values of an organisation have an impact on the success of its BM. In the healthcare technology sector, a culture that prioritises patient well-being, ethical practices, and innovation is crucial. A strong organisational culture that aligns with the values of the healthcare industry fosters trust among stakeholders, including customers, partners, and regulators. It supports the development of ethical and compliant solutions, which are essential in gaining regulatory approval and earning the trust of both healthcare providers and patients. Culture and values also influence how collaborations are managed and how the organisation adapts to changes in the healthcare landscape, making them vital for long-term success.

On Level V:

- (F13) Training Support (Internal): Internal training support within a healthcare technology organisation plays a critical role in the successful development of BM, especially in the context of diagnostic technology. This factor represents the internal processes and resources dedicated to training employees and teams within the organisation. Adequate internal training ensures that employees are well-equipped to understand, develop, and implement diagnostic technologies effectively. It contributes to enhancing their skills and knowledge, which, in turn, supports the development of innovative solutions and the efficient management of collaborations. Internal training support also fosters a culture of continuous improvement and learning, which is essential in a rapidly evolving healthcare technology landscape.
- (F21) Training and support provided: The training and support provided by the healthcare technology organisation to external stakeholders, such as healthcare professionals, end-users, and partners, are crucial for the success of BMs. In the context of diagnostic

technology, this factor represents the efforts made to ensure that customers and collaborators receive comprehensive training and support to effectively use and integrate diagnostic solutions into their workflows.

On Level IV:

- (F14) R&D for sustaining innovations: This factor represents the critical process of research and development aimed at sustaining innovation within the BM. It involves continually improving existing products, services, or technologies. Being in the upper level of the TISM, it's influenced by lower-level factors. The identification of specific market needs and healthcare trends (F4) at lower levels directly informs the focus of R&D efforts. Understanding the market's demands is essential for directing research toward innovations that align with these needs. The level of innovation achievable in R&D is influenced by the organisation's overall technological innovativeness (F3).
- (F18) Adoption of Innovation: This factor represents the organisation's ability to successfully introduce and integrate innovations into the market. It's influenced by several lower-level factors. Factors like "Having Clear Customer Needs" (F19) and "Satisfying Customer Requirements" (F11) determine the demand for innovation in the market. If these needs are not met, the adoption of innovations may be hindered.
- (F25) Outsourcing Value Creation: Outsourcing involves leveraging external partners or resources to create value for the organisation. It is influenced by the following lower-level factors. The decision to outsource value creation is often driven by cost considerations (F33). Factors like "Managing Costs" (F33) play a critical role in determining the financial feasibility of outsourcing certain aspects of the value chain.

5.3.3 Highest level

Finally, at the top of the TISM hierarchy are the BM factors with the highest dependence power. These factors rely on the contributions and characteristics of all the lower-level factors to achieve their objectives. While they may have limited driving power, they are vital to the overall functioning of the BM.

On Level III:

- (F26) Sustaining Value Ecosystem: A robust value ecosystem is crucial for the long-term sustainability of the BM. Lower-level factors, such as "Securing Regulatory Approval" (F10) and "Protecting Intellectual Property" (F29), directly impact the relationships and collaborations within the ecosystem. Regulatory challenges or intellectual property disputes can disrupt the stability of the ecosystem, affecting the upper-level factor's sustainability.
- (F31) Adaptive Revenue Stream: Developing adaptive revenue streams is essential for financial resilience. Factors at lower levels, such as "Funding Capacity" (F30) and "Investors Support" (F32), can determine the organisation's financial flexibility. Changes in funding availability or investor sentiment can influence the organisation's ability to implement adaptive revenue strategies effectively.
- (F34) Knowledge Exchanges: Knowledge exchanges are critical for staying informed and innovative. Factors like "Identified Market Based on Health Focus" (F4) can influence the availability of relevant knowledge and expertise for exchange.

Factors at Level I and Level II, such as "Awareness Initiatives" (F23) and "Platform for Collaboration" (F8) are positioned at the upper levels of the hierarchy due to their critical roles in shaping the overall success of the BM. However, it's essential to acknowledge that these factors are easily influenced and affected by factors at lower levels within the TISM hierarchy.

- (F23) Awareness Initiatives: While awareness initiatives are essential for introducing and promoting healthcare technology, their effectiveness is closely tied to factors at lower levels. Factors such as "Meeting the Needs of Current Standard of Care" (F1) and "Navigating Economic and Political Considerations" (F2) can influence the context and timing of awareness initiatives. For example, changes in healthcare policies or the introduction of new standards of care can impact the messaging and focus of awareness campaigns.
- (F8) Platform for Collaboration: Collaboration platforms play a pivotal role in fostering innovation and efficiency. However, their functionality and utilisation can be significantly impacted by factors at lower levels. For instance, "Managing Costs" (F33) directly affects the resources available for developing and maintaining collaboration platforms. Similarly, "Investors Support" (F32) can influence the organisation's capacity to invest in advanced collaboration tools and technologies.

5.4 MICMAC analysis and results

The MICMAC is abbreviated as Matrice d'Impacts croises-multiplication applique' a classment (cross-impact matrix multiplication applied to classification). MICMAC analysis is founded on the multiplication properties of matrices. The main objective of MICMAC is to assess the driving power and dependence among variables, classifying them into driving, autonomous, dependent and linkage factors (Manjunatheshwara and Vinodh, 2018). The TISM matrix was subjected to MICMAC analysis to determine the driving and dependence power of each factor (Manjunatheshwara and Vinodh, 2018; Vaishnavi, Suresh and Dutta, 2019).

1. Calculation of Driving Power and Dependence

MICMAC takes all levels of transitivity into account. For instance, if element A directly impacts element B, and B directly impacts element C, any changes affecting A can potentially have consequences for C, establishing an indirect connection between A and C. Numerous indirect relationships of the A \rightarrow C type, present in the final reachability matrix. Using the final reachability matrix (Table 5.3), the driving power and dependence of each factor were calculated by summing the rows and columns, respectively, for each factor in the matrix resulting in Table 5.7. MICMAC is used to explain the interrelationship between factors and to do ranking.

Factor no.	Factor Name	Driving power	Dependence power	Driving power/ Dependence power	MICMAC Rank
F1	Meeting the needs of current standard of care	34	8	4.25	1
F2	Navigating economic and political considerations	34	8	4.25	1
F10	Securing regulatory approval	34	8	4.25	1
F16	Establishing effective distribution channels	34	8	4.25	1
F17	Earning the trust of stakeholders	34	8	4.25	1
F19	Having clear customer needs	34	8	4.25	1

Table. 5.7 MICMAC ranking of BM factors

F20	Satisfied regulatory clearance	34	8	4.25	1
F33	Managing costs	34	8	4.25	1
F11	Satisfying customer requirements	26	14	1.86	2
F15	Onboarding of customers	26	14	1.86	2
F27	Securing team expertise	26	14	1.86	2
F29	Protecting intellectual property	26	14	1.86	2
F30	Funding capacity	26	14	1.86	2
F32	Investors support	26	14	1.86	2
F4	Identified market based on health focus	20	17	1.18	3
F6	Ensuring ease of use	20	17	1.18	3
F24	Cultivating health champions for technology adoption	20	17	1.18	3
F3	Fostering technological innovation	17	20	0.85	4
F5	Enabling early detection	17	20	0.85	4
F7	Maintaining cost-effectiveness	17	20	0.85	4
F9	Offering portability	14	22	0.64	5
F12	Effectively managing collaborations	14	22	0.64	5
F22	Timely delivery of value	12	24	0.50	6
F28	Organisational culture	12	24	0.50	6
F13	Training support (internal)	10	26	0.38	7
F21	Training and support provided	10	26	0.38	7
F14	R&D for sustaining innovations	8	29	0.28	8
F18	Driving adoption of innovation	8	29	0.28	8
F25	Outsourcing value creation	8	29	0.28	8
F26	Sustaining the value ecosystem	5	32	0.16	9
F31	Adaptive revenue stream	5	32	0.16	9
F34	Promoting knowledge exchanges	5	32	0.16	9
F8	Providing a platform for collaboration	2	33	0.06	10
F23	Implementing awareness initiatives	1	34	0.03	11

2. Plotting the MICMAC diagram

The results are further visualised in a scatter plot in Figure 5.4, with the dependence power on the x-axis and the driving power on the y-axis.

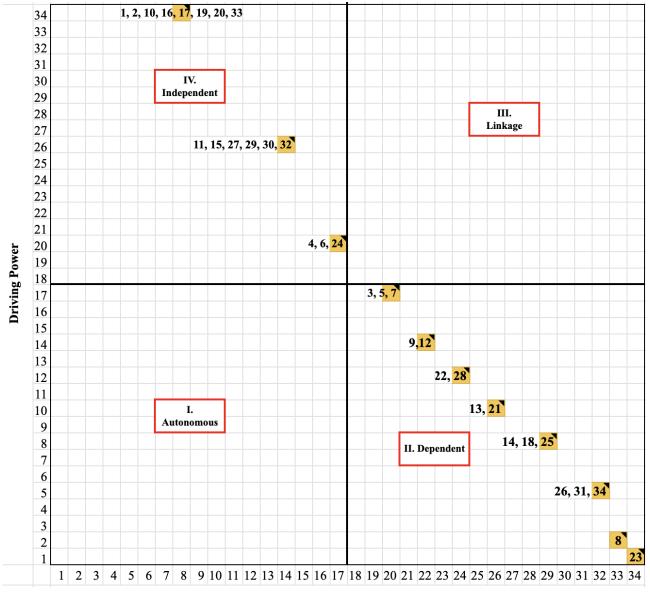


Figure 5.4 MICMAC analysis of BM factors

3. Categorise factors

Finally, the factors are classified into Autonomous, Dependent, Linkage and Independent factors in respective Quadrants I, II, III and IV as shown in Figure 5.4.

5.4.1 Cluster I: Autonomous factor

Autonomous variables (Cluster I) are those variables which have a low level of dependence and low level of driving power. They are referred to as excluded variables as they do not affect the functioning of the systems. In this study, no such variables fall into this category, validating that all variables have some driving and dependence power (Ong *et al.*, 2022).

5.4.2 Cluster II: Dependence factors

Dependence factors have strong dependence power and weak driving power. These factors rely heavily on other elements in the system for improvement and have a characteristic of strong dependence but weak influence on other elements. This cluster (Cluster II) of variables is sensitive to changes in influential variables and linkage factors, and it represents the output of the system. This dependence cluster comprises seventeen BM factors, including F3 Technological innovativeness, F5 Early detection, F7 Cost-effectiveness, F9 Portability, F12 Managing collaborations, F22 Timely delivery of value, F28 Culture and values, F13 Training support (internal), F21 Training and support provided, F14 R&D sustaining innovations, F18 Adoption of innovation, F25 Outsourcing value creation, F26 Sustaining value ecosystem, F31 Adaptive revenue stream, F34 Knowledge exchanges, F8 Platform for collaboration, and F23 Awareness initiatives (Ong *et al.*, 2022). In the TISM model, these factors constitute the top levels, depending on other BM factors that collectively influence BM design.

5.4.3 Cluster III: Linkage factors

Linkage factors have a strong driving power as well as strong dependence power. No factors fell in this cluster (Ong *et al.*, 2022).

5.4.4 Cluster IV: Independent/Driving factors

Cluster IV shows the influential variable that acts on the systems as a key force of inertia or movement. This cluster has seventeen BM factors, including F1 Meeting the needs of current standard of care, F2 Economic and political consideration, F10 Regulatory approval, F16 Effective sales channel, F17 Earning trust of stakeholders, F19 Clear customer needs, F20 Satisfied regulatory clearance, F33 Managing costs, F11 Satisfying customer requirement, F15 Onboarding customers, F27 Team expertise, F29 Intellectual property, F30 Funding, F32 Investors support, F4 Identified market based on health focus, F6 Ease of use, F24 Health champions for technology adoption, F3 Innovativeness, F5 Early detection, F7 Cost effective, F9 Portability, F12 Managing collaborations, F22 Timely delivery of value, F28 Culture and values, F13 Training support (internal), F21 Training and support provided, F14 R&D sustaining innovations, F18 Adoption of innovation, F25 Outsourcing value creation, F26 Sustaining value ecosystem, F31 Adaptive revenue stream, F34 Knowledge exchanges, F8 Platform for collaboration and F23 Awareness initiatives (Ong *et al.*, 2022).

5.5 Development of healthcare technology BM value circle

This section presents how the BM value circle of healthcare technology has been developed based on empirical findings of this phase. The TISM has validated the interrelationships of the BM factors. As Figure 5.5 illustrates, the value circle consists of several layers. At its core is the healthtech BM surrounded by the four BM dimensions: value offering, value delivery, value network and value capture. Beyond that, the BM components that make up each dimension are described. Further into the coloured area, the factors are segmented into their level of importance based on the MICMAC analysis. For reference, the factor names have been abbreviated in the diagram. A dedicated legend in Appendix G provides the abbreviations along with their corresponding full factor names. Factors with the highest priority are closest to the centre while the low priority factors are at the outermost layer. This overall contributes to a total of thirty-four factors that make up a healthcare technology BM.

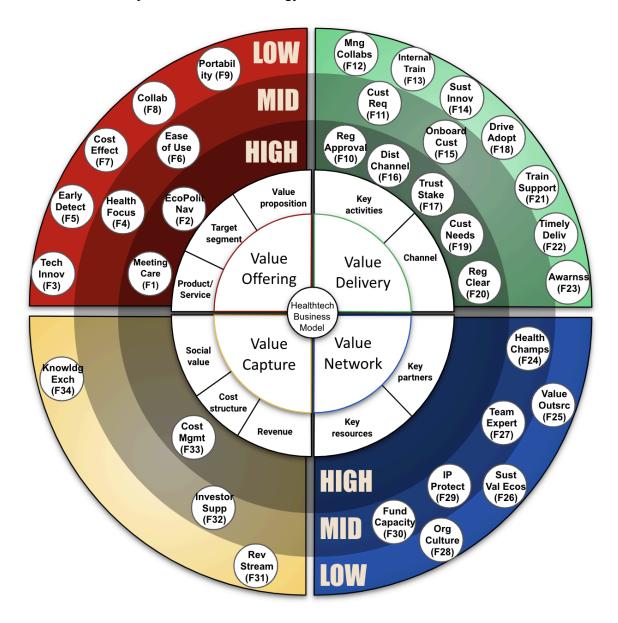


Figure 5.5 Healthcare technology BM value circle

The model is depicted in a circle because of the following reasons:

- These factors are not isolated; they influence and impact one another.
- Also, the BM for healthcare innovations is not a one-time design; it's an iterative process.
- Organisations must continuously revisit and adapt their BMs to evolving market conditions, technology advancements, and changing customer needs. This ongoing refinement process resembles a cycle, where the BM is revisited and enhanced over time.

5.6 Summary

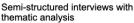
This chapter presented the final phase of the empirical study applying TISM and MICMAC analysis to healthcare and diagnostic technology BMs. This methodology offered a comprehensive framework for understanding the complex interdependencies among the factors influencing healthcare and diagnostic technology BMs enabling the identification of key drivers and dependencies that can inform policy interventions and strategic decision-making. The process of data collection, TISM construction, and MICMAC analysis application has been presented revealing 11 levels of the TISM and the hierarchical structure of influential factors within the healthcare and diagnostic technology BMs. Finally, the healthtech BM value circle was developed based on the findings. This comprehensive understanding of factor dynamics provides a solid foundation for strategic decision-making and the design of effective BMs in the healthcare and diagnostic technology domain.

Chapter 6 Discussion

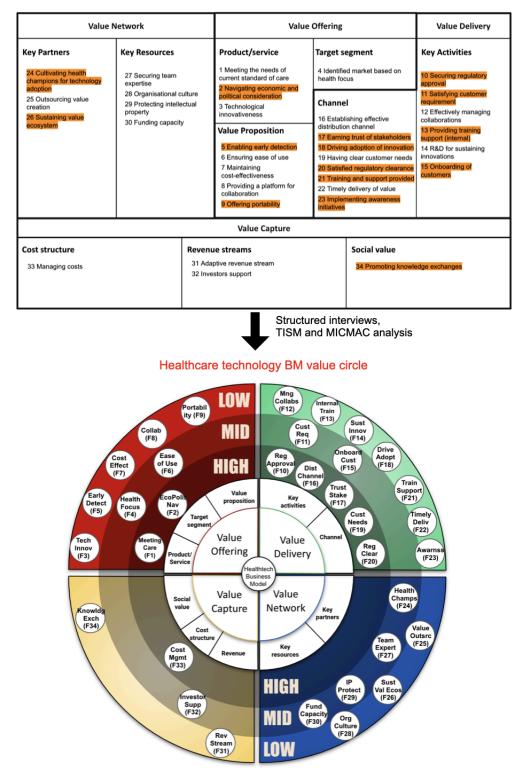
6.1 Introduction

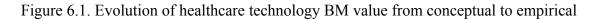
The primary objective of this chapter is to compare the empirical findings with those presented in literature. The results of this study align with certain aspects of the literature, while diverging from or not supporting others. This study conducted multiple qualitative approaches to investigate BM of healthcare technologies. The evolution of the healthcare technology BM value circle is illustrated in Figure 6.1. To start, the conceptual BM (Figure 2.9) was initially constructed using a systematic literature review to address the research objectives of this study. Then, the conceptual BM was refined through the initial empirical phase of the study using semi-structured interviews and thematic analysis resulting in 34 BM factors being identified. In the image, the new factors are highlighted which were not present in the SLR. Finally, the value circle was developed after the second empirical phase through structured interviews with TISM and MICMAC analysis. The following subsections provide an in-depth discussion of the evolution to the healthcare technology BM value circle. Section 6.2 explains the evolution from conceptual BM to refined BM. Then, Section 6.3 and Section 6.4 interpret the TISM and MICMAC analysis, respectively. BM prioritisation results compared with literature are further discussed in Section 6.5. Finally, the chapter is summarised in Section 6.4.





Refined BM





6.2 Conceptual to refined BM

In the top half of Figure. 6.1 illustrates the evolution of the conceptual to the refined BM, highlighted in orange are the distinct factors discovered during the first phase of the study. The conceptual BM started with vague characteristics of each of the components interpreted from the SLR, which was then refined to a total of 34 distinct BM factors in Chapter 4. This contributes to achieving research objective one: To understand and identify the key BM value dimensions, components and factors that can be used by stakeholders associated with the development of medical technology for diagnosis and healthcare. Table 6.1 presents a comprehensive comparison between BM factors identified in the existing literature and those empirically uncovered in this research. This study also aligns with several studies which investigated medical device start-up success factors (Lee, Park and Lee, 2019), hospital BM (Viswanadham, 2021). Notably, the empirical investigation revealed additional factors (highlighted in orange) that were not explicitly emphasised in prior research.

BM value dimension	BM Component	No.	BM Factors revealed in empirical study	BM factors in literature
	Product/ service	1	Meeting the needs of current standard of care	Market analysis skills
		2	Navigating economic and political consideration	
		3	Technological innovativeness	Technology innovativeness
Value offering	Target segment	4	Identified market based on health focus	Product's market size
value offering	Value proposition	5	Enabling early detection	
		6	Ensuring ease of use	Ease of use
		7	Maintaining cost-effectiveness	Product competitiveness
		8	Providing a platform for collaboration	Personalised platform
		9	Offering portability	

Table 6.1 BM factors in literature vs empirical

		10	Securing regulatory approval	Clinical standards
Value delivery	Key activities			Customer-oriented
		11	Satisfying customer requirement	approach
		12	Effectively managing collaborations	Performance monitoring
		13	Providing training support (internal)	
		14	R&D for sustaining innovations	R&D facilities and infrastructure
		15	Onboarding of customers	
	Channel	16	Establishing effective distribution channel	Effective communication
		17	Earning trust of stakeholders	
		18	Driving adoption of innovation	
		19	Having clear customer needs	Clear vision
		20	Satisfied regulatory clearance	
		21	Training and support provided	
		22	Timely delivery of value	Service quality
		23	Implementing awareness initiatives	
Value network	Key partners	24	Cultivating health champions for technology adoption	
		25	Outsourcing value creation	Network utilisation
		26	Sustaining value ecosystem	
	Key resources	27	Securing team expertise	Securement of a professional workforce
		28	Organisational culture	Organisational culture
		29	Protecting intellectual property	Patent retention
		30	Funding capacity	Funding capacity
Value capture	Revenue	31	Adaptive revenue stream	Potential growth of profit
		32	Investors support	Initial capital
	Cost	33	Managing costs	Available funds
	Social value	34	Promoting knowledge exchanges	Social profit

Value offering dimension

In the value offering dimension, three factors (2, 5 and 9) have been identified which were not emphasised in literature, which in total, validated 9 key BM factors in this dimension. The inclusion of BM factor 2 underscores the importance of acknowledging and proactively addressing economic and political influences on healthcare technology innovation. Literature has tended to focus on technical aspects of the BM (Korsgaard, Hasenkam and Vesterby, 2021; Oderanti *et al.*, 2021; Viswanadham, 2021), but the empirical findings align with real-world challenges faced by industry players. As healthcare landscapes are subject to shifting policies and fiscal considerations, understanding and navigating these complexities is imperative for BM success.

With the context-specific of this research in the diagnostic field, factors 5 (early detection) and 9 (offering portability) highlighted the need to not only prioritise early detection and portability in technology but also consider it as an integral part of the BM. The ability to detect and address health issues at their nascent stages has become a pivotal factor in improving patient outcomes and reducing healthcare costs, influencing revenue streams and market positioning. In an era characterised by mobile technology and the demand for seamless access to healthcare solutions, the portability of healthcare technologies has gained prominence (Acheampong and Vimarlund, 2015; Fürstenau *et al.*, 2021). Patients and healthcare providers increasingly value solutions that offer flexibility and mobility. Therefore, this factor finds its place in the refined BM as a response to this evolving trend.

Value delivery dimension

In the value delivery dimension, another 9 factors have been unveiled: 10 Securing regulatory approval, 11 Satisfying customer requirement, 13 Providing training support (internal), 15 Onboarding of customers, 17 Earning trust of stakeholders, 18 Driving adoption of innovation, 20 Satisfied regulatory clearance, 21 Training and support provided, 23 Implementing awareness

initiatives. Resulting in fourteen key BM factors in this dimension. The introduction of nine additional factors in the value delivery dimension represents a comprehensive understanding of the intricacies involved in delivering successful healthcare technology solutions. Each factor plays a crucial role in shaping the BM and ensuring effective value delivery.

Reflecting the rigorous regulatory landscape of healthcare technology, factor 10 and 20 aligns with the necessity of expeditiously navigating these requirements to ensure the successful delivery of innovative solutions. While securing regulatory approval is discussed by prior literature it was not explicitly integrated in the BM (Garmann-Johnsen and Eikebrokk, 2017; Hofmann *et al.*, 2020; Kelley *et al.*, 2020) and was considered an external factor to the BM (Nikou and Bouwman, 2017). Factor 11 echoes the customer-centric approach advocated in the literature, however not explicitly integrated in the BM (Laya, Markendahl and Lundberg, 2018; Al Thawadi *et al.*, 2019). It underlines the importance of not only meeting but exceeding customer expectations, aligning with the ever-increasing focus on patient-centred care and solutions.

The inclusion of Factor 13 internal training support and Factor 21 training and support provided as a BM factor emphasises the role of well-prepared internal teams as it ensures that all stakeholders can effectively utilise the technology. In other studies, the specialised training for consumers was discussed (Rose, Jiang and Mangematin, 2017; García-Holgado, Marcos-Pablos and García-Peñalvo, 2019; Christie et al., 2020) but not explicitly counted as a BM factor. Thus, Factors 13 and 21 as key BM factors were validated in the empirical investigation. Not highlighted in prior studies, factor 13 explicitly looks into the internal team training as a critical process of introducing and integrating customers into the healthcare technology ecosystem. Internal training support ensures that the teams are well-equipped to handle the intricacies of the technology, enhancing operational efficiency. Consequently, a smoother value delivery process. While training and support provided stresses the significance of continuous support, aligning with the evolving needs of users and maintaining the relevance of the technology.

In the empirical findings, Factor 15 was added as a key BM factor which highlights the importance of a well-defined onboarding process, enhancing the customer experience and contributing to the overall success of the BM. Seamless onboarding is critical for customer satisfaction and the successful integration of the technology into the customer's workflow (Denicolai and Previtali, 2020; Nigam, Mbarek and Boughanmi, 2021). In literature, this has been used as a method for data collection (Kelley *et al.*, 2020) but not explicitly counted as a key BM factor.

While prior literature acknowledges trust as a cornerstone in healthcare, it was not explicitly identified as a BM factor (Dupont *et al.*, 2017; Coan *et al.*, 2018; Denicolai and Previtali, 2020; Palas and Bunduchi, 2021). Studies have integrated it in their value propositions such as creating a trustworthy platform (Coan *et al.*, 2018) and this value of trust is identified as a characteristic of the product instead of as a key activity. In the empirical findings, Factor 17 explicitly underscores the need to build and maintain trust, contributing to the value delivery dimension of the BM in the healthcare ecosystem.

Innovation adoption is crucial for staying competitive and delivering cutting-edge solutions (Kelley *et al.*, 2020; Bhattacharya, Wainwright and Whalley, 2021; Fürstenau *et al.*, 2021). This factor has been studied in literature as a goal to be achieved such as in digital health innovations (Chen, Liu and Hu, 2020; Kelley *et al.*, 2020) and identifying barriers to market adoption (Denicolai and Previtali, 2020). In the empirical findings, Factor 18 highlights the proactive role in driving innovation adoption, positioning the BM as a leader in introducing and integrating innovative solutions into the market.

Finally in this dimension, implementing awareness initiatives (Factor 23) is added as a key factor. Studies have found that there is a significant difference between business and consumers' perceptions indicating that marketing is not closely aligned to customer's needs (Ward *et al.*, 2017; Denicolai and Previtali, 2020; Thiebes *et al.*, 2020). In this study creating awareness initiatives was found to be vital for market visibility and acceptance, contributing to a positive market perception and facilitating successful value delivery.

Value network dimension

For the value network dimension, BM factors 24 Cultivating health champions for technology adoption and 26 Sustaining value ecosystems were found. Altogether, there are seven key BM factors in this dimension. In literature, the key partners component has only considered the network utilisation (Denicolai and Previtali, 2020; Palas and Bunduchi, 2021; Viswanadham, 2021). In the empirical study, this component has been elaborated to include cultivating champions within the healthcare community to foster advocacy and accelerate the adoption of innovative technologies and sustaining value ecosystems which are critical for long-term success, ensuring the continuous delivery of value to stakeholders. This implies the need to sustain and nurture value ecosystems, aligning with the interconnected relationships among stakeholders and fostering a resilient BM.

Value capture dimension

Finally in the value capture dimension, four key BM factors have been identified, encompassing various aspects crucial for sustainable value capture. Adaptive Revenue Stream (Factor 31) aligns with prior literature that the ability to adapt revenue streams ensures flexibility in responding to changing market conditions and evolving customer needs (Khuntia, Mithas and Agarwal, 2017; Vimarlund and Mettler, 2017). This factor emphasises the strategic importance of designing revenue streams that can adapt to dynamic circumstances, contributing to the overall resilience of the BM. Investor Support (Factor 32) plays a pivotal role in providing financial backing and strategic guidance for sustainable growth (Terra, Rodrigues and Maia, 2019; Kelley *et al.*, 2020; Nigam, Mbarek and Boughanmi, 2021). This underscores the importance of cultivating and maintaining investor support as a critical component in the BM, ensuring access to resources and expertise.

Managing costs (Factor 33) impacts the cost structure of the business, influencing how resources are allocated and utilised (García-Holgado, Marcos-Pablos and García-Peñalvo, 2019; Bhattacharya, Wainwright and Whalley, 2021; Nigam, Mbarek and Boughanmi, 2021; Palas and Bunduchi, 2021; Chen, 2022). This strategic approach ensures that the healthcare technology business remains financially viable and competitive in a dynamic market. The social value component has been updated to Factor 34 Promoting knowledge exchanges. This highlights the ways through which part of the value created flows back to the organisation and how it is shared with other stakeholders and considers not only the profit equation but also social outcomes (van Dijk-De Vries *et al.*, 2020; Lehoux *et al.*, 2021; Schiavone *et al.*, 2021).

6.3 TISM discussion

This section looks at each of the BM factors and how they are positioned along with their relationships in the TISM hierarchy model (Figure 5.3) and MICMAC diagram (Figure 5.4).

1 Meeting the needs of current standard of care

This factor underscores the importance of aligning healthcare technologies with existing standards of care as acknowledged by prior literature (Al Thawadi *et al.*, 2019; Christie *et al.*, 2020; Sibalija *et al.*, 2021). In the TISM, this factor is positioned at the lowest level, which means that this factor holds a pivotal role in the BM. Also, looking at its connection in the model, it directly influences and enhances the aspect of navigating economic and political considerations within the BM. This implies that meeting the needs of current standards of care are fundamental to align with the established healthcare standards as it ensures that the healthcare technology complies with industry norms, protocols, and best practices. In return, the BM ensures that diagnostic products and services align with established healthcare practices in a cost-effective manner (Vimarlund, Nikula and Nøhr, 2021). This alignment positively influences economic considerations by optimising resource

utilisation (Chen, Liu and Hu, 2020; Nigam, Mbarek and Boughanmi, 2021). In the TISM model, this factor also has a transitive connection that influences and enhances the aspect of protecting intellectual property within the BM. The BM, by focusing on meeting healthcare standards, is likely to develop innovative diagnostic solutions which become intellectual property (Nigam, Mbarek and Boughanmi, 2021). This relationship not only safeguards innovative technologies but also creates a conducive environment for sustained growth, market leadership, and global expansion within the healthcare technology sector (Denicolai and Previtali, 2020).

2 Navigating economic and political consideration

Being situated at the lowest level in the TISM underscores the fundamental influence and critical importance of this factor in shaping and directing various facets of the BM. Specifically, its relationships with other key factors further illuminate its strategic significance. Navigating economic and political considerations is intricately linked with "Meeting the needs of current standard of care," emphasising its foundational role in aligning diagnostic products and services with prevailing healthcare standards (Bhattacharya, Wainwright and Whalley, 2021; Denoo, Yli-Renko and Clarysse, 2021). Additionally, its influence extends to "Protecting intellectual property," showcasing its impact on safeguarding proprietary innovations in the complex landscape of economic and political variables. The adaptive nature of this factor is evident in its influence on "Funding capacity," implying that effective navigation of economic and political considerations enables the business to secure necessary financial support. The strategies employed to navigate these considerations are dynamic, as reflected in its influence on "Managing costs," indicating an adaptive approach to cost structures influenced by the economic and political landscape.

3 Technological innovativeness

In the TISM hierarchy model, Factor 3, "Technological innovativeness," occupies an intermediate level, positioning it in the middle of the hierarchical structure. This placement signifies its role as a key bridge, progressively influenced by factors at lower levels while concurrently influencing factors at higher levels. As an intermediate factor, Technological innovativeness plays a crucial role in shaping the strategic dynamics of the BM. Its relationship with "Maintaining cost-effectiveness" exemplifies its impact on the efficient allocation of resources through reduced resource consumption (Palas and Bunduchi, 2021; Vimarlund, Nikula and Nøhr, 2021; Chen, 2022). Conversely, the influence is reciprocal, highlighting that maintaining cost-effectiveness is contingent on the innovative use of technology and strategic resource allocations (Nigam, Mbarek and Boughanmi, 2021).

Furthermore, the relationship with "Effectively managing collaborations" underscores how technological innovativeness enhances collaboration through the provision of tools and platforms (Malm, Pikkarainen and Hyrkäs, 2020; Fürstenau *et al.*, 2021; Schiavone *et al.*, 2021; Viswanadham, 2021). This transitive influence further extends to "Cultivating health champions for technology adoption," where technological innovativeness fosters the cultivation of champions, driving technology adoption within the healthcare ecosystem. In this context, technological innovativeness emerges as a dynamic factor that not only responds to lower-level influences but also plays a pivotal role in influencing and enhancing higher-level strategic components within the BM.

4 Identified market based on health focus

Factor 4, "Identified market based on health focus," holds a foundational position at the lowest level of the TISM hierarchy within the BM. In the context of the BM, Identified market based on health focus plays a pivotal role in driving key strategic components. Its relationship with "Cultivating

health champions for technology adoption" reflects its influence in promoting technology adoption within the identified health-focused market (Fürstenau *et al.*, 2021). By identifying and targeting a specific health-focused market, the BM can cultivate champions who champion the adoption of healthcare technology within that market. Additionally, its influence extends to "Technological innovativeness," where the identified market provides insights and demands that enhance the innovative aspects of the technology (Palas and Bunduchi, 2021).

5 Enabling early detection

Factor 5, "Enabling early detection," is in an intermediate position within the TISM hierarchy, situated in the middle tier where factors are subject to progressive influence from those at lower levels. This placement underscores its role as an intermediary driver that connects foundational elements to higher-level strategic components within the BM. Its relationship with "Maintaining cost-effectiveness" signifies its impact on cost-related considerations. By enabling early detection, the BM is positioned to lead efforts in maintaining cost-effectiveness, as timely detection can contribute to efficient and resource-effective healthcare solutions (Denicolai and Previtali, 2020; Hofmann *et al.*, 2020; Chen, 2022). Furthermore, the factor's influence extends to "Offering portability," where the capability for early detection enhances the value proposition by providing a portable solution. The ability to detect health issues early and offer a portable solution aligns with the value proposition of convenience and accessibility for users (Hofmann *et al.*, 2020; Khatab and Yousef, 2021).

6 Ensuring ease of use

Factor 6, "Ensuring ease of use," is positioned at the lowest level of the TISM hierarchy, signifying its status as a core driver deeply embedded in the foundational elements of the BM. As a primary factor, it underscores the significance of user-centric considerations in shaping the overall BM

strategy (Denicolai and Previtali, 2020; Oderanti *et al.*, 2021). Within the BM, this factor influences other factors such as "Cultivating health champions for technology adoption." The factor plays a crucial role in strengthening the adoption of healthcare technology by ensuring that the technology is user-friendly (Oderanti and Li, 2016; Nikou and Bouwman, 2017; Mueller, 2020). A user-friendly interface and functionality contribute to building champions who advocate for the technology, fostering its adoption within healthcare practices. Additionally, the factor's impact extends to "Enabling early detection." By ensuring that the technology is easy to use, the BM is poised to facilitate early detection efforts, as user-friendly interfaces can enhance the efficiency and effectiveness of early detection processes.

7 Maintaining cost-effectiveness

Factor 7, "Maintaining cost-effectiveness," assumes a position at the intermediate level within the TISM hierarchy. This placement signifies its role as a factor that bridges core drivers at the lowest level with higher-level factors, progressively influencing and shaping the BM. Within the BM framework, Maintaining cost-effectiveness exhibits multifaceted relationships with various factors as seen in the TISM model (Figure 5.3). Its influence on "Technological innovativeness" underscores its pivotal role in shaping innovative solutions in a cost-effective manner. This relationship highlights the strategic importance of managing costs to drive and sustain technological innovation within the healthcare technology sector(Khuntia, Mithas and Agarwal, 2017; Vimarlund, Nikula and Nøhr, 2021). Furthermore, Maintaining cost-effectiveness plays a crucial role in "Enabling early detection." By managing costs effectively, the BM is positioned to enhance the efficiency and affordability of early detection processes, contributing to the overall effectiveness of healthcare technology solutions. The factor's impact extends to "Offering portability," where cost-effectiveness influences the design and delivery of portable healthcare solutions in Chamjamrassri *et al.*, 2018). This relationship emphasises the importance of cost considerations in

offering flexible and portable technologies that align with evolving healthcare needs. Lastly, Maintaining cost-effectiveness influences "Effectively managing collaborations," showcasing its role in shaping collaborative efforts within the BM. Efficient cost management facilitates collaborative initiatives, ensuring that partnerships and collaborations contribute to overall cost-effectiveness (Marceglia *et al.*, 2018; Nigam, Mbarek and Boughanmi, 2021; Vimarlund, Nikula and Nøhr, 2021).

8 Providing a platform for collaboration

Factor 8, "Providing a platform for collaboration," situated at the top of the TISM hierarchy, exhibiting the highest dependence power, relying on the contributions and characteristics of all lower-level factors to accomplish their objectives. Although this may possess limited driving power, these factors are indispensable to the holistic functioning of the BM. In the context of the study, Providing a platform for collaboration plays a central role in fostering collaborative efforts and partnerships within the healthcare technology ecosystem (Viswanadham, 2021). By facilitating a space for effective collaboration, this factor enhances the overall synergy among stakeholders, including healthcare providers, technology developers, and other key participants (Malm, Pikkarainen and Hyrkäs, 2020; Schiavone et al., 2021; Vimarlund, Nikula and Nøhr, 2021; Viswanadham, 2021). The influence of this factor extends to "Implementing awareness initiatives." This connection underscores the strategic importance of collaboration in driving initiatives aimed at raising awareness and promoting the adoption of healthcare technologies (Denicolai and Previtali, 2020). Collaborative efforts, facilitated by a dedicated platform, play a pivotal role in amplifying the impact of awareness initiatives, reaching a broader audience and fostering a culture of innovation. While Providing a platform for collaboration may exhibit limited driving power, its significance lies in its capacity to create an environment conducive to shared innovation and mutual benefit.

9 Offering portability

Factor 9, "Offering portability," is positioned at an intermediate level within the TISM hierarchy, being progressively influenced by those at lower levels and, in turn, influencing higher-level factors. The influence of Offering portability extends to "Effectively managing collaborations." This relationship underscores the significance of portability in fostering seamless collaboration within the healthcare technology ecosystem (García-Holgado, Marcos-Pablos and García-Peñalvo, 2019; Pundziene, Heaton and Teece, 2019; Denicolai and Previtali, 2020). By offering solutions that prioritise portability, the BM creates an environment conducive to collaborative efforts, ensuring that stakeholders can easily engage and contribute to shared initiatives. This connection highlights the interdependence between factors at the intermediate level and those related to collaboration, emphasising the role of portability in shaping collaborative dynamics.

Additionally, offering portability contributes to the "Timely delivery of value." The portability of healthcare technologies enhances their accessibility and usability, facilitating the timely delivery of value to end-users (Bhattacharya, Wainwright and Whalley, 2021; Schiavone *et al.*, 2021; Vimarlund, Nikula and Nøhr, 2021). This relationship reinforces the importance of portability in ensuring that the benefits and value propositions embedded in healthcare technologies can be efficiently and effectively delivered to users, aligning with the dynamic nature of the healthcare landscape.

10 Securing regulatory approval

Factor 10, "Securing regulatory approval," occupies the lowest level within the TISM hierarchy, signifying its status as a core driver of the healthcare technology BM. One of its critical relationships is with "Earning trust of stakeholders." The successful navigation of regulatory processes instils confidence among stakeholders, fostering trust in the BM. This connection

underscores the integral role that regulatory approval plays in building and maintaining positive relationships with stakeholders, whose support is crucial for the success of healthcare technology (Oderanti and Li, 2016; Nikou and Bouwman, 2017). Additionally, Securing regulatory approval is linked to "Satisfied regulatory clearance." This relationship signifies the importance of regulatory compliance and clearance in the BM (Rose, Jiang and Mangematin, 2017). Successfully securing regulatory approval contributes to a state of regulatory clearance satisfaction, aligning with the stringent requirements imposed on healthcare technologies (Kelley *et al.*, 2020; Thiebes *et al.*, 2020; Denoo, Yli-Renko and Clarysse, 2021). This connection highlights the intricate interplay between regulatory processes and the achievement of regulatory clearance objectives. Furthermore, the influence of Securing regulatory approval extends to "Securing team expertise." The expertise required to navigate regulatory landscapes is essential for obtaining approval. This connection highlights that regulatory success not only depends on the approval itself but also on the expertise of the team involved (Denoo, Yli-Renko and Clarysse, 2021; Khatab and Yousef, 2021). The regulatory landscape necessitates a team with the knowledge and skills to ensure compliance, further underscores the foundational role of regulatory approval.

Lastly, Securing regulatory approval influences "Investors support." Investors seek assurance of regulatory adherence, making regulatory approval a critical factor in garnering support (Rose, Jiang and Mangematin, 2017; Terra, Rodrigues and Maia, 2019; Kelley *et al.*, 2020; Denoo, Yli-Renko and Clarysse, 2021). Successfully navigating regulatory processes enhances the attractiveness of healthcare technology to investors, showcasing a BM that is aligned with regulatory standards and best practices.

11 Satisfying customer requirements

Factor 11, "Satisfying customer requirements," is in the lowest level within the TISM hierarchy, underscoring its foundational role as a core driver of the healthcare technology BM. This factor

influences various aspects critical to its functionality. One significant relationship is with "Cultivating health champions for technology adoption." By satisfying customer requirements, the BM can enhance its appeal and usability (Christie *et al.*, 2020), directly influencing the cultivation of health champions. This connection highlights that meeting and exceeding customer expectations contributes to the successful adoption of healthcare technology (van Dijk-De Vries *et al.*, 2020). As health champions advocate for and promote the technology, it further solidifies the BM's position within the healthcare landscape. Moreover, Satisfying customer requirements influences "Funding capacity." A satisfied customer base positively impacts the BM's financial outlook, leading to increased funding capacity (Marceglia *et al.*, 2018; Marcos-Pablos, García-Holgado and García-Pēalvo, 2019). Meeting customer needs and delivering value enhance the business's reputation and attract financial support, facilitating its growth and sustainability. This connection underscores the vital role of customer satisfaction in securing the financial resources necessary for advancing healthcare technology (Bhattacharya, Wainwright and Whalley, 2021).

In addition, Satisfying customer requirements extends its influence to "Investors support." Satisfied customers contribute to the overall value proposition of healthcare technology, adding value for investors (Bhattacharya, Wainwright and Whalley, 2021). By prioritising customer satisfaction, the BM aligns with investor expectations and underscores the technology's potential for success in the market (Sibalija *et al.*, 2021). This relationship emphasises the integral connection between customer satisfaction and investor support, both of which are crucial for the BM's viability and growth.

12 Effectively managing collaborations

Factor 12, "Effectively managing collaborations," is in an intermediate level within the TISM hierarchy, signifying its role as a factor that is progressively influenced by those at lower levels

while influencing factors at higher levels. It has a direct relationship with "Organisational culture." By effectively managing collaborations, the BM can cultivate a collaborative and cohesive organisational culture (Harrington and Burge, 2018; Nguyen Dang Tuan, Nguyen Thanh and Le Tuan, 2019; Khatab and Yousef, 2021). The transitive influence implies that the successful management of collaborations contributes to shaping the overall culture of the healthcare technology enterprise.

Furthermore, Effectively managing collaborations has a reciprocal relationship with "Offering portability." While Offering portability influences effective collaboration by increasing accessibility, the reverse is also true. Effectively managing collaborations can enhance Offering portability by contributing to the development and implementation of portable solutions. This mutual influence underscores the synergy between collaboration management and the development of portable healthcare technology, emphasising the interconnectedness of these BM factors.

The relationship extends to "Maintaining cost-effectiveness." Effective collaboration influences strategic resource allocation, which, in turn, contributes to maintaining cost-effectiveness. This transitive influence underscores how strategic collaboration management optimises resource allocation, ensuring efficient and cost-effective operations within the BM.

13 Providing internal training support

Factor 13, "Providing internal training support," assumes an intermediate-level position within the TISM hierarchy. This intermediate placement highlights the progressive impact of internal training support on the healthcare technology BM, connecting lower-level operational aspects with higher-level strategic considerations. The first relationship involves its influence on "R&D for sustaining innovations." Providing internal training support enhances the value offering by contributing to research and development efforts, ensuring a skilled workforce capable of sustaining innovative initiatives. This connection reinforces the role of internal training in fostering an

environment conducive to ongoing research and development, a critical component for the BM's sustained innovation.

The second relationship extends to "Training and support provided." Providing internal training support enhances the overall training and support infrastructure, ensuring comprehensive and effective training programs for stakeholders (Christie *et al.*, 2020). This influence underscores the importance of internal training in contributing to the broader training and support mechanisms provided by the BM, creating a robust support system for users (García-Holgado, Marcos-Pablos and García-Peñalvo, 2019).

The third relationship involves "Outsourcing value creation." Providing internal training support, in a transitive manner, influences the BM's capacity to outsource value creation. By ensuring an adept internal team through training, the BM enhances its capability to collaborate with external partners for value creation, emphasising the interconnectedness of internal training with the broader value creation strategy (Christie *et al.*, 2020).

14 R&D for sustaining innovations

Factor 14, "R&D for Sustaining Innovations," occupies an intermediate-level position within the TISM hierarchy, symbolising its role as a factor progressively influenced by those at lower levels while exerting influence on higher-level components. Notably, it establishes a relationship with "Outsourcing Value Creation." The influence of R&D for Sustaining Innovations on outsourcing value creation strengthens the collaboration and partnerships involved in the creation of value within the BM (Denicolai and Previtali, 2020). This connection underscores the importance of robust R&D practices in enhancing collaborative efforts, fostering external partnerships, and expanding the scope of value creation. Moreover, R&D for Sustaining Innovations influences "Adaptive Revenue Stream." By supporting adaptive revenue strategies, this factor plays a pivotal role in shaping how the BM generates revenue in response to changing market dynamics (Khuntia,

Mithas and Agarwal, 2017; Nikou and Bouwman, 2017; Vimarlund and Mettler, 2017; Fidrich *et al.*, 2018). The relationship highlights the strategic role of sustained R&D efforts in ensuring the adaptability of revenue streams, aligning with the dynamic nature of the healthcare technology industry.

15 Onboarding customers

Factor 15, "Onboarding Customers," assumes a foundational role within the TISM hierarchy, representing a core driver of healthcare technology BM. Onboarding Customers is instrumental in influencing "Securing Team Expertise." By fostering effective onboarding processes, the BM ensures the sustained development and retention of a skilled workforce (Nguyen Dang Tuan, Nguyen Thanh and Le Tuan, 2019; Chen, Liu and Hu, 2020). This relationship underscores the importance of well-structured onboarding strategies in sustaining human resources, ultimately contributing to the expertise required for the successful execution of the BM.

Additionally, Onboarding Customers has a transitive influence on "Ensuring Ease of Use." Effective onboarding processes generate valuable feedback from customers, providing insights that can be utilised to enhance the ease of use of healthcare technology (Hofmann *et al.*, 2020; Malm, Pikkarainen and Hyrkäs, 2020; Denoo, Yli-Renko and Clarysse, 2021; Sibalija *et al.*, 2021). This connection highlights the dual role of onboarding: not only introducing customers to the technology but also serving as a mechanism for continuous improvement by gathering user experiences and preferences.

16 Establishing an effective distribution channel

Factor 16, "Establishing an Effective Distribution Channel," is positioned at the lowest level within the TISM hierarchy, signifying a core driver in shaping the healthcare technology BM. This factor has a direct and substantial impact on "Onboarding of Customers." By ensuring an efficient flow of transactions, the distribution channel becomes integral to the onboarding process, streamlining the introduction and integration of customers into the healthcare technology ecosystem (Yang *et al.*, 2016; Khuntia, Mithas and Agarwal, 2017; Sibalija *et al.*, 2021). Furthermore, an effective distribution channel influences "Earning Trust of Stakeholders." The efficiency and reliability demonstrated by a well-established distribution channel contribute to building confidence among stakeholders. This relationship emphasises the critical role that distribution plays in fostering trust, a key element in the success and sustainability of the BM (Bhattacharya, Wainwright and Whalley, 2021). The relationship between "Establishing an Effective Distribution Channel" and "Having Clear Customer Needs" underscores the channel's role in facilitating the efficient delivery of value. A clear and effective distribution mechanism ensures that customer needs are met promptly and accurately (Yang *et al.*, 2016; Malm, Pikkarainen and Hyrkäs, 2020; Bhattacharya, Wainwright and Whalley, 2021). Finally, the transitive influence on "Securing Team Expertise" highlights that an established distribution channel enhances the value delivery process. This connection emphasises the strategic importance of distribution in supporting and augmenting the expertise required for the successful execution of the BM.

17 Earning the trust of stakeholders

Factor 17, "Earning the Trust of Stakeholders," is at the lowest level of the TISM hierarchy. This factor holds importance in establishing and nurturing positive relationships with stakeholders, essential for the BM's overall success. It directly influences "Securing Regulatory Approval." The positive reputation garnered through trust-building activities positively influences stakeholders' perceptions, potentially facilitating smoother regulatory approval processes. This connection underscores the symbiotic relationship between trust and regulatory success, with stakeholder trust acting as a valuable asset in gaining regulatory approval. Additionally, the relationship between "Earning Trust of Stakeholders" and "Establishing an Effective Distribution Channel" emphasises

how trust fosters positive relationships. A well-established distribution channel relies on trust to function efficiently, and reciprocally, an effective distribution channel contributes to building and maintaining stakeholder trust (Denicolai and Previtali, 2020). Moreover, the transitive influence on "Securing Team Expertise" suggests that earning stakeholder trust benefits the team's development of expertise. Trustworthy relationships with stakeholders create an environment conducive to collaboration, fostering the development of a knowledgeable and skilled team. This highlights the integral role of stakeholder trust in enhancing the expertise required for the successful execution of the BM.

18 Driving adoption of innovation

Factor 18, "Driving Adoption of Innovation," occupies an intermediate level in the TISM hierarchy, signifying its role as a mediator influenced by lower-level factors and influencing higher-level factors. The relationship between "Driving Adoption of Innovation" and "Outsourcing Value Creation" suggests that fostering innovation adoption enhances the value network. By driving the adoption of innovative solutions, an organisation can strengthen its ties within the value network, contributing to the efficient creation and delivery of value. This connection highlights the pivotal role of innovation in shaping the collaborative dynamics of the broader value network (Fürstenau *et al.*, 2021; Lehoux *et al.*, 2021).

Similarly, the relationship between "Driving Adoption of Innovation" and "Sustaining Value Ecosystem" underscores how the adoption of innovative practices contributes to the sustainability of the broader value ecosystem. By actively driving the adoption of innovation, a business can contribute to the development and maintenance of a robust and sustainable value ecosystem (Vimarlund, Nikula and Nøhr, 2021; Viswanadham, 2021).

19 Having clear customer needs

Factor 19, "Having Clear Customer Needs," is at the lowest level in the TISM hierarchy, signifying its foundational role as a core driver of the healthcare technology BM. Its relationship with "Onboarding of Customers" highlights the critical role of understanding customer needs in tailoring an effective onboarding process. When an organisation has a clear understanding of the specific requirements and preferences of its customers, it can tailor the onboarding experience to align with those needs (Thamjamrassri *et al.*, 2018). This ensures a seamless integration of customers into the healthcare technology ecosystem, fostering positive interactions and user experiences (Fidrich *et al.*, 2018; Marceglia *et al.*, 2018; Al Thawadi *et al.*, 2019; Terra, Rodrigues and Maia, 2019).

Moreover, the connection between "Having Clear Customer Needs" and "Establishing Effective Distribution Channel" underscores the importance of aligning the distribution channel with the identified customer needs. A clear understanding of customer needs enables the organisation to design and implement a distribution channel that efficiently meets those needs. This alignment ensures that the distribution of value is carried out in a manner that resonates with the expectations and requirements of the customer base (Malm, Pikkarainen and Hyrkäs, 2020; Bhattacharya, Wainwright and Whalley, 2021; Sibalija *et al.*, 2021).

20 Satisfied regulatory clearance

Factor 20, "Satisfied Regulatory Clearance," holds a foundational position at the lowest level of the TISM hierarchy, signifying its pivotal role as a core driver within the healthcare technology BM. Its relationship to "Securing Regulatory Approval" emphasises the preventive nature of regulatory clearance. By obtaining regulatory clearance, an organisation ensures that its healthcare technology adheres to established standards, preventing unauthorised distribution. This not only safeguards the integrity of the technology but also aligns with regulatory requirements, contributing to the overall compliance and legitimacy of the BM (Terra, Rodrigues and Maia, 2019; Hofmann *et al.*, 2020; Kelley *et al.*, 2020; Mueller, 2020; Denoo, Yli-Renko and Clarysse, 2021).

Furthermore, the connection between "Satisfied Regulatory Clearance" and "Satisfying Customer Requirement" underscores the positive impact on customer satisfaction. Regulatory clearance serves as a quality assurance measure, instilling confidence in customers by assuring them that the technology meets regulatory standards (Khatab and Yousef, 2021). This, in turn, enhances customer satisfaction, aligning with the organisation's commitment to meeting and exceeding customer requirements.

21 Training and support provided

Factor 21, "Training and Support Provided," is in an intermediate position within the TISM hierarchy, signifying its role as a key influencer that is progressively shaped by factors at lower levels. Its connection with "Driving Adoption of Innovation" highlights the driving force that effective training and support mechanisms can exert on the adoption of innovative solutions. By providing comprehensive training and support, an organisation facilitates the understanding and integration of innovations, thereby promoting their successful adoption (Rose, Jiang and Mangematin, 2017; García-Holgado, Marcos-Pablos and García-Peñalvo, 2019). This connection reinforces the importance of equipping stakeholders with the knowledge and resources needed to embrace and implement technological advancements.

Additionally, the link between "Training and Support Provided" and "Outsourcing Value Creation" underscores the transitive influence on engaging value networks. Effective training and support contribute to creating a collaborative environment, fostering meaningful interactions within value networks (Christie *et al.*, 2020). As organisations outsource value creation, the provision of training and support becomes instrumental in ensuring that external partners can seamlessly integrate into the collaborative ecosystem.

22 Timely delivery of value

Factor 22, "Timely Delivery of Value," is positioned in the middle of the hierarchy. Its connection with "Training and Support Provided" underscores the influence that timely value delivery can have on sustaining end users. By ensuring that value is delivered promptly, organisations contribute to the satisfaction and sustained engagement of customers (Verhees, van Kuijk and Simonse, 2017; Denicolai and Previtali, 2020; Khatab and Yousef, 2021). Furthermore, the link between "Timely Delivery of Value" and "Organisational Culture" emphasises the transitive influence on positively shaping the organisational culture. Timely delivery of value fosters a culture of efficiency, responsiveness, and customer-centricity. As value is delivered in a timely manner, it positively influences the overall organisational culture, contributing to a work environment that values timeliness, innovation, and customer satisfaction (Khatab and Yousef, 2021).

23 Implementing awareness initiatives

Factor 23, "Implementing Awareness Initiatives," is situated at the topmost of the TISM hierarchy, signifying its critical role as a factor with the highest dependence power within the healthcare technology BM. This factor may have limited driving power individually but is indispensable to the overall functioning of the BM. As a factor with high dependence power, it acts as a catalyst, drawing upon the strengths and attributes of lower-level factors to effectively implement initiatives aimed at raising awareness within the target audience. It holds particular significance within the context of an innovative diagnostic technology BM. In the ever-evolving landscape of healthcare technology, where advancements occur rapidly, creating awareness is pivotal for the successful integration and adoption of innovative diagnostic solutions (Denicolai and Previtali, 2020). The effectiveness of this factor lies in its ability to orchestrate targeted initiatives that reach diverse stakeholders, including healthcare professionals, end-users, and potential investors (Ward *et al.*, 2017; Thiebes *et al.*, 2020). This may involve educational campaigns, workshops, seminars, and collaborations with healthcare institutions to showcase the technology's capabilities and advantages.

24 Cultivating health champions for technology adoption

Factor 24, "Cultivating Health Champions for Technology Adoption," occupies a foundational position at the lowest level of the TISM hierarchy, signifying its pivotal role as a core driver in the BM. In the context of innovative diagnostic technology, cultivating health champions involves identifying and nurturing individuals or entities who passionately endorse and support the adoption of cutting-edge technologies in healthcare (Bhattacharya, Wainwright and Whalley, 2021; Oderanti *et al.*, 2021; Palas and Bunduchi, 2021). These champions could be influential healthcare professionals, opinion leaders, patient advocates, or organisations committed to advancing healthcare through technological innovations.

One of the primary impacts of this factor is seen in the dimension of "Technological Innovativeness." Health champions play a pivotal role in fostering a culture that values and embraces technological advancements. By actively promoting the adoption of innovative diagnostic technologies, they contribute to the continuous evolution and improvement of technological solutions within the healthcare domain (Denicolai and Previtali, 2020).

Furthermore, "Cultivating Health Champions for Technology Adoption" directly impacts the identification of the target market based on health focus. By tailoring the health focus according to the insights and advocacy of these champions, the BM can align its offerings with the specific needs and priorities of the healthcare market, ensuring a more precise and effective market strategy.

In the dimensions of "Enabling Early Detection" and "Ensuring Ease of Use," this factor becomes a driving force. Health champions, by actively promoting and advocating for technologies that enable early detection and ensure ease of use, drive the adoption of these features within the healthcare ecosystem (Hofmann *et al.*, 2020). Moreover, the influence of health champions extends to "Maintaining Cost-Effectiveness." Through their advocacy efforts, champions can influence the perception and acceptance of cost-effective solutions, aligning with the overarching goal of

ensuring economic viability in healthcare technology adoption (Lee, Park and Lee, 2019; Korsgaard, Hasenkam and Vesterby, 2021; Vimarlund, Nikula and Nøhr, 2021).

25 Outsourcing value creation

Factor 25, "Outsourcing Value Creation," occupies an intermediate position in the TISM hierarchy. In the context of the healthcare technology landscape, where rapid advancements and specialised knowledge are paramount, outsourcing becomes a strategic imperative for businesses aiming to stay at the forefront of innovation. Thus, outsourcing value creation involves leveraging external resources, expertise, and collaborations to optimise various facets of the BM. This strategic approach allows the business to tap into specialised knowledge, skills, and technologies that may not be available in-house, fostering innovation and efficiency.

Its relationship with "Driving Adoption of Innovation" is symbiotic. By outsourcing certain aspects of value creation, the business can enhance its overall value offering. External partnerships may bring in novel ideas, technologies, and perspectives that contribute to the development and adoption of innovative diagnostic solutions. Furthermore, outsourcing value creation influences "Promoting Knowledge Exchanges." Collaborating with external partners fosters an environment where knowledge is exchanged between entities. This exchange of insights, expertise, and information contributes to the continuous improvement and adaptation of the business model, promoting a dynamic and informed approach to value creation.

The impact of outsourcing extends to "R&D for Sustaining Innovations." By outsourcing specific research and development activities, the business can optimise its operations. External collaborations may provide cost-effective solutions, accelerate the pace of innovation, and ensure that the business remains agile in responding to evolving technological landscapes.

26 Sustaining the value ecosystem

Factor 26, "Sustaining the Value Ecosystem," assumes a top level in the TISM hierarchy, signifying its crucial dependence on the cumulative contributions of all lower-level factors. The concept of the value ecosystem encompasses a dynamic network of stakeholders, resources, and processes (Fürstenau *et al.*, 2021; Korsgaard, Hasenkam and Vesterby, 2021; Lehoux *et al.*, 2021). Sustaining this ecosystem becomes paramount for BM success. Its relationship to "Providing a Platform for Collaboration" highlights the integral role of fostering meaningful collaboration that goes beyond individual transactions. By providing a conducive platform for stakeholders to engage, share insights, and work cohesively, the business ensures a sustainable ecosystem that can adapt to changing market dynamics (Bhattacharya, Wainwright and Whalley, 2021; Palas and Bunduchi, 2021; Schiavone *et al.*, 2021). Moreover, the connection between sustaining the value ecosystem and "Promoting Knowledge Exchanges" highlights the factor's role in enhancing the intellectual capital of the business. Actively promoting knowledge exchanges ensures that the value network remains vibrant and responsive to emerging trends and industry developments (Fürstenau *et al.*, 2021; Lehoux *et al.*, 2021; Nigam, Mbarek and Boughanmi, 2021; Palas and Bunduchi, 2021; Schiavone *et al.*, 2021).

27 Securing team expertise

Factor 27, "Securing Team Expertise," stands as a foundational element in the innovative diagnostic technology BM, embodying the critical importance of a knowledgeable and skilled team to drive success (Khatab and Yousef, 2021). Situated at the lowest level of the TISM hierarchy, this factor represents one of the core drivers that shape the entire BM. It underscores the significance of assembling a team with the right expertise, knowledge, and skills to navigate the complexities inherent in the innovative diagnostic technology landscape (Khatab and Yousef, 2021).

Its connection is with the factor "Ensuring Ease of Use" means that by securing a team with the requisite expertise, the business is poised to enhance the value offering of its products and services. A skilled team can contribute to the development of user-friendly solutions, improving the overall customer experience. The influence of securing team expertise extends to the "Onboarding of Customers." A knowledgeable team is better equipped to facilitate effective onboarding processes, leading to increased customer retention. The expertise of the team plays a pivotal role in guiding and supporting customers through the initial stages of engagement, fostering long-term relationships (Chen, Liu and Hu, 2020; Denoo, Yli-Renko and Clarysse, 2021). Moreover, securing team expertise contributes to the "Timely Delivery of Value." A skilled team can optimise operations, ensuring that the delivery of value, whether in the form of products or services, is conducted efficiently and within expected timelines. In the realm of securing support from investors, securing team expertise becomes a critical factor. A team with a high level of expertise enhances the value delivery of the business, instilling confidence and trust among investors (Nigam, Mbarek and Boughanmi, 2021). This, in turn, fortifies the business's overall capability to attract and retain financial support.

28 Organisational culture

Factor 28, "Organisational Culture," occupies an intermediate position in the TISM hierarchy, representing a critical element that is influenced by lower-level factors while, in turn, exerting influence on higher-level aspects of the innovative diagnostic technology BM. The relationship between organisational culture and "Providing Training Support (Internal)" is symbiotic. The prevailing culture within an organisation significantly influences its approach to internal training. A positive and supportive culture fosters a learning environment where employees are encouraged to acquire new skills, contributing to the effectiveness of internal training initiatives. The alignment of organisational culture with training practices ensures that the workforce remains adaptable and

well-prepared to navigate the complexities of the diagnostic technology landscape. (Khatab and Yousef, 2021). In the context of "Timely Delivery of Value," organisational culture plays a pivotal role. A supportive culture contributes to the efficient and timely delivery of value. When an organisation nurtures a culture that values efficiency, collaboration, and a commitment to meeting customer needs, it positively impacts the overall ability to deliver value in a timely manner.

29 Protecting intellectual property

Factor 29, "Protecting Intellectual Property," stands as a foundational pillar, being positioned at the lowest level of the TISM hierarchy in shaping the landscape of the innovative diagnostic technology BM. The role of protecting intellectual property cannot be overstated in an industry driven by innovation and technological advancements (Tao and Yu, 2019; Nigam, Mbarek and Boughanmi, 2021). This factor encompasses strategies and measures to safeguard the unique ideas, inventions, and creations that contribute to the competitive advantage of the BM. By securing intellectual property rights, organisations operating in the healthcare technology sector can fortify their position in the market and ensure the longevity of their innovations. The relationship between protecting intellectual property and "Funding Capacity" underscores its critical role in enhancing funding success. Investors and funding agencies are more likely to support ventures that have robust intellectual property protection in place, as this safeguards their investments and encourages innovation (Lee, Park and Lee, 2019; Khatab and Yousef, 2021). The connection with "Identified Market Based on Health Focus" reflects the broader impact of intellectual property protection in identifying and capitalising on growth opportunities within specific health-focused markets.

30 Funding capacity

Factor 30, "Funding Capacity," assumes a pivotal role as one of the foundational elements shaping the innovative diagnostic technology BM being positioned at the lowest level of the TISM hierarchy. The significance of funding capacity in the healthcare technology sector cannot be overstated. This factor encompasses the financial resources and investment capabilities that organisations can leverage to drive innovation, research, and development initiatives. In an industry characterised by rapid advancements and the need for cutting-edge solutions, adequate funding capacity serves as the lifeblood that sustains the growth and evolution of the BM.

The relationships established with other factors further underscore the critical role of funding capacity in influencing other factors. Its impact on "Identified Market Based on Health Focus" reflects the strategic allocation of resources to strengthen investments in specific target segments, aligning the BM with the unique needs of identified markets (Lee, Park and Lee, 2019; Oderanti *et al.*, 2021; Vimarlund, Nikula and Nøhr, 2021). The connection with "Protecting Intellectual Property" emphasises the role of funding capacity in sustaining intellectual property (IP) through the implementation of robust IP protection measures. This is crucial for preserving the competitive edge of innovative solutions. Furthermore, the transitive relationship with "Satisfying Customer Requirement" highlights how funding capacity contributes to enhancing customer satisfaction by providing the necessary resources to meet and exceed customer expectations (Malm, Pikkarainen and Hyrkäs, 2020; Sibalija *et al.*, 2021).

31 Adaptive revenue stream

Factor 31, "Adaptive Revenue Stream," is at the top of the TISM hierarchy, positioned as a factor with the highest dependence power. It relies on the contributions and characteristics of all the lower-level factors to achieve its objectives. In the context of healthcare technology, the Adaptive Revenue Stream represents the capacity to dynamically adjust and diversify revenue sources. This adaptability is crucial for navigating the intricacies of the healthcare industry, which is characterised by evolving market conditions, technological advancements, and changing customer needs. The top-down influence of Factor 31 on the entire BM reflects its overarching impact on financial sustainability, innovation, and collaboration. Its influence on "Providing a Platform for Collaboration" highlights how diverse revenue streams can provide essential support for collaborative platforms. Thus, contributing to the financial resources needed to facilitate effective collaboration, fostering an environment conducive to innovation and value creation (Khuntia, Mithas and Agarwal, 2017; Nikou and Bouwman, 2017).

Similarly, the connection with "Promoting Knowledge Exchanges" underscores the role of adaptive revenue strategies in investing in knowledge-sharing initiatives. This relationship recognizes that a dynamic revenue stream provides the financial foundation to support initiatives that promote the exchange of valuable knowledge within the healthcare technology ecosystem (Nikou and Bouwman, 2017).

32 Investor support

Factor 32, "Investor Support," stands as a foundational element at the lowest level of the TISM hierarchy, embodying one of the core drivers of the innovative diagnostic technology BM. The high driving power of investor support is rooted in its pivotal role in providing the financial backing essential for initiating and sustaining various facets of the BM (Terra, Rodrigues and Maia, 2019; Kelley *et al.*, 2020; Nigam, Mbarek and Boughanmi, 2021). The relationship between investor support and ensuring ease of use underscores the vital connection between financial backing and the enhancement of the value offering. Investors, by supporting initiatives related to user-friendly design and functionality, contribute significantly to the overall appeal and competitiveness of the diagnostic technology, thus fortifying the BM's value proposition.

Similarly, investor support's influence on satisfying customer requirements highlights its transitive role in investing resources to meet and exceed customer needs. This financial backing enables the development and delivery of solutions that align closely with customer expectations, fostering a positive customer experience and satisfaction (Verhees, van Kuijk and Simonse, 2017; Tao and Yu,

2019; Denicolai and Previtali, 2020; Nigam, Mbarek and Boughanmi, 2021). Furthermore, the connection between investor support and cultivating health champions for technology adoption illustrates how financial backing plays a crucial role in enhancing market adoption (Kelley *et al.*, 2020). Investors contribute to initiatives that promote the adoption of technology by key stakeholders, fostering a supportive environment for widespread acceptance and use.

Lastly, the positive influence of investor support on securing team expertise accentuates its role in sustaining a skilled and proficient workforce. Financial backing facilitates the recruitment, training, and retention of talented individuals, contributing to the development and maintenance of the expertise required for the effective functioning of the BM.

33 Managing costs

Factor 33, "Managing Costs," is at the lowest level of the TISM hierarchy, integral to the core drivers that shape the entire BM. The strategic management of costs is pivotal in ensuring the model's sustainability, efficiency, and overall success (García-Holgado, Marcos-Pablos and García-Peñalvo, 2019; Nguyen Dang Tuan, Nguyen Thanh and Le Tuan, 2019; Bhattacharya, Wainwright and Whalley, 2021; Nigam, Mbarek and Boughanmi, 2021; Palas and Bunduchi, 2021; Vimarlund, Nikula and Nøhr, 2021; Chen, 2022). The relationship between managing costs and navigating economic and political considerations highlights its transitive impact on positioning the BM in a stronger stance during economic and political discussions. By effectively managing costs, the BM can navigate the intricate landscape of economic and political factors with resilience and adaptability, ensuring its relevance and success in diverse contexts (Khatab and Yousef, 2021; Palas and Bunduchi, 2021; Vimarlund, Nikula and Nøhr, 2021).

Similarly, managing costs plays a crucial role in satisfying customer requirements, as it enables businesses to allocate resources efficiently to meet and exceed customer expectations (Nguyen Dang Tuan, Nguyen Thanh and Le Tuan, 2019). The ability to manage costs effectively contributes to the enhancement of the overall customer experience, ensuring that the diagnostic technology aligns closely with the evolving needs of its user base. The relationship with satisfied regulatory clearance emphasises the transitive role of managing costs in investing strategically in compliance measures (Rose, Jiang and Mangematin, 2017). Efficient cost management allows for the allocation of resources to ensure that the business model complies with regulatory standards, facilitating a smoother and more expedited clearance process. Furthermore, the influence of managing costs on funding capacity underscores its role in enhancing return on investment (ROI). By optimally managing costs, the BM can increase its financial capacity, attracting more significant investments and generating higher returns, thereby contributing to the model's sustained growth and development (Bhattacharya, Wainwright and Whalley, 2021; Nigam, Mbarek and Boughanmi, 2021; Palas and Bunduchi, 2021).

34 Promoting knowledge exchanges

Factor 34, "Promoting Knowledge Exchanges," is at the top of the TISM hierarchy, exemplifying its role as a high-dependence power factor. While it may not wield significant driving power independently, its influence permeates throughout the entire innovative diagnostic technology BM. At its core, promoting knowledge exchanges is essential for fostering a sustainable and dynamic value ecosystem (Fürstenau *et al.*, 2021; Lehoux *et al.*, 2021; Schiavone *et al.*, 2021; Vimarlund, Nikula and Nøhr, 2021; Viswanadham, 2021). The exchange of knowledge not only enriches the BM's intellectual capital but also contributes to the creation and capture of value within the business ecosystem. Moreover, the influence of this factor extends to the revenue dimension, enhancing the adaptability of revenue streams. By promoting knowledge exchanges, the model can identify and capitalise on new opportunities, thus contributing to the generation of diverse and adaptive revenue streams. This adaptability is fundamental for navigating the evolving landscape of healthcare technologies.

In terms of collaboration, promoting knowledge exchanges plays a transformative role. It directly influences and improves the platforms that facilitate collaboration among stakeholders. A rich exchange of knowledge ensures that collaborative efforts are informed, innovative, and aligned with the strategic goals of the BM.

6.4 MICMAC discussion

This section will discuss the results of the MICMAC analysis, its diagram is found in Figure 5.4.

6.4.1 Cluster I

This group, which are autonomous factors, revealed a notable finding that none of the factors in this study fell into this category. This result underscores the interconnectedness and interdependence of all identified BM factors. It means that each factor, regardless of its nature, possesses some degree of both driving and dependence power within the system. The absence of autonomous factors indicates a lack of elements that exert minimal influence on or are unaffected by other variables, highlighting the cohesive and integrated nature of the identified factors in shaping the innovative diagnostic technology BM (Ong *et al.*, 2022).

6.4.2 Cluster II

This group is characterised by dependence factors, encapsulates variables with strong dependence power but weak driving power. These factors are particularly sensitive to changes in influential variables and linkage factors, constituting the output of the system. In this study, seventeen BM factors populate this cluster, encompassing dimensions such as:

• Technological Innovativeness: While playing a crucial role in the BM's success, it depends on other factors for its effective development and adoption. It relies on the identification of a market based on health focus, satisfying customer requirements, and enabling early detection. The identified market provides a targeted context for innovation, customer satisfaction is a key metric for the success of technological advancements, and early detection sets the stage for innovative solutions in the healthcare technology landscape.

- Early Detection: This factor is dependent on factors such as maintaining cost-effectiveness, ensuring ease of use, and offering portability. Cost-effectiveness ensures accessibility, ease of use facilitates efficient early detection processes, and portability contributes to the seamless integration of early detection technologies into existing healthcare practices. While serving as an essential component, early detection is intricately dependent on the successful interplay of multiple factors shaping the overall BM.
- Cost-Effectiveness: This factor is critical to shaping the BM's cost structure, which is influenced by factors such as managing costs, regulatory approval, and customer satisfaction requirements. It plays a pivotal role in the overall model. Its driving power is evident, yet it relies on a symbiotic relationship with other factors for optimal implementation.
- Portability: As a factor in the innovative diagnostic technology BM, it is marked by its strong dependence on factors like providing training support (internal), satisfying regulatory clearance, and ensuring ease of use. Internal training support ensures stakeholders can effectively handle portable solutions, regulatory clearance validates the viability of portable technologies, and ease of use is crucial for seamless integration into healthcare workflows.
- Managing Collaborations: The effectiveness of managing collaborations within the BM is contingent on several key factors such as effective sales channels, earning trust of stakeholders, and providing a platform for collaboration. Sales channels contribute to collaborative opportunities, trust is fundamental for successful collaborations, and collaborative platforms are essential for effective management and coordination of collaborative efforts.

- Timely Delivery of Value: This is influenced by other factors like onboarding customers, organisational culture, and training and support provided. Onboarding customers efficiently contributes to the timely delivery of value, a supportive organisational culture facilitates streamlined processes, and effective training and support ensure that value is delivered in a timely manner.
- Culture and Values: Integral to the internal dynamics of the BM, exhibit a strong dependence on factors such as providing a platform for collaboration, internal training support, and organisational culture itself. Collaboration platforms foster a shared culture, internal training supports the development of a values-driven culture, and the existing organisational culture plays a significant role in shaping the overall culture and values of the BM.
- Internal Training Support: The impact of internal training support is intricately linked to factors such as providing a platform for collaboration, organisational culture, and ensuring ease of use. Collaboration platforms facilitate shared training resources, a supportive organisational culture encourages continuous learning, and ensuring ease of use ensures effective internal training and utilisation of technology.
- Training and Support Provided: The effectiveness of training and support provided to customers is closely intertwined with factors like driving adoption of innovation, outsourcing value creation, and providing a platform for collaboration. Driving adoption of innovation necessitates effective training, outsourcing value creation may involve training initiatives, and collaboration platforms enhance the delivery of training and support services.
- R&D for Sustaining Innovations: This exhibits a dependence on factors like adoption of innovation, outsourcing value creation, and promoting knowledge exchanges. Innovations drive the need for continuous R&D, outsourcing contributes to specialised R&D capabilities, and knowledge exchanges provide insights for sustained innovative practices.

- Adoption of Innovation: The adoption of innovation is intricately linked to factors such as effective sales channels, satisfying customer requirements, and technological innovativeness. For instance, the availability of efficient sales channels ensures that innovative products or services reach the market effectively. Similarly, meeting customer requirements is crucial for the successful adoption of innovative solutions. The technological innovativeness factor plays a pivotal role as it sets the stage for the development and implementation of novel ideas.
- Outsourcing Value Creation: This relies on factors like driving adoption of innovation, promoting knowledge exchanges, and sustaining the value ecosystem. When adopting innovation is a driving force, outsourcing becomes a strategic approach to enhance value. Knowledge exchanges contribute to the optimization of outsourced processes, and sustaining the value ecosystem ensures a conducive environment for effective value creation through outsourcing.
- Sustaining Value Ecosystem: This depends on various factors within the BM such as
 outsourcing value creation, adaptive revenue stream, and promoting knowledge exchanges
 are crucial components. Outsourcing contributes to the diversity and efficiency of the
 ecosystem, adaptive revenue stream ensures financial support for sustainability, and
 knowledge exchanges facilitate the continuous improvement and adaptation of the value
 ecosystem.
- Adaptive Revenue Stream: The adaptive revenue stream, depends on factors like providing a
 platform for collaboration, promoting knowledge exchanges, and sustaining the value
 ecosystem. A diverse revenue stream is achievable through effective collaboration
 platforms, shared knowledge, and a sustainable value ecosystem. The driving power of
 adaptive revenue is limited, underlining its reliance on a cooperative relationship with other
 influential factors.

- Knowledge Exchanges: Knowledge exchanges within the BM are dependent on factors like sustaining the value ecosystem, adaptive revenue stream, and providing a platform for collaboration. Sustaining the value ecosystem enhances meaningful knowledge exchanges, while the adaptive revenue stream supports investments in knowledge-sharing initiatives. Providing a platform for collaboration facilitates the exchange of insights and expertise, emphasising the interconnected nature of these factors.
- Platform for Collaboration: Providing a platform for collaboration depends on factors like knowledge exchanges, sustaining the value ecosystem, and promoting awareness initiatives. Knowledge exchanges contribute to the content and expertise shared on the collaboration platform, while a sustainable value ecosystem provides a conducive environment for collaborative efforts. Promoting awareness initiatives ensures that the collaboration platform is effectively utilised and engaged with.
- Awareness Initiatives: This depends on factors like providing a platform for collaboration, promoting knowledge exchanges, and sustaining the value ecosystem. The effectiveness of awareness initiatives is heightened when supported by collaborative efforts, shared knowledge, and a sustainable value ecosystem. These factors collectively shape the success and impact of awareness initiatives within the comprehensive BM.

The factors in this cluster illustrate their strong dependence on other factors within the BM. While each factor contributes to the overall design, they are particularly sensitive to changes in influential variables and linkage factors. This cluster mirrors the top levels in the TISM model, highlighting their dependence on other BM factors that collectively influence the overall design and functionality of the innovative diagnostic technology BM.

6.4.3 Cluster III

MICMAC analysis did not identify any factors falling into Cluster III, which represents linkage factors with strong driving and dependence power. This absence suggests that the identified BM factors in the study operate more independently or lack a significant driving force with a simultaneous need for external dependence.

6.4.4 Cluster IV

The factors identified in Cluster IV, classified as independent/driving factors, have been recognised for their pivotal role in steering and influencing the overall dynamics of the innovative diagnostic technology BM. This comprises a substantial set of seventeen BM factors, discussing each factor in detail:

- Meeting the Needs of the Current Standard of Care: This factor directly addresses the core requirements of the current healthcare standards, ensuring that the diagnostic products and services align seamlessly with established norms. It has a strong driving force in shaping the BM by meeting fundamental healthcare expectations.
- Economic and Political Considerations: These are key drivers influencing the strategic positioning and decision-making within the healthcare landscape. These factors significantly guide the BM to navigate complex economic and political landscapes.
- Regulatory Approval: Regulatory approval is a fundamental aspect of healthcare technology adoption. Its inclusion in Cluster IV signifies its driving force in shaping the BM, ensuring compliance and authorisation for innovative solutions.
- Effective Sales Channels: Establishing efficient sales channels is crucial for the successful distribution and adoption of healthcare technologies. This factor drives the design of the BM by ensuring an effective and streamlined approach to reaching end-users.

- Earning the Trust of Stakeholders: Trust is foundational in the healthcare industry. This factor, by earning the trust of stakeholders, becomes a driving force in influencing the overall perception and acceptance of the technology within the ecosystem.
- Clear Customer Needs: Understanding and meeting customer needs is a driving force for success. This factor ensures that the BM is aligned with the explicit requirements of end-users, enhancing satisfaction and adoption.
- Satisfied Regulatory Clearance: Similar to regulatory approval, ensuring ongoing regulatory clearance is a driving force. It maintains the compliance status, contributing to the overall success and sustainability of the BM.
- Managing Costs: Cost management is a critical driver influencing various aspects of the BM, from resource allocation to strategic decision-making. It ensures that the BM remains efficient and financially viable.
- Satisfying Customer Requirements: Beyond meeting basic needs, satisfying customer requirements involves exceeding expectations, contributing significantly to customer retention and the overall success of the BM.
- Onboarding Customers: The onboarding process is a key driver in integrating customers into the healthcare technology ecosystem. It shapes the initial user experience, influencing long-term adoption and success.
- Team Expertise: The expertise of the internal team is a driving force for innovation and effective implementation. This factor ensures that the BM is developed and executed by a skilled and knowledgeable team.

These explanations demonstrate that the factors in Cluster IV exert a substantial influence on diverse dimensions of the innovative diagnostic technology BM. Their driving power is crucial for steering the system, making them integral elements in the overall design and success of the BM.

6.5 BM factor prioritisation

In the bottom half of Figure. 6.1, the BM factors identified and validated through the empirical findings in the first phase were ranked based on the TISM and MICMAC analysis. This has been incorporated in the BM value circle as visualised if in a high, medium or low priority. Earlier work derived the success factors of medical device start-ups through an AHP analysis (Lee, Park and Lee, 2019). They have ranked their factors based on subcategories which is equivalent to the BM factors in this study. In this study, eight factors were ranked with the highest priority: F1 Meeting the needs of current standard of care, F2 Navigating economic and political considerations, F10 Securing regulatory approval, F16 Establishing effective distribution channels, F17 Earning the trust of stakeholders, F19 Having clear customer needs, F20 Satisfied regulatory clearance, and F33 Managing costs. In the study of Lee et al. 2019, in the subcategory of funds which is with the revenue component, were initial capital, funding capacity, available funds and revenue growth potential.

Nine factors are plotted in the middle priority: F11 Satisfying customer requirements, F15 Onboarding of customers, F27 Securing team expertise, F29 Protecting intellectual property, F30 Funding capacity, F32 Investors support, F4 Identified market based on health focus, F6 Ensuring ease of use, F24 Cultivating health champions for technology adoption.

Finally, the seventeen factors were placed in the lowest priority. F3 Fostering technological innovation, F5 Enabling early detection, F7 Maintaining cost-effectiveness, F9 Offering portability, F12 Effectively managing collaborations, F22 Timely delivery of value, F28 Organisational culture, F13 Training support (internal), F21 Training and support provided, F14 R&D for sustaining innovations, F18 Driving adoption of innovation, F25 Outsourcing value creation, F26 Sustaining the value ecosystem, F31 Adaptive revenue stream, F34 Promoting knowledge exchanges, F8

Providing a platform for collaboration, F23 Implementing awareness initiatives. These factors are considered dependent because they exhibit strong dependence power and weak driving power in the empirical findings. This means that while they rely heavily on other elements in the system for improvement, they have limited influence on other elements. Placing them in the lowest priority acknowledges their sensitivity to changes in influential variables and linkage factors, reflecting their role as outputs of the system and their dependence on other BM factors.

6.4 Summary

This chapter discussed in-depth how far the literature aligns and deviates with the empirical findings of the current study. Also demonstrated how the conceptual framework is refined across different research phases, including the conceptual phase, empirical phase one, and empirical phase two. The inclusion of factors in the refined BM reflects the growing real-world importance of addressing these factors to ensure the viability and sustainability of healthcare technology BMs. The findings of the TISM analysis offer valuable insights into the complex dynamics and interrelationships among BM factors while the MICMAC analysis results describe the driving power and dependence characteristics of the identified BM factors. The absence of autonomous and linkage factors suggests a dynamic but more self-contained system, while the prevalence of dependence and driving factors underscores the pivotal role of specific elements in shaping the innovative diagnostic technology BM. Finally, the prioritisation allows for a focused approach to addressing the factors with higher driving power over others. This targeted approach enables a more efficient allocation of resources, leading to improved decision-making and implementation.

Chapter 7 Conclusion and Future Direction

7.1 Introduction

The research aim of this study is to design an innovative BM founded on the concept of value co-creation and will seek to provide a holistic view of the healthcare technology value chain. This chapter describes conclusions across all stages of the project. In other words, it shows how three research questions were answered through conducting empirical research phase one, empirical research phase two, and how the research gaps in existing knowledge were addressed through the key contributions of this study, facilitated by the adoption of a suitable research methodology. Additionally, the chapter discusses the theoretical contributions and managerial implications of the findings, underscores the limitations of the study, and proposes potential avenues for future research.

7.2 Conclusion across all project stages

The overall aim of the study is to design an innovative BM founded on the concept of value co-creation and will seek to provide a holistic view of the healthcare technology value chain. To effectively illustrate how the research questions were addressed and how research gaps were filled through various research activities, it is essential to present a holistic picture. Figure 7.1 provides a visual representation of conclusions across all research phases, outlining key research activities.

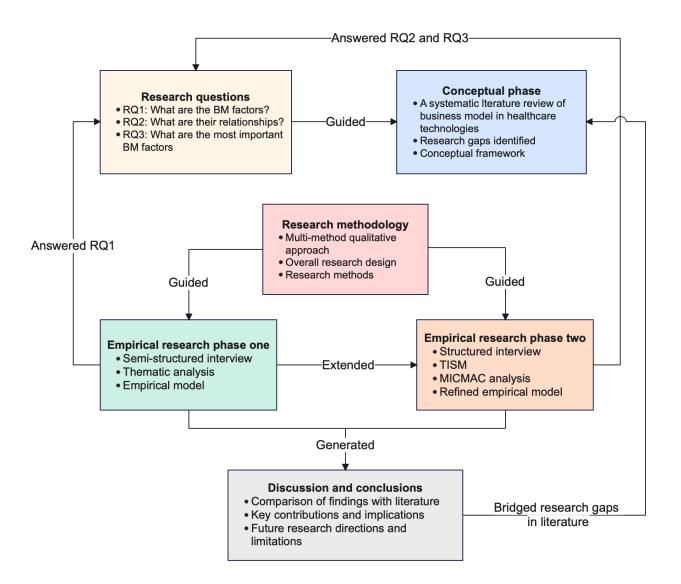


Figure 7.1 Conclusions across all project stages

This study has three research questions, as presented in the introduction chapter, they are:

RQ1: What are the components and factors of a BM that exist in healthcare diagnostic

technologies?

RQ2: What are the relationships that exist among the BM factors?

RQ3: What are the most important factors in designing a BM for healthcare diagnostic technologies?

In the beginning of this PhD research, the conceptual BM (see Figure 2.9) was built based on the systematic literature review (SLR) on BM in healthcare technologies. The use of SLR was effective to synthesise existing knowledge, particularly in identifying the important factors and gaps shaping BM design within healthcare technology contexts. Moreover, the transparency and rigour of SLR methodology enabled an evidence-based protocol to systematically evaluate and compare findings from multiple studies. The development of the conceptual model contributes to answering RQ1, which then serves as a foundation for the empirical phase of the study.

The phase one of the empirical study resolves RQ1 by exploring the four BM dimensions (namely, value offering, value delivery, value network, and value capture) in the conceptual BM (Figure 2.9). Semi-structured interviews were conducted with 30 experienced healthcare technology stakeholders, where thematic analysis was used to analyse the data. Based on the data analysis results, different factors and their categorisations for designing the BM dimensions were identified: value offering (see Table 4.4), value delivery (see Table 4.5), value network (see Table 4.6), and value capture (see Table 4.7). This is how research question one was answered through the study. The main outcome of phase one of the empirical study is the refined BM for healthcare technologies (see Figure 4.2).

Phase two of the empirical study answers RQ2 and RQ3. RQ2 focused on investigating the relationships among key BM factors, while RQ3 aimed to prioritise these factors. To achieve this, the Total Interpretive Structural Modeling (TISM) methodology was utilised to establish a hierarchical framework among various BM factors (see Figure 5.3). Additionally, the MICMAC analysis was applied to classify these factors into different categories. The research outcomes revealed that several factors, including F1 Meeting the needs of current standard of care, F2 Economic and political considerations, F10 Regulatory approval, F16 Effective sales channels, F17 Earning the trust of stakeholders, F19 Clear customer needs, F20 Satisfied regulatory clearance, and F33 Managing costs, were identified as critical for designing the BM for health tech. Based on these

empirical findings, a healthcare technology BM value circle (see Figure 5.5) was developed. This value circle integrates key BM factors and their categorisations within the BM. Consequently, phase two of the empirical study effectively addresses research questions two and three.

7.3 Contributions

In this thesis, a comprehensive approach was adopted to examine the development of BMs within the healthcare technology sector. The research process encompassed a thorough exploration of existing BMs, followed by empirical investigations that culminated in the formulation of the BM value circle. The theoretical contributions and managerial implications are described separately in the following subsections.

7.3.1 Theoretical contributions

The key findings of this study contribute to the existing body of knowledge significantly, listed as follows.

Firstly, a new BM framework has been developed taking consideration of the full value circle (refer to Figure 5.5). The model included all the four key BM dimensions (value offering, value delivery, value network and value capture), its components (Product/ service, Target segment, Value proposition, Key activities, Channel, Key partners, Key resources, Revenue, Cost, and Social value) and all the BM factors mapped according to priority in the outer layer. This study addressed the need for an effective framework tailored to guide the development of healthcare technologies (Gand, 2018; Denicolai and Previtali, 2020; Palas and Bunduchi, 2021; Ong et al., 2022). While the majority of the prior literature had widely used the Business Model Canvas (BMC), it had a broad applicability not fit towards the health sector. Thus, this study filled this gap by refining the model incorporating a network perspective into BM design. Further acknowledging

the interconnected nature of stakeholders in the healthcare technology ecosystem (Lehoux et al. 2021; Vimarlund et al. 2021; Viswanadham 2021). The healthcare technology BM value circle developed is a novel contribution in designing BMs for healthcare technologies.

Secondly, this research advances the theoretical understanding of healthcare BMs by ✨ identifying a total of thirty-four (34) BM factors. Specifically, utilising Systematic Literature Review (SLR) methodology to comprehensively review and synthesise existing literature on BMs in this field. Then empirical study to validate and identify further BM factors as shown in the refined BM (Figure 4.2), several factors are considered as new. In the value offering dimension, three factors are novel: 2 Navigating economic and political consideration, 5 Enabling early detection, and 9 Offering portability. The incorporation of BM factor 2 highlights the need to recognise and actively engage with the economic and political forces that shape innovation in healthcare technology. Factors 5 and 9 highlighted the need to not only prioritise early detection and portability in technology but also consider it as an integral part of the BM. Prior studies have identified market analysis skills, technology innovativeness, product's market size, ease of use, product competitiveness, and personalised platform as key factors in the value offering (Lee, Park and Lee, 2019; Pundziene, Heaton and Teece, 2019; Terra, Rodrigues and Maia, 2019; Oshaviani Annisya and Rochman, 2020; Nigam, Mbarek and Boughanmi, 2021; Palas and Bunduchi, 2021). This study also confirms that these factors are useful for designing BMs in the healthcare industry.

Nine new factors were discovered in the value delivery dimension: 10 Securing regulatory approval, 11 Satisfying customer requirement, 13 Providing training support (internal), 15 Onboarding of customers, 17 Earning trust of stakeholders, 18 Driving adoption of innovation, 20 Satisfied regulatory clearance, 21 Training and support

provided, and 23 Implementing awareness initiatives. These factors were discussed in literature but not explicitly integrated in the BM (Garmann-Johnsen and Eikebrokk, 2017; Nikou and Bouwman, 2017; Coan *et al.*, 2018; Laya, Markendahl and Lundberg, 2018; Al Thawadi *et al.*, 2019; Hofmann *et al.*, 2020; Kelley *et al.*, 2020). It underscores the importance of incorporating patient-centred care and solutions in this dimension.

Two new factors were found in the value network dimension: 24 Cultivating health champions for technology adoption and 26 Sustaining value ecosystems. In literature, the key partners component has only considered the network utilisation (Denicolai and Previtali, 2020; Palas and Bunduchi, 2021; Viswanadham, 2021). In the empirical findings, this factor has been elaborated to include cultivating champions within the healthcare community to foster advocacy and accelerate the adoption of innovative technologies and sustaining value ecosystems which are critical for long-term success, ensuring the continuous delivery of value to stakeholders.

In the value capture dimension, a factor has been updated to Factor 34 Promoting knowledge exchanges from social profit. This forms a more specific way of how the value created flows back to the organisation and how it is shared with other stakeholders (van Dijk-De Vries *et al.*, 2020; Lehoux *et al.*, 2021; Schiavone *et al.*, 2021). The remaining factors conforms with previous literature such as: Factor 31 Adaptive Revenue (Khuntia, Mithas and Agarwal, 2017; Vimarlund and Mettler, 2017), 32 Investor Support (Terra, Rodrigues and Maia, 2019; Kelley *et al.*, 2020; Nigam, Mbarek and Boughanmi, 2021) and 33 Managing costs (García-Holgado, Marcos-Pablos and García-Peñalvo, 2019; Bhattacharya, Wainwright and Whalley, 2021; Nigam, Mbarek and Boughanmi, 2021; Palas and Bunduchi, 2021; Chen, 2022)..

Third, a structural model for BM factors particularly in the context of healthcare technologies has been developed. Establishing relationships among the BM factors in the TISM hierarchy model where different levels of dependencies and types of links have been made. The relationships established among BM factors in the TISM hierarchy are crucial in comprehending the intricate web of dependencies. The model illuminates how factors at lower levels influence and shape those at higher levels, and vice versa. It further captures the essence of how various elements collaboratively contribute to the overall success of the BM.

Fourthly, the prioritisation of BM factors based on both driving power and dependence power makes a significant contribution to the existing literature, particularly within the context of the healthcare technology sector. Empirical findings identified the following factors with the highest priority: F1 Meeting the needs of current standard of care, F2 Navigating economic and political considerations, F10 Securing regulatory approval, F16 Establishing effective distribution channels, F17 Earning the trust of stakeholders, F19 Having clear customer needs, F20 Satisfied regulatory clearance, F33 Managing costs.

7.3.2 Managerial implications

BM is a vital concept for ensuring success of any organisation. The findings of this research have significant managerial implications for healthcare technology startups, investors, incubators, and biotech entrepreneurs These implications can help them navigate the complex landscape of healthcare BMs effectively, elaborated in the following:

• Strengthening startup BMs: For startup founders in the diagnostics healthcare industry, the identification of key BMs factors is invaluable. The BM value circle is flexible and provides strategies that can be used in part and in a forward (development) and backward (summative evaluation) process. Entrepreneurs can adapt this strategy to real-world constraints, including time, policies, and financial considerations. This knowledge equips

them to develop their BMs, thus enhancing their prospects for success in a highly competitive sector. It provides a structured approach to addressing critical factors that can impact their viability and sustainability.

- Interpreting the hierarchical structure: The hierarchical structure of driving and dependent enablers, as revealed through TISM and MICMAC, offers a unique lens for managerial decision-making. This study makes biotech entrepreneurs aware of the importance of the most influential BM factors (F1 Addresses needs in the current standard of care, F2 Economic and political context, F10 Regulatory approval, F16 Effective sales channel, F17 Earning trust of stakeholders, F19 Clear customer needs, F20 Satisfied regulatory clearance, and F33 Managing costs) for which they can give critical attention. This helps in resource allocation and strategy formulation.
- Awareness of influential factors: Furthermore, the categorisation of BM factors into autonomous, dependent, linkage, and independent variables offers clarity for biotech entrepreneurs. The classification of BM factors facilitates effective management across various departments and partners in the healthcare value chain. This perspective is vital for coordinating efforts, ensuring alignment, and managing the complex interplay of factors that impact the success of healthcare technologies.
- Investment decision-making: Investors in health-tech startups can leverage the identified BM factors as a valuable screening tool. By assessing startups based on these factors, investors can make more informed decisions about which ventures to support. This not only enhances the chances of selecting promising startups but also provides a degree of assurance regarding potential returns on investment.
- Support and mentorship by incubators: incubators, which play a pivotal role in nurturing startups, can utilise the BM factors as a guide for mentorship, training, and resource allocation. Understanding these factors enables incubators to tailor their support to address

the specific needs and challenges faced by health-tech startups. It aids in preparing startups to effectively enter and thrive in the healthcare market.

7.4 Limitations of the study

In the pursuit of academic inquiry, it's a well-established fact that no study, no matter how rigorous, is devoid of certain limitations and potential issues that might affect its validity. Especially in qualitative research, certain inherent limitations are associated such as inability to manipulate independent variables, the risk of misinterpretation, constraints related to randomisation and control, the complexities of deductibility, the challenges associated with ensuring repeatability, and limitations in terms of generalizability (Creswell and Poth, 2023; Marshall, Rossman and Blanco, 2023).

A limitation related to descriptive validity is that the study's findings may not be generalisable beyond the specific sample or population studied. While the study includes participants from Europe and Asia, there's a clear imbalance in the representation, with a majority of interviewees from Europe. This regional bias might affect the applicability of the findings to a more diverse global context. Additionally, Europe and Asia are culturally and regulatory distinct regions. The differences in regulatory frameworks, cultural norms, and business practices could influence the perspectives and experiences of the interviewees. While efforts were made to include participants from various backgrounds, industries, and regions, the sample may not fully represent the breadth and depth of the healthcare diagnostic technologies sector.

Furthermore, this study relied on cross-sectional data, which collected data from a specific group or population at a single point in time. Given the dynamic nature of the healthcare industry, BMs within this sector are subject to evolution and adaptation in the long run. Consequently, the confines of this cross-sectional approach may render the study susceptible to an incomplete representation of modifications and adjustments that will happen over the long term. This research primarily concentrated on the biotech industry within the healthcare diagnostic sector, potentially limiting the representation in other segments of the healthcare industry.

7.5 Recommendations for further research

As the present study, "New Business Models for Technology Innovation in Healthcare: A Value Network Perspective," has laid a foundation for exploring BMs in healthcare technology, it opens up various avenues for future research and development. This chapter outlines potential directions that can further enrich the understanding of BMs within the healthcare technology domain.

- Future studies should strive for a more balanced and diversified geographic sampling strategy. This involves deliberately including participants from regions that were underrepresented in the current study, ensuring a broader global perspective. Targeting regions with distinct regulatory and cultural contexts will contribute to a more comprehensive understanding of healthcare technology BMs.
- To build on the qualitative findings, future studies could employ quantitative methods to measure the effectiveness and impact of the identified BM value dimensions. Developing measurement tools or models would allow for a more rigorous evaluation of value co-creation within healthcare technology development.
- To track the evolution of innovative BMs in healthcare technology, long-term studies can be done to capture changes in BMs, stakeholder interactions, and value networks over time. Understanding the adaptability and sustainability of these models in a dynamic healthcare landscape is a critical research area.
- To foster a holistic understanding of value networks in healthcare technology, future research may encourage interdisciplinary collaboration between healthcare experts, technology innovators, and business scholars. This collaboration can help bridge the gap

between different domains, facilitating a more comprehensive exploration of value co-creation and innovative BMs.

Finally, exploring how the findings and recommendations from this study can be effectively disseminated and applied in healthcare technology management and education is crucial. Future directions may involve the development of workshops, training programs, or curricula for professionals and students interested in healthcare technology BMs.

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Appendix A: Business model definitions

Author/s	Year	Definition	1	2	3	4
Timmers, P.	1998	The business model is "an architecture of the product, service and information flows, including a description of the various business actors and their roles; a description of the potential benefits for the various business actors; a description of the sources of revenues" (p. 4)		~	~	~
Venkatraman & Henderson	1998	"An architecture along three dimensions: customer interaction, asset configuration and knowledge leverage."		~	2	
Selz	1999	"A business model is architecture for the firm's product, service and information flows. This includes a description of the various economic agents and their roles. A business model also describes the potential benefits for the various agents and provides a description of the potential revenue flows".			2	
Finnie	2000 "the major components of a business model [are] customer interface, core strategy, strategic resources, and value network. These basic components are linked by three, bridging components: customer benefits, configuration of activities, and company boundaries" (p. 10)		~	v	2	
Hamel, G.	2000 "A business model is simply a business concept that has been put into practice. A business concept has four major components: Core Strategy, Strategic Resources, Customer Interface and Value Network."		V		~	
Linder & Cantrell	2000	"The hypiness model is the organization's core logic		v		
Stewart, D. W. & Zhao, Q.	2000	"A business model is a statement of how a firm will make money and sustain its profit stream over time" (p. 290)				~
Amit, R. & Zott, C.	2001	"A business model depicts the content, structure, and governance of transactions designed so as to create value through the exploitation of business opportunities" (p. 511)		V		V
Petrovic et al.	A "business model describes the logic of a business system for creating value that lies behind the actual processes".			~		

Dimension: 1 Value offering, 2 Value delivery, 3 Value network, 4 Value capture

Author/s	Year	Definition		2	3	4
Weill & Vitale	2001	"A description of the roles and relationships among a firm's consumers, customers, allies and suppliers that identifies major flows of product, information and money and the major benefits to participants"		7	~	V
Chesbrough and Rosenbloom	2002	The business model is "the heuristic logic that connects technical potential with the realization of economic value" (p. 529)."The business model provides a coherent framework that takes technological characteristics and potentials as inputs and converts them through customers and markets into economic outputs" (p. 532).		2		2
Dubosson-To rbay, Osterwalder, and Pigneur	2002	"The architecture of a firm and its network of partners for creating, marketing, and delivering value and relationship capital to one or several segments of customers in order to generate profitable and sustainable revenue streams" (p. 7)		>	~	~
Hawkins	 2002 "In other words, a business model describes how an enterprise gears up its resources, planning capabilities and processes to the revenue producing potential of a specific product or service. By focusing in on this relationship to revenue producing potential, a new context is provided for assessing the planning and operational aspects of an enterprise, and for assessing the relationship between on-line and off-line trading environments" (p. 308) 			2		2
Knyphausen- Aufsess and Meinhardt	2002	A business model is a simplified representation of a profit aimed venture, consisting of its essential elements and their interconnections.				~
MagrettaEventeenes und them interconnections:Business models are "stories that explain how enterprises work. A good business model answers Peter Drucker's age old questions: Who is the customer? And what does the customer value? It also answers the fundamental questions every manager must ask: How do we make money in this business? What is the underlying economic logic that explains how we can deliver value to customers at an appropriate cost?".		V	2		~	
Afuah and Tucci	2003	Method by which a firm builds and uses its resources to offer its customers better value than its competitors and to make money while doing so. It details how a firm makes money now and how it plans to do so in the long term.		>		~
Mitchell and Coles	2004	Combination of 'who', 'what', 'where', 'when', 'why', 'how' and 'how much' an organisation uses	~	~		7

Author/s	Year	ear Definition		2	3	4
		to provide its goods and service and develop resources to continue its efforts				
Morris, M., Schindehutte, M., & Allen	2005	A business model is a "concise representation of how an interrelated set of decision variables in the areas of venture strategy, architecture, and economics are addressed to create sustainable competitive advantage in defined markets".				5
Osterwalder et al.	2005	A conceptual tool that contains a set of elements and their relationships and allows expressing the business logic of a specific firm. It is a description of the value a company offers to one or several segments of customers and the architecture of the firm and its network of partners for creating, marketing and delivering this value and relationship capital, to generate profitable and sustainable revenue stream".		~	2	~
Shafer, Smith and Linder	2005	"A representation of a firm's underlying core logic and strategic choices for creating and capturing value within a value network" (p. 202)			~	5
Barringer and Ireland	2006	"A firm's plan or diagram for how it competes, uses its resources, structure its relationships, interfaces with customers, and creates value to sustain itself on the basis of the profit its earns" (p. 100)		~	~	~
Chesbrough	"The business model is a useful framework to link ideas and technologies to economic outcomes." "It also has value in understanding how companies of all sizes can convert technological potential (e.g.		V			V
Bruce Rasmussen	Bruce 2007 The business model captures the key features of a business to inform a judgement (by investors, for example) on whether the business is likely to achieve financial and other objectives. It should answer a series of questions essential to any			V		V
Aziz, et al	2008	This literature refers to the concept of the business model as "the ways of creating value for customers, and the way in which a business turns market opportunities into profit through sets of actors,			~	V

Author/s	Author/s Year Definition		1	2	3	4
		activities, and collaboration" (Rajala and Westerlund, 2007).				
Johnson et al.	2008	Business models "consist of four interlocking elements, that, taken together, create and deliver value": customer value proposition, profit formula, key resources, and key processes.		>		\$
L. Applegate	2008	The business model defines how an organisation interacts with its environment to define a unique strategy, attract the resources and build capabilities required to execute the strategy and create value for all stakeholders.		\$		2
Morris, Schindehutte, Richardson and Allen	2008	"describe a company's unique value proposition (the business concept), how the firm uses its sustainable competitive advantage to perform better than its rivals over time (strategy), and whether, as well as how the firm can make money now and in the future (revenue model)				>
Mutaz M. Al-Debei Ramzi El- Haddadeh David Avison	2008	The business model is an abstract representation of an organisation, be it conceptual, textual and/or graphical, of all core interrelated architectural, co-operational and financial arrangements designed and developed by an organisation presently and in the future, as well as all core products and/or services the organisation offers, or will offer, based on these arrangements that are needed to achieve its strategic goals and objectives.		2	~	5
Skarzynski & Gibson	2008	"The business model is a conceptual framework for identifying how a company creates, delivers, and extracts value. It trainally includes a whole set of		2		2
Westerlund et. al.	2008 The business model of a firm spells out how the organisation generates revenue by specifying the nature of relationships with other actors as well as the firm's position in its value- creating network. The business model of a firm spells out how the organisation generates revenue by specifying the nature of relationships with other actors as well as the firm's position in its value- creating network.			2	~	۷
Florian Lüdeke- Freund	2009	A "business model for sustainability" is the blueprint of an organisation's business logic which internalises the business case for sustainability.				~

Author/s	Year	Definition		2	3	4
Baden-Fuller, Morgan	2010	A business model clearly describes the way a company creates and captures value				>
Casadesus-M asanell & Ricart	2010	"A business model is [] a reflection of the firm's realized strategy." A representation of a firm's underlying core logic and strategic choices for creating and capturing value within a value network.			2	2
Demil & Lecoq	2010	The way activities and resources are used to ensure sustainability and growth		5		>
Erwin Fielt	2010	A business model describes the value logic of an organisation in terms of how it creates and captures customer value.				2
Florian Lüdeke- Freund	ian eke- 2010 They have been defined as business models that create competitive advantage through superior customer value while contributing to sustainable		>			~
Gambardella & McGahan			7			~
Itami & Noshino	2010 business model is a profit model, a business delivery system and a learning system					
Ken Kaufman	2010	The business model is how the business makes money. It is the accumulation of sales, marketing, operations, administration, R&D, finance, strategies and tactics that determine if the organisation makes money or doesn't.		>		>
Michael Rappa	chael 2010 The business model is the method by which an organisation sustains itself that is, generates revenue. The business model discussion explains		2	2		2
Osterwalder and Pigneur 2010 Blueprint for a strategy to be implemented through organisation structures, processes and systems. A business model describes the rationale of how an organisation creates, delivers, and captures value.		2	2		>	
Теесе	2010 "A business model articulates the logic, the data and other evidence that support a value proposition for the customer, and a viable structure of revenues and costs for the enterprise delivering that value." //How a firm delivers value to customers and converts payment into profits		2	2		V
Williamson	2010	cost innovation business model offers advantages in radically new ways meaning more for less	~			

Author/s	Year	Definition	1	2	3	4
Yunus et al.	unus et al. 2010 "among the plethora of definitions [of business models], three elements are usually distinguished: the product/service proposed to customers, the way the company is organised so as to deliver this product and service to its customers, and the revenue model." (p. 311) A value system plus a value constellation		~	2		2
Zott, Amitt	"We conceptualize a firm's business model as a system of interdependent activities that transcends the focal firm and spans its boundaries. The activity system enables the firm, in concert with its partners, to create value and also to appropriate a share of that value [and is defined by] design elements - content, structure and governance - that describe the		V	~	~	~
Integrated Reporting	2011	the chosen system of inputs, business activities, outputs and outcomes that aims to create value over the short, medium and long term.		2		
Zott et al.	"the business model as a new unit of analysis, offering a systemic perspective on how to do business, encompassing boundary-spanning		~			2

Appendix B: Interview guide

Interview questions

Part 1: General questions:

a. Scope of your business/research. Tell me about your work in general.
 -Academe, Industry

-Country.

-How long have you been in this field?

-When did you start your position?

- b. Tell me about your role in general.
 -Researcher, professor, CEO, etc.
 -Projects involved in
- c. Can you tell me about your products/services/research?-What do you research in? Biomedical devices, software, training..?
- d. How is healthcare funded in your region? Can you explain it further?-Government? Insurance? Private
- e. What is your outlook on technological innovations for brain cancer diagnosis/ healthcare diagnostics in general?

Part 2: Business Model specific questions (brief intro about business model will be given):

- f. How would you define a successful business model? (e.g. sustainable, adopted by the stakeholders, efficiently operated and captures value)
- g. What factors need to be considered in developing a successful business model in the healthcare environment, particularly in brain cancer diagnostics? (e.g. innovation, ethics, regulation, stakeholders, value networks, etc.)
- h. Who are the key stakeholders in brain cancer diagnostics (e.g. diagnostic company, patient, academic researchers, oncologist, etc.)?
- i. What are the current challenges in developing the business model for healthcare diagnostic technologies? How do you solve these challenges?
- j. How do you ensure that the healthcare innovation is adopted by the stakeholders?
- k. What is/are the social value/s of the business model in the healthcare diagnostic environment?
- I. What is/are the economic value/s of the business model in the healthcare diagnostic environment?

Part 3: Validating the conceptual framework:

Value Proposition:

- m. How do you determine the nature of application the diagnostic technology?
- n. What value is offered in this healthcare innovation?

<u>Technology system:</u>

- o. What is the product/service?
- p. How is the innovation integrated in the healthcare setting?
- q. What is the data infrastructure of the technology system?

Customer Segments:

- r. Who are the main customers?
- s. How do you segment the customers in the healthcare industry?

Value Network:

- t. What values are exchanged within the business model in the healthcare setting?
- u. Who are the key stakeholders in the business model for brain cancer diagnostics?
- v. What are the key activities and interactions in the business model?
- w. How is the value delivered? What channels are used?

Financial aspects:

- x. What are the main costs (e.g. hardware, software, development, maintenance, consultancy, employees' training, business process re-engineering, organisational restructuring, etc.) associated with the technology system and the value network?
- y. How is the value captured in the business?

Appendix C: Consent form

CONSENT FORM

Title of research project:

Innovative business model addressing the full value circle for technology development in brain cancer diagnosis and healthcare

Name and position of researcher:

Aira Patrice Rueda Ong, PhD student, Graduate School, University of Plymouth

Please put an x box

	Yes	No
1. I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions.		
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason.		
3. I agree to take part in the study.		
4. I agree to the interview being audio recorded.		
5. I agree to the use of anonymised quotes in publications.		

Name of participant:	Date:	Signature:
Aira Patrice Rueda Ong (Researcher)		Signature:

Date of interview: _____

Place of Interview: _____

Appendix D: Interpretive Logic–Knowledge Base'

Bold	means	significant	link
Duiu	means	Significant	IIIII

Series no.	Element no.	Paired comparison of factors	Y/N	In what way a factor will influence/enhance the other factor? Give reason in brief
1	F1-F2	Meeting the needs of current standard of care will influence/enhance Navigating economic and political consideration	Y	Positive social and impact
2	F2-F1	Navigating economic and political consideration will influence/enhance Meeting the needs of current standard of care	Y	Receive support from both the public and policymakers
3	F1-F3	Meeting the needs of current standard of care will influence/enhance Technological innovativeness	Y	Sets foundation, encourages innovation
4	F3-F1	Technological innovativeness will influence/enhance Meeting the needs of current standard of care	N	
5	F1-F4	Meeting the needs of current standard of care will influence/enhance Identified market based on health focus	Y	Defines focus, guides market development
6	F4-F1	Identified market based on health focus will influence/enhance Meeting the needs of current standard of care	N	
7	F1-F5	Meeting the needs of current standard of care will influence/enhance Enabling early detection	Y	Enables timely diagnosis and intervention.
8	F5-F1	Enabling early detection will influence/enhance Meeting the needs of current standard of care	N	
9	F1-F6	Meeting the needs of current standard of care will influence/enhance Ensuring ease of use	Y	Ensures accessibility and adoption.
10	F6-F1	Ensuring ease of use will influence/enhance Meeting the needs of current standard of care	N	
11	F1-F7	Meeting the needs of current standard of care will influence/enhance Maintaining cost-effectiveness	Y	Makes healthcare sustainable and affordable.
12	F7-F1	Maintaining cost-effectiveness will influence/enhance Meeting the needs of current standard of care	N	
13	F1-F8	Meeting the needs of current standard of care will influence/enhance Providing a platform for collaboration	Y	Fosters continued collaboration for improvement.
14	F8-F1	Providing a platform for collaboration will influence/enhance Meeting the needs of current standard of care	N	
15	F1-F9	Meeting the needs of current standard of care will influence/enhance Offering portability	Y	Enables care across settings and devices.
16	F9-F1	Offering portability will influence/enhance Meeting the needs of current standard of care	N	
17	F1-F10	Meeting the needs of current standard of care will influence/enhance Securing regulatory approval	Y	Ensures compliance, aids market entry.
18	F10-F1	Securing regulatory approval will influence/enhance Meeting the needs of current standard of care	Y	Regulatory approval ensures meeting care standards.

19	F1-F11	Meeting the needs of current standard of care will influence/enhance Satisfying customer requirement	Y	Aligns with customer needs and trust.
20	F11-F1	Satisfying customer requirement will influence/enhance Meeting the needs of current standard of care	N	
21	F1-F12	Meeting the needs of current standard of care will influence/enhance Effectively managing collaborations	Y	Promotes effective teamwork and collaboration
22	F12-F1	Effectively managing collaborations will influence/enhance Meeting the needs of current standard of care	N	
23	F1-F13	Meeting the needs of current standard of care will influence/enhance Providing training support (internal)	Y	Equips employees for quality care.
24	F13-F1	Providing training support (internal) will influence/enhance Meeting the needs of current standard of care	N	
25	F1-F14	Meeting the needs of current standard of care will influence/enhance R&D for sustaining innovations	Y	Supports innovation for better outcomes.
26	F14-F1	R&D for sustaining innovations will influence/enhance Meeting the needs of current standard of care	N	
27	F1-F15	Meeting the needs of current standard of care will influence/enhance Onboarding of customers	Y	Ensures positive customer experience.
28	F15-F1	Onboarding of customers will influence/enhance Meeting the needs of current standard of care	N	
29	F1-F16	Meeting the needs of current standard of care will influence/enhance Establishing effective distribution channel	Y	transitive
30	F16-F1	Establishing effective distribution channel will influence/enhance Meeting the needs of current standard of care	Y	Effective sales channels ensure the delivery of the current standard of care.
31	F1-F17	Meeting the needs of current standard of care will influence/enhance Earning trust of stakeholders	Y	transitive
32	F17-F1	Earning trust of stakeholders will influence/enhance Meeting the needs of current standard of care	Y	transitive
33	F1-F18	Meeting the needs of current standard of care will influence/enhance Driving adoption of innovation	Y	transitive
34	F18-F1	Driving adoption of innovation will influence/enhance Meeting the needs of current standard of care	N	
35	F1-F19	Meeting the needs of current standard of care will influence/enhance Having clear customer needs	Y	Aligns products with patient needs.
36	F19-F1	Having clear customer needs will influence/enhance Meeting the needs of current standard of care	Y	Clear customer needs inform the standard of care.
37	F1-F20	Meeting the needs of current standard of care will influence/enhance Satisfied regulatory clearance	Y	transitive
38	F20-F1	Satisfied regulatory clearance will influence/enhance Meeting the needs of current standard of care	Y	transitive
39	F1-F21	Meeting the needs of current standard of care will influence/enhance Training and support provided	Y	Ensures comprehensive care delivery.

40	F21-F1	Training and support provided will influence/enhance Meeting the needs of current standard of care	N	
41	F1-F22	Meeting the needs of current standard of care will influence/enhance Timely delivery of value	Y	Provides value promptly to customers
42	F22-F1	Timely delivery of value will influence/enhance Meeting the needs of current standard of care	N	
43	F1-F23	Meeting the needs of current standard of care will influence/enhance Implementing awareness initiatives	Y	Educates stakeholders and patients.
44	F23-F1	Implementing awareness initiatives will influence/enhance Meeting the needs of current standard of care	N	
45	F1-F24	Meeting the needs of current standard of care will influence/enhance Cultivating health champions for technology adoption	Y	Drives technology adoption and advocacy.
46	F24-F1	Cultivating health champions for technology adoption will influence/enhance Meeting the needs of current standard of care	N	
47	F1-F25	Meeting the needs of current standard of care will influence/enhance Outsourcing value creation	Y	Leverages external expertise for value.
48	F25-F1	Outsourcing value creation will influence/enhance Meeting the needs of current standard of care	N	
49	F1-F26	Meeting the needs of current standard of care will influence/enhance Sustaining value ecosystem	Y	Supports an innovative ecosystem.
50	F26-F1	Sustaining value ecosystem will influence/enhance Meeting the needs of current standard of care	N	
51	F1-F27	Meeting the needs of current standard of care will influence/enhance Securing team expertise	Y	Maximises team skills and knowledge.
52	F27-F1	Securing team expertise will influence/enhance Meeting the needs of current standard of care	N	
53	F1-F28	Meeting the needs of current standard of care will influence/enhance Organisational culture	Y	Encourages a success-oriented culture for better health outcomes.
54	F28-F1	Organisational culture will influence/enhance Meeting the needs of current standard of care	N	
55	F1-F29	Meeting the needs of current standard of care will influence/enhance Protecting intellectual property	Y	transitive: secure competitive advantages
56	F29-F1	Protecting intellectual property will influence/enhance Meeting the needs of current standard of care	N	
57	F1-F30	Meeting the needs of current standard of care will influence/enhance Funding capacity	Y	Secures funding for innovation and growth.
58	F30-F1	Funding capacity will influence/enhance Meeting the needs of current standard of care	N	
59	F1-F31	Meeting the needs of current standard of care will influence/enhance Adaptive revenue stream	Y	Creates adaptable income sources
60	F31-F1	Adaptive revenue stream will influence/enhance Meeting the needs of current standard of care	N	
61	F1-F32	Meeting the needs of current standard of care will influence/enhance Investors support	Y	Attracts investor support for growth

62	F32-F1	Investors support will influence/enhance Meeting the needs of current standard of care	N	
63	F1-F33	Meeting the needs of current standard of care will influence/enhance Managing costs	Y	transitive
64	F33-F1	Managing costs will influence/enhance Meeting the needs of current standard of care	Y	Efficient cost management contributes to meeting care standards.
65	F1-F34	Meeting the needs of current standard of care will influence/enhance Promoting knowledge exchanges	Y	Facilitates continuous improvement in healthcare.
66	F34-F1	Promoting knowledge exchanges will influence/enhance Meeting the needs of current standard of care	N	
1111	F31-F32	Adaptive revenue stream will influence/enhance Investors support	N	
1112	F32-F31	Investors support will influence/enhance Adaptive revenue stream	Y	transitive
1113	F31-F33	Adaptive revenue stream will influence/enhance Managing costs	N	
1114	F33-F31	Managing costs will influence/enhance Adaptive revenue	37	Efficient cost management can aid in
		stream	Y	developing adaptive revenue streams.
1115	F31-F34	stream Adaptive revenue stream will influence/enhance Promoting knowledge exchanges	Y	invest in knowledge-sharing
1115 1116	F31-F34 F34-F31	Adaptive revenue stream will influence/enhance		
		Adaptive revenue stream will influence/enhance Promoting knowledge exchanges Promoting knowledge exchanges will	Y	invest in knowledge-sharing enhance revenue-generating
1116	F34-F31	Adaptive revenue stream will influence/enhance Promoting knowledge exchanges Promoting knowledge exchanges will influence/enhance Adaptive revenue stream	Y Y	invest in knowledge-sharing enhance revenue-generating
1116 1117	F34-F31 F32-F33	Adaptive revenue stream will influence/enhance Promoting knowledge exchanges Promoting knowledge exchanges will influence/enhance Adaptive revenue stream Investors support will influence/enhance Managing costs	Y Y N	invest in knowledge-sharing enhance revenue-generating opportunities Efficient cost management can contribute to garnering support from
1116 1117 1118	F34-F31 F32-F33 F33-F32	Adaptive revenue stream will influence/enhance Promoting knowledge exchanges Promoting knowledge exchanges will influence/enhance Adaptive revenue stream Investors support will influence/enhance Managing costs Managing costs will influence/enhance Investors support Investors support will influence/enhance Promoting	Y Y N Y	invest in knowledge-sharing enhance revenue-generating opportunities Efficient cost management can contribute to garnering support from investors. Investor backing encourages knowledge exchange for
1116 1117 1118 1119	F34-F31 F32-F33 F33-F32 F32-F34	Adaptive revenue stream will influence/enhance Promoting knowledge exchanges Promoting knowledge exchanges will influence/enhance Adaptive revenue stream Investors support will influence/enhance Managing costs Managing costs will influence/enhance Investors support Investors support will influence/enhance Promoting knowledge exchanges Promoting knowledge exchanges will influence/enhance	Y Y N Y Y	invest in knowledge-sharing enhance revenue-generating opportunities Efficient cost management can contribute to garnering support from investors. Investor backing encourages knowledge exchange for
1116 1117 1118 1119 1120	F34-F31 F32-F33 F33-F32 F32-F34 F34-F32	Adaptive revenue stream will influence/enhance Promoting knowledge exchanges Promoting knowledge exchanges will influence/enhance Adaptive revenue stream Investors support will influence/enhance Managing costs Managing costs will influence/enhance Investors support Investors support will influence/enhance Promoting knowledge exchanges Promoting knowledge exchanges Managing costs will influence/enhance Promoting knowledge exchanges Promoting knowledge exchanges will influence/enhance Investors support Managing costs will influence/enhance Promoting	Y Y N Y Y	invest in knowledge-sharing enhance revenue-generating opportunities Efficient cost management can contribute to garnering support from investors. Investor backing encourages knowledge exchange for improvement.

Note: this is the concise version of the Interpretive Logic-Knowledge Base'

Appendix E: Partitioning the final reachability matrix into different

levels (Iterations 1-11)

Factors	Reachability Set (RS)	Antecedent Set (AS)	Intersection set (RS ∩ AS)	Level
Iteration	1			
F1	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	
F2	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	
F3	3, 5, 7, 8, 9, 12, 13, 14, 18, 21, 22, 23, 25, 26, 28, 31, 34	1, 2, 3, 4, 5, 6, 7, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	3, 5, 7	
F4	3, 4, 5, 6, 7, 8, 9, 12, 13, 14, 18, 21, 22, 23, 24, 25, 26, 28, 31, 34	1, 2, 4, 6, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	4, 6, 24	
F5	3, 5, 7, 8, 9, 12, 13, 14, 18, 21, 22, 23, 25, 26, 28, 31, 34	1, 2, 3, 4, 5, 6, 7, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	3, 5, 7	
F6	3, 4, 5, 6, 7, 8, 9, 12, 13, 14, 18, 21, 22, 23, 24, 25, 26, 28, 31, 34	1, 2, 4, 6, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	4, 6, 24	
F7	3, 5, 7, 8, 9, 12, 13, 14, 18, 21, 22, 23, 25, 26, 28, 31, 34	1, 2, 3, 4, 5, 6, 7, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	3, 5, 7	
F8	8, 23	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	8	
F9	8, 9, 12, 13, 14, 18, 21, 22, 23, 25, 26, 28, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	9, 12	
F10	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	
F11	3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 18, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 34	1, 2, 10, 11, 15, 16, 17, 19, 20, 27, 29, 30, 32, 33	11, 15, 27, 29, 30, 32	
F12	8, 9, 12, 13, 14, 18, 21, 22, 23, 25, 26, 28, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	9, 12	
F13	8, 13, 14, 18, 21, 23, 25, 26, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 15, 16, 17, 19, 20, 21, 22, 24, 27, 28, 29, 30, 32, 33	13, 21	
F14	8, 14, 18, 23, 25, 26, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 24, 25, 27, 28, 29, 30, 32, 33	14, 18, 25	
F15	3, 4, 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 18, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 34	1, 2, 10, 11, 15, 16, 17, 19, 20, 27, 29, 30, 32, 33	11, 15, 27, 29, 30, 32	
F16	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27,	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	

	28, 29, 30, 31, 32, 33, 34			
F17	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	
F18	8, 14, 18, 23, 25, 26, 31, 34	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 24, 25, 27, 28, 29, 30, 32, 33	14, 18, 25	
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Iteration				
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Iteration 8

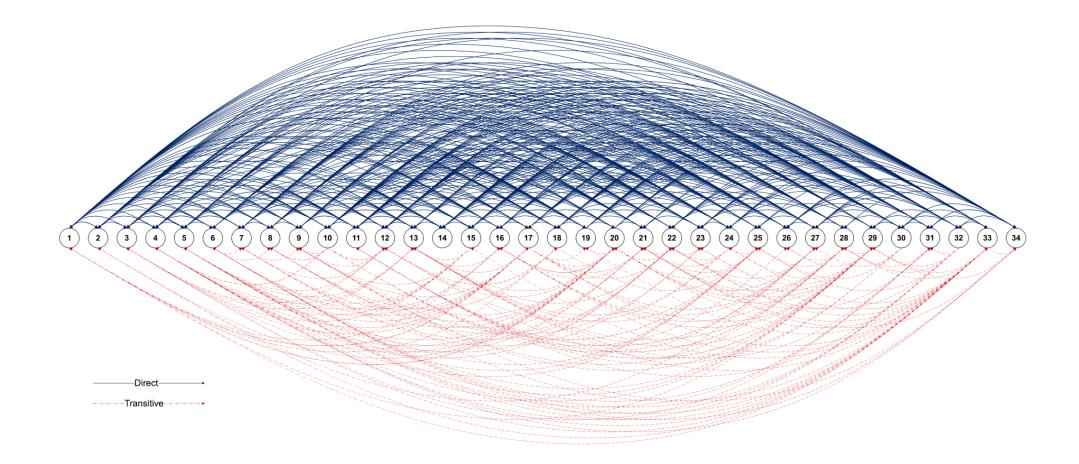
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F3	3, 5, 7	1, 2, 3, 4, 5, 6, 7, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	3, 5, 7	VIII
F4	3, 4, 5, 6, 7, 24	1, 2, 4, 6, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	4, 6, 24	
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F11	4, 6, 11, 15, 24, 27, 29, 30, 32	1, 2, 10, 11, 15, 16, 17, 19, 20, 27, 29, 30, 32, 33	11, 15, 27, 29, 30, 32	
F15	4, 6, 11, 15, 24, 27, 29, 30, 32	1, 2, 10, 11, 15, 16, 17, 19, 20, 27, 29, 30, 32, 33	11, 15, 27, 29, 30, 32	
F16	1, 2, 4, 6, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	
F17	1, 2, 4, 6, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	
F19	1, 2, 4, 6, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	
F20	1, 2, 4, 6, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	
F24	4, 6, 24	1, 2, 4, 6, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	4, 6, 24	IX
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F32	4, 6, 11, 15, 24, 27, 29, 30, 32	1, 2, 10, 11, 15, 16, 17, 19, 20, 27, 29, 30, 32, 33	11, 15, 27, 29, 30, 32	
F33	1, 2, 4, 6, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	
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F2	1, 2, 4, 6, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	
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F15	4, 6, 11, 15, 24, 27, 29, 30, 32	1, 2, 10, 11, 15, 16, 17, 19, 20, 27, 29, 30, 32, 33	11, 15, 27, 29, 30, 32	X
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F16	1, 2, 4, 6, 10, 11, 15, 16, 17, 19, 20, 24, 27, 29, 30, 32, 33	1, 2, 10, 16, 17, 19, 20, 33	1, 2, 10, 16, 17, 19, 20, 33	XI
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Appendix F: Initial diagraph based on final reachability matrix



Appendix G: List of abbreviations and factors in the TISM model

Level in TISM	Factor no.	Abbreviation	Factor Name
1	23	Awarnss	Implementing awareness initiatives
2	8	Collab	Providing a platform for collaboration
3	26	Sust Val Ecos	Sustaining the value ecosystem
3	31	Rev Stream	Adaptive revenue stream
3	34	Knowldg Exch	Promoting knowledge exchanges
4	14	Sust Innov	R&D for sustaining innovations
4	18	Drive Adopt	Driving adoption of innovation
4	25	Value Outsrc	Outsourcing value creation
5	13	Internal Train	Training support (internal)
5	21	Train Support	Training and support provided
6	22	Timely Deliv	Timely delivery of value
6	28	Org Culture	Organizational culture
7	9	Portability	Offering portability
7	12	Mng Collabs	Effectively managing collaborations
8	3	Tech Innov	Fostering technological innovation
8	5	Early Detect	Enabling early detection
8	7	Cost Effect	Maintaining cost-effectiveness
9	4	Health Focus	Identified market based on health focus
9	6	Ease of Use	Ensuring ease of use
9	24	Health Champs	Cultivating health champions for technology adoption
10	11	Cust Req	Satisfying customer requirements
10	15	Onboard Cust	Onboarding of customers
10	27	Team Expert	Securing team expertise
10	29	IP Protect	Protecting intellectual property
10	30	Fund Capacity	Funding capacity
10	32	Investor Supp	Investors support
11	1	Meeting Care	Meeting the needs of current standard of care
11	2	Eco Polit Nav	Navigating economic and political considerations
11	10	Reg Approval	Securing regulatory approval
11	16	Dist Channel	Establishing effective distribution channels
11	17	Trust Stake	Earning the trust of stakeholders
11	19	Cust Needs	Having clear customer needs

List of abbreviations and factors in the TISM model (sorted by their levels in TISM)

11	20	Reg Clear	Satisfied regulatory clearance
11	33	Cost Mgmt	Managing costs

Appendix H: TISM Model links explained

To further explain the 90 links between the BM factors as follows capturing insights from the structured interview data collection:

1. F1-F2: Meeting the needs of the current standard of care will influence/enhance Navigating economic and political considerations.

Positive Social and Economic Impact: "When we meet the current standard of care, it positively impacts our ability to navigate economic and political considerations. This is because achieving the standard can lead to increased support from both the public and policymakers, resulting in a positive social and economic impact."

2. F2-F1: Navigating economic and political considerations will influence/enhance Meeting the needs of the current standard of care.

Receive Support from Both the Public and Policymakers: Navigating economic and political considerations is crucial for receiving support from both the public and policymakers. *"This support is vital in ensuring that we can meet the current standard of care effectively."*

3. F1-F29: Meeting the needs of the current standard of care will influence/enhance Protecting intellectual property.

Secure Competitive Advantages: Meeting the current standard of care has a transitive effect on protecting intellectual property. "It helps secure competitive advantages in the market, making it essential for safeguarding our intellectual property."

4. F2-F29: Navigating economic and political considerations will influence/enhance Protecting intellectual property.

Adapt its strategies: "Navigating economic and political considerations requires us to adapt our strategies continuously. This adaptability is essential for protecting our intellectual property effectively."

5. F2-F30: Navigating economic and political considerations will influence/enhance Funding capacity.

Influenced by Economic and Political Factors: "Our ability to secure funding capacity is influenced by economic and political factors. Navigating these considerations plays a vital role in determining our funding capacity."

6. F2-F33: Navigating economic and political considerations will influence/enhance Managing costs.

Impact the Cost Structure: "Navigating economic and political considerations has a significant impact on our cost structure. Effectively managing costs is closely tied to how well we navigate these considerations."

7. F33-F2: Managing costs will influence/enhance Navigating economic and political considerations.

Stronger Position in Economic and Political Discussions: "By managing costs effectively, we can strengthen our position in economic and political discussions. This strengthens our ability to navigate these considerations successfully."

8. F4-F3: Identified market based on health focus will influence/enhance Technological innovativeness.

Enhance: "Identifying a market based on health focus enhances our technological innovativeness. It provides a clear direction for our innovation efforts."

9. F3-F7: Technological innovativeness will influence/enhance Maintaining cost-effectiveness.

Reduced Resource Consumption: Being technologically innovative often leads to reduced resource consumption, which is critical for maintaining cost-effectiveness.

10. F7-F3: Maintaining cost-effectiveness will influence/enhance Technological innovativeness.

Strategic Resource Allocations: Maintaining cost-effectiveness allows for strategic resource allocations, which can further enhance technological innovativeness.

11. F3-F12: Technological innovativeness will influence/enhance Effectively managing collaborations.

Providing Tools and Platforms: Technological innovativeness can provide tools and platforms that are essential for effective collaboration.

12. F24-F3: Cultivating health champions for technology adoption will influence/enhance Technological innovativeness.

Foster: Cultivating health champions for technology adoption fosters technological innovativeness by creating advocates for innovative solutions.

13. F11-F4: Satisfying customer requirements will influence/enhance Identified market based on health focus.

Positive Feedback: Satisfying customer requirements generates positive feedback, which can promote the identified market's growth based on health focus.

14. F4-F24: Identified market based on health focus will influence/enhance Cultivating health champions for technology adoption.

Promote Technology Adoption: The identified market's growth can promote technology adoption by creating a receptive environment.

15. F24-F4: Cultivating health champions for technology adoption will influence/enhance Identified market based on health focus.

Tailored Health Focus: "Cultivating health champions can tailor the market's health focus, making it more aligned with our offerings."

16. F29-F4: Protecting intellectual property will influence/enhance Identified market based on health focus.

Identify Growth Opportunities: Protecting intellectual property can lead to identifying growth opportunities within the identified market.

17. F30-F4: Funding capacity will influence/enhance Identified market based on health focus.Strengthen the Investment for Target Segment: *"Funding capacity strengthens our ability to invest in the target market segment."*

18. F5-F7: Enabling early detection will influence/enhance Maintaining cost-effectiveness.

Lead: Enabling early detection leads to maintaining cost-effectiveness by preventing later-stage interventions.

19. F7-F5: Maintaining cost-effectiveness will influence/enhance Enabling early detection.Develop Cost-Effective Diagnostic Tool: Maintaining cost-effectiveness requires the development of cost-effective diagnostic tools.

20. F5-F9: Enabling early detection will influence/enhance Offering portability.

Enhance Value Proposition: Enabling early detection enhances the value proposition by making it more accessible.

21. F24-F5: Cultivating health champions for technology adoption will influence/enhance Enabling early detection.

Drives: Cultivating health champions can drive the adoption of early detection technologies.

22. F15-F6: Onboarding of customers will influence/enhance Ensuring ease of use.Generate Feedback to Improve Ease of Use: Onboarding customers generates feedback that can be used to continually improve ease of use.

23. F6-F24: Ensuring ease of use will influence/enhance Cultivating health champions for technology adoption.

Strengthen: Ensuring ease of use strengthens the perception of technology among champions.

24. F24-F6: Cultivating health champions for technology adoption will influence/enhance Ensuring ease of use.

Advocate: Health champions can advocate for the ease of use, making it a key selling point.

25. F27-F6: Securing team expertise will influence/enhance Ensuring ease of use.

Improve Value Offering: A well-equipped team can improve the value offering by ensuring ease of use.

26. F32-F6: Investors support will influence/enhance Ensuring ease of use.

Support Value Offering: Investor support can enhance the value offering, including ease of use.

27. F7-F9: Maintaining cost-effectiveness will influence/enhance Offering portability.

Enhance Value Offering: Maintaining cost-effectiveness enhances the value offering, which includes portability.

28. F7-F12: Maintaining cost-effectiveness will influence/enhance Effectively managing collaborations.

Strategic Resource Allocation: Maintaining cost-effectiveness enables strategic resource allocation for effective collaborations.

29. F24-F7: Cultivating health champions for technology adoption will influence/enhance Maintaining cost-effectiveness.

Influence: Health champions can influence the cost-effectiveness of technologies.

30. F8-F23: Providing a platform for collaboration will influence/enhance Implementing awareness initiatives.

Collaboration Supports the Implementation of Awareness Initiatives: Collaborative platforms facilitate the implementation of awareness initiatives.

31. F26-F8: Sustaining value ecosystem will influence/enhance Providing a platform for collaboration.

Integration of Key Stakeholders for Meaningful Collaboration: A sustained value ecosystem integrates key stakeholders for more meaningful collaboration.

32. F31-F8: Adaptive revenue stream will influence/enhance Providing a platform for collaboration. Diverse Revenue Can Support Collaboration Platforms: A diverse revenue stream can support the development and maintenance of collaboration platforms.

33. F34-F8: Promoting knowledge exchanges will influence/enhance Providing a platform for collaboration.

Improve Collaboration Platforms: Promoting knowledge exchanges can improve the functionality of collaboration platforms.

34. F9-F12: Offering portability will influence/enhance Effectively managing collaborations.Increase Accessibility: Offering portability increases the accessibility of collaborative tools, enhancing effective management.

35. F12-F9: Effectively managing collaborations will influence/enhance Offering portability.Contribute to Development: Effective collaboration management contributes to the development and improvement of portable solutions.

36. F9-F22: Offering portability will influence/enhance Timely delivery of value.

Strengthen Value Delivery: Offering portability strengthens the delivery of value to customers.

37. F10-F17: Securing regulatory approval will influence/enhance Earning trust of stakeholders.

Provides Validation and Assurance: Regulatory approval provides validation and assurance to stakeholders, enhancing trust.

38. F17-F10: Earning trust of stakeholders will influence/enhance Securing regulatory approval.Positively Influences its Reputation: Earning trust positively influences the reputation, making regulatory approval smoother.

39. F10-F20: Securing regulatory approval will influence/enhance Satisfied regulatory clearance. Expedite the Clearance Process to Enter the Market: Regulatory approval expedites the clearance process, ensuring quicker market entry.

40. F20-F10: Satisfied regulatory clearance will influence/enhance Securing regulatory approval. Prevent Unauthorised Distribution: Satisfied regulatory clearance helps prevent unauthorised distribution.

41. F10-F27: Securing regulatory approval will influence/enhance Securing team expertise.Improve the Development: Securing regulatory approval contributes to improving team expertise.

42. F10-F32: Securing regulatory approval will influence/enhance Investors support.

Enhance: Securing regulatory approval enhances investor support.

43. F20-F11: Satisfied regulatory clearance will influence/enhance Satisfying customer requirement.

Enhance: Satisfied regulatory clearance enhances the satisfaction of customer requirements.

44. F11-F24: Satisfying customer requirements will influence/enhance Cultivating health champions for technology adoption.

Increase Adoption: Satisfying customer requirements increases the adoption of technology.

45. F11-F30: Satisfying customer requirements will influence/enhance Funding capacity. Increase Business Growth: Satisfying customer requirements contributes to increased business growth.

46. F30-F11: Funding capacity will influence/enhance Satisfying customer requirement. Further Satisfy Customer: Funding capacity further satisfies customer needs.

47. F11-F32: Satisfying customer requirements will influence/enhance Investors support.Added Value to Investors: Satisfying customer requirements adds value to investors' interests.

48. F32-F11: Investors support will influence/enhance Satisfying customer requirement.Invest in Meeting Customer Needs: Investor support leads to investments in meeting customer needs.

49. F33-F11: Managing costs will influence/enhance Satisfying customer requirement.

Enhance: Managing costs enhances the satisfaction of customer requirements.

50. F12-F28: Effectively managing collaborations will influence/enhance Organisational culture. Influence: Effective collaboration management influences organisational culture.

51. F13-F14: Providing training support (internal) will influence/enhance R&D for sustaining innovations.

Enhance Value Offering: Internal training support enhances the value offered in research and development for sustaining innovations.

52. F13-F21: Providing training support (internal) will influence/enhance Training and support provided.

Enhance Comprehensive Training Provided: Internal training support enhances the comprehensiveness of training provided.

53. F21-F13: Training and support provided will influence/enhance Providing training support (internal).

Improves: Effective training and support improve the internal provision of training support.

54. F13-F25: Providing training support (internal) will influence/enhance Outsourcing value creation.

Capacity to Further Develop Value: Providing internal training support increases the capacity to further develop value in outsourcing.

55. F28-F13: Organisational culture will influence/enhance Providing training support (internal).

Encourages: Organisational culture encourages the provision of internal training support.

56. F14-F25: R&D for sustaining innovations will influence/enhance Outsourcing value creation.Strengthens: Research and development for sustaining innovations strengthens the value creation in outsourcing.

57. F25-F14: Outsourcing value creation will influence/enhance R&D for sustaining innovations. Optimise Operations: Outsourcing value creation optimises operations for sustaining innovations.

58. F14-F31: R&D for sustaining innovations will influence/enhance Adaptive revenue stream. Support Adaptive Revenue Strategies: Research and development for sustaining innovations supports adaptive revenue strategies.

59. F16-F15: Establishing an effective distribution channel will influence/enhance Onboarding of customers.

Efficient Flow of Transactions: Establishing an effective distribution channel ensures the efficient flow of transactions during onboarding.

60. F19-F15: Having clear customer needs will influence/enhance Onboarding of customers.Tailor the Onboarding Process Effectively: Clear customer needs allow for the effective tailoring of the onboarding process.

61. F15-F27: Onboarding of customers will influence/enhance Securing team expertise.Sustain Human Resources: Onboarding of customers sustains human resources within the team.

62. F27-F15: Securing team expertise will influence/enhance Onboarding of customers.

Increase Customer Retention: Securing team expertise increases customer retention during onboarding.

63. F16-F17: Establishing an effective distribution channel will influence/enhance Earning trust of stakeholders.

Builds Confidence and Reliability: Establishing an effective distribution channel builds confidence and reliability among stakeholders.

64. F17-F16: Earning trust of stakeholders will influence/enhance Establishing an effective distribution channel.

Fosters Positive Relationships: Earning trust fosters positive relationships in establishing an effective distribution channel.

65. F16-F19: Establishing an effective distribution channel will influence/enhance Having clear customer needs.

Efficient Delivery of Value: Establishing an effective distribution channel ensures efficient delivery of value based on clear customer needs.

66. F19-F16: Having clear customer needs will influence/enhance Establishing an effective distribution channel.

Aligned Distribution Channel: Clear customer needs align the distribution channel effectively.

67. F16-F27: Establishing an effective distribution channel will influence/enhance Securing team expertise.

Enhances Value Delivery: Establishing an effective distribution channel enhances the delivery of value through team expertise.

68. F17-F27: Earning trust of stakeholders will influence/enhance Securing team expertise.Benefit the Team's Development of Expertise: Earning trust benefits the team's development of expertise.

69. F21-F18: Training and support provided will influence/enhance Driving adoption of innovation.Drive Innovation Adoption: Training and support provided drive the adoption of innovation.

70. F18-F25: Driving adoption of innovation will influence/enhance Outsourcing value creation.Enhance Value Network: Driving the adoption of innovation enhances the value network in outsourcing.

71. F25-F18: Outsourcing value creation will influence/enhance Driving adoption of innovation.Enhance Value Offering: Outsourcing value creation enhances the value offering related to the adoption of innovation.

72. F18-F26: Driving adoption of innovation will influence/enhance Sustaining value ecosystem.Contributes to a Robust Value Ecosystem: Driving the adoption of innovation contributes to a robust value ecosystem.

73. F20-F33: Satisfied regulatory clearance will influence/enhance Investors support.Increase Investor Support: Satisfied regulatory clearance increases support from investors.

74. F20-F33: Satisfied regulatory clearance will influence/enhance Managing costs.

Reduce Costs Linked with Prolonged Regulatory Processes: Satisfied regulatory clearance helps reduce costs associated with prolonged regulatory processes.

75. F33-F20: Managing costs will influence/enhance Satisfied regulatory clearance.Invest in Compliance Measures: Managing costs leads to investments in compliance measures.

76. F22-F21: Timely delivery of value will influence/enhance Training and support provided.Sustain End Users: Timely delivery of value sustains end users' engagement and their need for training and support.

77. F21-F25: Training and support provided will influence/enhance Outsourcing value creation.Engage Value Networks: Training and support provided facilitate the engagement of value networks in outsourcing value creation.

78. F27-F22: Securing team expertise will influence/enhance Timely delivery of value. Contribute: Securing team expertise contributes to the timely delivery of value.

79. F22-F28: Timely delivery of value will influence/enhance Organisational culture.Positively Influence: Timely delivery of value positively influences the organisational culture.

80. F32-F24: Investors support will influence/enhance Cultivating health champions for technology adoption.

Enhance Market Adoption: Investors' support enhances the market adoption of health champions for technology.

81. F25-F34: Outsourcing value creation will influence/enhance Promoting knowledge exchanges.Lead to Knowledge Exchanges: Outsourcing value creation leads to knowledge exchanges.

82. F26-F34: Sustaining value ecosystem will influence/enhance Promoting knowledge exchanges.Enhance Value Network Activity: Sustaining the value ecosystem enhances the activity within the value network, including knowledge exchanges.

83. F34-F26: Promoting knowledge exchanges will influence/enhance Sustaining value ecosystem.Promote Knowledge Value Capture: Promoting knowledge exchanges promotes the capture of knowledge value within the ecosystem.

84. F27-F32: Securing team expertise will influence/enhance Investors support.

Enhance Value Delivery: Securing team expertise enhances the delivery of value and, consequently, investor support.

85. F32-F27: Investors support will influence/enhance Securing team expertise.Positive Influence: Investor support positively influences the securing of team expertise.

86. F29-F30: Protecting intellectual property will influence/enhance Funding capacity.Enhances Funding Success: Protecting intellectual property enhances the success of funding initiatives.

87. F30-F29: Funding capacity will influence/enhance Protecting intellectual property. Sustain IP: Funding capacity sustains the protection of intellectual property.

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88. F33-F30: Managing costs will influence/enhance Funding capacity.

Increase ROI: Managing costs increases the return on investment, thus enhancing funding capacity.

89. F31-F34: Adaptive revenue stream will influence/enhance Promoting knowledge exchanges.

Invest in Knowledge-Sharing: Adaptive revenue streams promote investments in knowledge-sharing.

90. F34-F31: Promoting knowledge exchanges will influence/enhance Adaptive revenue stream.

Enhance Revenue-Generating Opportunities: Promoting knowledge exchanges enhances opportunities for generating revenue through adaptive streams.

Appendix I: AiPBAND Project Overview

Introduction, objectives and overview of the research programme

In 2012, there were 14.1 million new cancer cases and 8.2 million deaths from cancer worldwide, including 1.25 million deaths in Europe (www.ec.europa.eu). This causes huge social, political and financial pressures. Brain tumours deaths are rising, representing 2.6% of all deaths from cancer and kill more children and people under 40 than any other cancer. Every two hours, someone is diagnosed with a brain tumour in England alone. In this proposal, we focus on gliomas: a term describing a range of devastating and progressive brain tumours affecting around 25,000 people each year in Europe and are responsible for the majority of death from primary brain tumours1 . The most common symptoms of gliomas are due to increased intracranial pressure (headache, vomiting, and nausea), focal neurological deficits, seizures etc. Despite intensive efforts, there are currently no effective disease-modifying treatments or preventive strategies for gliomas in part due to lack of the effective early diagnostic techniques. Therefore, developing improved patient-oriented strategies for combating cancer, such as gliomas, - ranging from prevention to more effective and earlier diagnosis, to better treatment with minimal side effects, is still one of the leading medical and societal challenges faced by the EU.

Currently, gliomas are diagnosed by neuroimaging, such as computer tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET), and refined diagnosis requires surgical biopsy for further histopathological classification and grading2. Besides the insensitivity and high-cost, neuroimaging may not be able (1) to clearly detect infiltrating diffuse low-grade gliomas or distinguish gliomas from other tumours or other pathologies; (2) to document tumour progression; and (3) to differentiate the effects of

different treatments (e.g. radio-necrosis). Despite extensive study in the field, to date there is no validated diagnostic method based on the analysis of biological molecules in the blood. Developing such a reliable, less expensive diagnostic technique with short time intervals is utmost important and required for personalised therapy, which may potentially help patients to avoid harmful biopsy 3. Therefore, it is urgent to have a new generation of biosensing techniques and diagnostic systems that can provide diagnosis, prognosis, and monitoring to aid accurate clinical decision- making and improve therapy.

Recent advances in blood biomarker discovery, the use of biomaterial and microelectronic biosensors, and big data methodology show the huge potential for developing less invasive blood biomarker-based diagnostic techniques for gliomas 4. However, turning these potentials into practices requires further complementary interdisciplinary research efforts and intensive intersectoral collaborations, involving a number of disciplines, including neurobiology, nanotechnology, biotechnology, electronics, biomaterial, biophysics, biochemistry, neuropathology, big data computing, medical informatics, and bioinformatics. The long-term fight against cancer and the lack of young interdisciplinary talents in the gliomas diagnostic field highly requires an intensive training of a new generation of researchers. AiPBAND is proposed to provide such an excellent triple-i (interdisciplinary, intersectoral and international) research and training platform with multidisciplinary expertise and advanced technologies for developing innovative diagnostic techniques for gliomas. Through this platform, a new generation of innovative, entrepreneurial and creative early-stage researchers (ESRs) will be trained with triple-i knowledge/skills and broad vision to maximize their ability of knowledge transformation and employability, and become the future leaders in both academia and industry.

The AiPBAND consortium consists of leading academic and industrial experts drawn from 4 existing consortia across Europe, i.e. H2020-PHC-ULTRAPLACAD, MSCA-ITN-BBDiag, MSCA-ITN-ND4ID, MSCA-ITN- iSwitch. These experts will bring to the ETN state-of-the-art of their respective consortia to provide the core multidisciplinary expertise of the network. The triple-i dimension of the consortium is illustrated by Table 1.0. Nine academic, seven non-academic and two international institutions whose expertise span five major scientific disciplines (life science, engineering, physical science, healthcare and economics) are involved (Table 1). This will strongly enhance the cross-sectoral participation and contribution to the research and training programme.

The scientific objectives (SO) of the project include:

- 1. To develop novel plasmonic, graphene and digital ELISA-based multiplexed biosensing techniques.
- To discover reliable early gliomas blood biomarkers by employing innovative techniques.
- 3. To develop a novel disease prediction model and strategies for intelligent information management.
- 4. To develop an integrated prototype cloud-based diagnostic system for gliomas.
- 5. To carry out validation for assessment of the biomarkers, biosensors and evaluate the performance of the AiPBAND diagnostic system.
- To develop an innovative business model and exploitation strategies for early gliomas diagnosis, and to explore novel commercial applications of the technologies developed in this ETN.

The AiPBAND aims to provide an excellent triple-i research and training platform for developing innovative diagnostic techniques for gliomas. This will have impacts both on (1)

the general application of molecular diagnostic technologies and big data decision-making support for health innovations, and on (2) the specific stratifying of early-stage glioma patients to aid the development of personalised treatment and preventive strategies. All of which are crucial to meeting the medical and societal challenges as recognized in the Health, Demographic Change and Wellbeing of H2020.

Our specific approaches are described as following.

- Biosensing techniques: aims to explore the three multiplexed biosensing techniques for the detection of biomarkers from blood samples based on proteomic, microRNA(miRNA) and DNA methylations (DNAm), namely digital ELISA assay-based, plasmonic-based and graphene-based biosensors. Detection protocols will be developed based on the outcome of biomarker discovery and validations. These biosensors will be assessed in the clinical trials for optimisation and improvement.
- 2. Biomarker discovery: aims at biomarker discovery through in silico studies (using public accessible cancer genomics & genetics databases, e.g. GEO, ArrayExpress, TCGA, TCPA, and the literature), and our own data generated using state-of-the-art technologies, e.g, MS for proteomics study, and NGS for miRNA (miRNAseq) and targeted DNA methylation (Methyseq). These biomarkers will be further validated in WP4 for diagnosis assessing their specificity and sensitivity.
- Diagnostic system development: aims to develop a Bayesian integration prediction model, an intelligent information management strategy, and a cloud-based diagnostic system for gliomas (see Figure 1.4).
- 4. Validation & trials: aims at preclinical & clinical validation. Biomarkers discovered will be cross-talk validated in brain tissues for preclinical study, and the diagnostics

system developed will be accessed by clinical trial. Novel designs for diagnostic trials, biostatistics analysis, recruitment strategy, patient characterization and stakeholder involvement are key topics in this work package. Retrospective clinical studies on well-defined, homogenous cohorts of patients will be set up to evaluate the suitability, sensitivity, specificity, and accuracy.

 Exploitation & Impact: aims to explore the innovative diagnostics and business models for potential industrial exploitations and clinical applications across Europe or worldwide.

The RTD research activities carried out in WP1-5 will focus on exploring a combination of theoretical and practical research issues, where methodologies such as experiments design, literature review, and case studies will be taken into account thoughtfully. Figure 1.3 illustrates the overview of the RTD research project and the main technologies and concepts that may be applied in current brain cancer studies. The fundamental part is our collaborative work in the neuroscience to generate biological data using state-of-the-art techniques. Spectrometry (MS) for in-depth proteomics such as Mass and proteogenomics6, next generation sequencing (NGS) for mRNA, microRNA, DNA mutation, and DNA methylation (DNAm); microarray chip for mRNA gene expression, DNA methylation and microRNA expression. Blood-based biomarkers (protein, microRNA or DNA methylation) will then be discovered using (1) public access available data (e.g. GEO https://www.ncbi.nlm.nih.gov/geo/, ArrayExpress https://www.ebi.ac.uk/arrayexpress/, TCGA http://cancergenome.nih.gov/, and TCPA http://tcpaportal.org/tcpa/); (2) privately available data from our collaborators, and (3) data newly generated in this project. Three innovative technologies will be employed for biosensor design, i.e. graphene, plasmonic and digital ELISA. A mixture Bayesian mathematical prediction model will be developed by integrating biomarker signals and the patient's phenotype data. Finally, an intelligent information management system and a cloud-based (e.g. Amazon EC2 cloud server) big-data-driven healthcare diagnostic system will be developed for proof-of-concept clinical trial as illustrated by Figure 1.4. This will allow hospital doctors or specialist to access the system via mobiles, iPads and desktop computers from anywhere and obtain the immediately available diagnostic results.

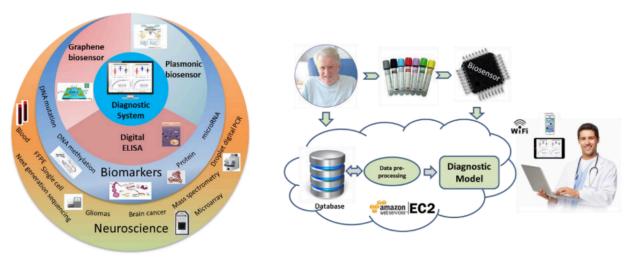


Figure 1.3 Overview of RTD research core.

Figure 1.4 Cloud-based big data-driven gliomas diagnostics system

The following are the Research Innovations (RI):

1. Advanced ultra-sensitive biosensing techniques. We will apply three of the advanced technologies to develop ultra-sensitive biosensors, i.e. graphene-based, plasmonic-based and digital ELISA-based as illustrated in Figure 1.3 for glioma biomarker detection. Graphene has superlative properties and offers benefits in sensitivity and low-cost for easy-use sensors. Through chemical modification or functionalization of the graphene7, graphene-sensing can offer the detection of DNA methylation biomarkers in this ETN. In addition, a compact plasmonic-based device8 with an integrated microfluidic circuit and functionalized nanostructures for the detection of microRNA biomarkers will be developed. Moreover, a novel digital

ELISA assay9 for protein detection will also be developed for gliomas. These three approaches will provide independent and complementary diagnostic techniques.

- 2. Novel blood biomarker discovery strategies. Many techniques such as high-throughput proteomics, mRNA and micro-RNA profiling, have been applied for biomarkers discovery in the gliomas field without conclusive results10 . AiPBAND proposes to employ four innovative biomarker discovery approaches: 1) big data mining in silico to discover a panel of best cross-validated biomarkers; 2) identification of neuronal protein fragments as pathological signatures specific to gliomas by using MS cross-talk between blood and Formalin-Fixed Paraffin-Embedded (FFPE) brain tissues; 3) microRNA biomarker discovery using state-of- the-art miRNAseg technique cross-talk between blood and FFPE. 4) DNA methylation biomarker discovery using targeted Methyseq cross-talk between blood and FFPE. Brain cancer studies on DNA methylation using FFPE tissue have been conducted by us and other researches, but to our knowledge, nobody has done targeted Methyseq on blood from glioma patients. The combination of these approaches and biomarkers with the clinical validation and trials in AiPBAND will have the potential for ground-breaking discoveries leading a panel of most reliable diagnostic, glioma blood biomarkers with predictive, prognostic and/or treatment-response prevision values. Furthermore, AiPBAND will generate new and valuable data resources for the brain cancer research community, which will greatly enhance and accelerate research in this field.
- 3. Novel disease prediction model and intelligent information management. Machine learning (ML) algorithms such as Support Vector Machine (SVM), Random Forest (RF), Logistic regression and Deep Learning (DL) have been demonstrated to be powerful tools in the big data area. By applying innovative ML & DL

algorithms, an optimal Bayesian mixture prediction model and intelligent information management system will be developed to integrate signals generated from different biomarker-based biosensors with phenotype information (e.g., gender, age and other demographic or clinical variables) to enrich the feature space and allow cross-validation within and between cohort subjects.

- 4. Innovative development of cloud-based healthcare diagnostic system. An innovative cloud-based big data driven system will be developed for gliomas diagnosis integrating the data collected from blood samples of early glioma patients and healthy volunteers using either graphene, plasmonic or digital ELISA assay-based biosensors. Such a diagnostic system (Figure 1.4) will allow us to upload the training dataset, trained prediction models and new cases to a cloud server (e.g. Amazon EC-2), through a specific web service interface. Computer applications will allow hospital doctors to secure access the system via mobiles, iPads and desktop computers from anywhere to obtain the immediately reported diagnostic results. tranSMART (http://transmartfoundation.org/) and Arvados (https://arvados.org/) open source Big Data Processing and Bioinformatics solutions will be deployed. The reusable infrastructure and the software applications (Apps) developed in this system will have great potential to expand to the detection of other diseases.
- 5. Novel strategy for biomarker validation and clinical trials The AiPBAND blood biomarkers, biosensors and diagnostic system will be evaluated in the new diagnostic environment. The blood biomarkers discovered in three labs at IRE, KI and RU will be cross-validated by in silico study (PU) and two brain FFPE studies (UCL & SU). A preliminary, retrospective clinical analysis conducted by MTA will then help in refining the most suitable biomarkers, and final candidates will be

validated based on new samples collected by MTA. The diagnostic system including biosensing will be evaluated based on clinical prospective data collected from recruited patients and healthy controls. In this way, we will be able to provide first-hand information to exploit the range of future potential applications of such techniques in research and healthcare settings, and to provide valid cost-efficacy to allow regulatory authorities, such as national health plans, to decide about remuneration of such tests in different clinical care applications. Cross-talk between blood and FFPE tissue, wet-lab (in vitro) and in silico studies, and clinical data will be a novel strategy applied in AiPBAND for biomarker discovery and validation. Using this approach, predictive, diagnostic, prognostic and treatment-response biomarkers could be defined not only for clinical application but also as potential tools for drug discovery and development.

6. The socioeconomic dimension. Patients with cancer and their families as well as healthcare communities will greatly benefit from early cancer diagnosis. AiPBAND will address the potential social benefits and economic savings for families, public administration and healthcare services through the identification and preventive treatment of early-stage gliomas; and reveal the relationship between incident and deprivation using income, occupation, and incident rate ratio (IRR) in different countries. This project, for the first time, will investigate an integrated approach to address the socioeconomic dimension to develop more comprehensive, well-balanced strategies and thus guide better provision of healthcare services to patients, their families and communities.

Contribution of all participants to the research and training programme

- Biosensing Techniques: This requires core expertise in nanomaterials/graphene, microfabrication of devices, multiplexed biosensing, embedded electronics; biochemistry, biotechnology, multiplexed digital ELISA assay; plasmonic chemistry and sensor functionalization and hybridisation, biomolecule science, microfluidics etc. These are drawn from three universities and one company (PU, UoC, KUL, and SCRIBA) across 3 countries in Europe. An international partner (HU), a State Key Laboratory of Chemo/Bio-Sensing & Chemometrics in China with leading expertise in disease diagnostic biosensing techniques and microelectronics engineering techniques will also make complementary contributions to the project in the form of training & secondments.
- Biomarker Discovery: The essential core expertise for this theme includes computational biostatistics & bioinformatics (in silico data mining), biochemistry and protein chemistry, neurobiology, proteomics, molecular biology, genomics and epigenetics. The participants are drawn from 3 universities (PU, KI, RU) in the UK, Sweden and Netherlands, and a non-profit research institute (IRE) in Italy. An industrial partner with expertise in NGS techniques (BGI) will contribute to this theme via network training events.
- Diagnostic System Development: The essential core expertise for this theme includes mathematical modelling, big data warehouse and integration, data visualization, cloud-computing, networking, web-interface, web-security, medical & health information and software engineering. The participants are drawn from one university (IC), and one company (HYVE) in the Netherlands.
- Validation and Clinical Trial: The core expertise for this theme includes brain tissues for preclinical validation and assessment of disease mechanisms of biomarkers, clinical trial design and medical statistics, clinical Neurology and Psychiatry, clinical

diagnosis of gliomas and related neurobiological stratification markers, including multimodal imaging, electrophysiology, blood, cost-efficacy and stakeholder involvement. To ensure the reliability of the clinical trials, the project strategically employs three independent preclinical settings provided by two universities (UCL & SU) and an industry company (MTA). An international hospital partner and an industrial partner (CMU, BBM) with clinical expertise in neurology and neurosurgery and equipped with high-grade precision equipment for the diagnosis and treatment of neurological disorders will add to an intersectoral and international dimension to this theme.

Exploitation & Impact: Core expertise for this theme includes business studies, operation management and decision-making, entrepreneurship and company start-up; IT healthcare system & big data technology. This theme will bring together the outcomes of the above 4 themes and apply them to the potential commercial exploitations of the prototype cloud-based system for diagnosis, prognosis and monitoring of gliomas. An innovative business model will also be developed for the commercial exploitation and patient care by an academic beneficiary (PU) to address the socio-economic dimension. An industrial partner with expertise in IP enterprising (EngA) will contribute via network event, co-supervision and secondment. Another industrial partner with expertise in public engagement and entrepreneurship (BioT) will contribute to this theme via network training events.

Entrepreneurial initiative Once the proof-of-concept biosensor & diagnostic system is successfully completed, the consortium will have the infrastructures and network for spin-off or start-ups to take the state- of-the-art technology into the market to add extra value to this ETN.

Innovative AiPBAND business model (Leader: PU, other participants: SCRIBA, HYVE, MTA): This task to develop an innovative business model for the commercial and clinical exploitations of the AiPBAND diagnostic tools. The model will address the socio- economic dimension by taking into account of the factors of business, economy, finance, patient needs, ethics, policy making, EU rules and also the business strategies of the 5 non-academic Beneficiaries/Partners of the ETN.

Project objectives: The aim of this ESR project is to investigate and develop an innovative and sustainable AiPBAND business model in order to adequately address the social-economic dimensions in the development of an integrated cloud based brain cancer diagnostic system. Relationships between business model qualifying factors (such as value, cost structure, potential revenue sources) and enabling factors (including entrepreneurial attributes, market uptake evaluation, business dynamics and sustainability) will be investigated, so that the innovative AiPBAND business model will be market-oriented, resilient, robust and sustainable to guide business strategy development. In order to achieve the overall aim, three key objectives have been identified.

- To address the entrepreneurial attributes through investigating business planning, valuing and financing, IPR and patent management, and commercialising based on the definition of an AiPBAND matrix integrating entrepreneurial knowledge, skills and competence.
- To address market uptake evaluation by exploring a multi-criteria decision-making framework through comparative analysis to take account of all stakeholders' preferences and concerns, to coherently evaluate the market opportunities and risks of the AiPBAND integrated platform.

 To address business dynamics and sustainability by investigating the dynamics of AiPBAND business environment and potential changes, so that long-term business sustainability can be maintained.

Expected results:

a.) Innovative and sustainable AiPBAND-oriented business models for brain cancer diagnosis, prognosis and monitoring; b.) Business strategies in facilitating the commercialisation and market uptake of the integrated platforms and brain cancer diagnostic tools; c.) Contribution to transferable skills training (such as IPR and entrepreneurial knowledge, skills and competence).

Planned secondments

KI (1m, year 1) for business model from biomarker perspective; SCRIBA (2m, year 1) for business model in biosensing; MTA (2m, year 2) for business model in clinical trial; HYVE (2m, year 3) for business in software engineering; EngA (2m, year 1) for entrepreneurial knowledge skills competence in industry; CMU of China (1m, year 2) for international dimension in business.

It is also important to highlight that three private established SMEs (SCRIBA, HYVE, MTA) are integrated as Beneficiaries to host three ESRs, and also provide strong commitment in training, secondment, and mentoring of other ESRs hosted by academic Beneficiaries. In addition, four private sector partners will offer to the ESRs the secondments and training in industrial IP enterprising (EngA) and public engagement (BioT). As the world's largest genomics organization, BGI will provide its expert training in NGS techniques and market development. A world leading medical and pharmaceutical device company (BBM) will provide in training in neurosurgery and healthcare through its Aesculap Academy China division. Moreover, two international academic partners will offer

international dimensions to the secondments and training of ESRs in biosensing (HU, China), and brain cancer clinical research (CMU, China). Such combination of intersectoral & international expertise will expose the ESRs to an unparalleled extent of research environments, which will greatly benefit their future career in either academia or private industry.

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