Turun yliopisto
University of Turku

BUSINESS MODELS FOR FINNISH BIOBANKS

Exploring commercial possibilities and barriers of biobanks

Master´s Thesis
in International Business

Author:
Heta Hytönen

Supervisor:
D.Sc.(Econ) Niina Nummela
D.Sc.(Econ) Anne Vihakara

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1 INTRODUCTION

1.1 Biobanks as instruments of modern healthcare

The continuous research and development in biomedicine during the last decade has remarkably increased the opportunities for business activities within the industry. Biomedicine and related technology has created new ways to improve the health of citizens, advance academia, and give birth to new services and concepts, resulting in the close collaboration of business and health industry. An embodiment of innovation stemming from the development of these industries is the recently introduced biobank concept, which is one of the latest trends in preserving human samples. Biobanks are centralized collections of human samples, which are stored for research purposes (BBMRI 2015). At the most basic level, a biobank is the systematic collection of biological specimens and health information on participants (Olson, Bielinski, Ryu, Winkler, Takahashi, Pathak & Cerhan 2014, 50).

In search of high quality treatment and developing academia, the gathering of human samples for clinical studies and diagnostic purposes (identifying and naming diseases) has been known to happen throughout the history of medicine. However, the new biobank concept differs in nature from traditional sample gathering. (BBMRI 2015.) Traditionally, samples have been gathered for a certain research purpose, e.g. studying a certain disease such as breast cancer, whereas the idea of a biobank is to establish an ample, centralized, collection of human samples for a myriad of (perhaps for the time being unknown) medical research purposes. This means that DNA, tissues and other samples are stored for many different research purposes to represent a larger population (Busby & Martin 2006, 237). With the consent of the patient, the samples are preserved in special storage and used for medical research purposes. Also collections of animal, plant and other non-human samples are in some instances referred to as biobanks, but the term is most commonly reserved for human material (Huttin & Liebman 2013, 184).

The purpose of biobanks is to be able to offer the best possible individualized care for patients, and concentrate on research and product development (Stjernschantz-Forsberg & Soini 2014, 6). It is believed that organized biobanking will improve national health care, generate employment, as well as tax revenues and investments within the health care industry (Sitra 2014). Furthermore, there has been increasing demand for this kind of integrated information database of human genomics by pharmaceutical companies (Busby & Martin 2006, 237). However, in order for biobanks to be able to influence health care issues on a national level, they have to be well organized and efficiently run.

Biobanks operate within intricate networks of many different public and private actors, having a large stakeholder network. Finnish biobanks are monitored by Valvira, the

National Supervisory Authority for Welfare and Health, and they are strongly influenced by Finnish legislation. Due to natural research advantages, biobanks are often situated close or within university hospitals, and they get a substantial share of their funds from universities. Therefore, university hospital boards and personnel are one of the most important stakeholders of biobanks. Currently, other vital stakeholder groups are municipalities, pharmaceuticals, researchers, hospital districts, and especially the end client: patients. The stakeholder network also reaches beyond the domestic field, as many parties involved, such as big pharmaceuticals, are international operators. (Tupasela & Snell 2012, 425.)

Biobanks are the newest trend in the healthcare scene, and there has been substantial media hype around them ever since the establishing of the first clinical biobank Auria, in 2013. The stakeholder network of biobanks is also expanding as the number of biobanks in Finland is rapidly increasing. More and more are affected by biobanks, and their role as healthcare operators is getting an increasingly stronger foothold on the modern Finnish healthcare system.

1.2 Finnish biobanks

In Finland, biobanks and their activities are relatively unknown to the general public. After the Biobank Act came into effect in the end of 2013, six biobanks have been registered: Auria Biobank, THL Biobank, the Finnish Hematology Register and Biobank (FHRB), Helsinki Urological Biobank (HUB), Academic Medical Center Helsinki biobank and Northern Finland Biobank Borealis (BBMRI 2015). There are also three pending biobank projects, all of which are monitored by Valvira, the National Supervisory Authority for Welfare and Health. (BBMRI 2015.) The newfound Biobank Act has stirred some discussion on ethical matters concerning sample collection and sharing. In particular, the question of international use of samples, e.g. transporting abroad samples and regarding information divides opinions (Tupasela & Snell, 2012, 426). Another aspect that has been under much discussion is the commercialization of biobanking; what is the role of business in biobanking and what are the ethics behind sample pricing and sharing? (See e.g. Turner, Dallaire-Fortier & Murtagh 2013.)

There are many on-going medical research projects dating back decades that are similar to the modern biobanking activities. For instance, THL (The National Institute for Health and Welfare) has been collecting data of pregnant women in their trimester to create FMC, Finnish Maternity Cohort, which includes centralized information regarding pregnancy. (Gissler & Surcel 2012, 53.) The success of these kinds of individual and specified databanks, as well as the comprehensive national health care system prevailing in Finland, form an opportune environment for launching biobanks. According to Busby

and Martin (2006, 237), countries with national health systems and records covering comprehensively the population are often the most suitable for such projects. There is also consensus, that Finnish biobanks have three internationally crucial advantages: a comprehensive public health care system, a population which is supportive and receptive towards medical research and a legally well-functioning Biobank Act (law defining and regulating biobanks) (Biopankkien liiketoimintamahdollisuudet 2014).

According to the Biobank Act, biobanks must act as non-profit organizations, and therefore cannot primarily pursue financial profit with donor samples (688/2012). Even though the core purpose of biobanks lies within creating health, not wealth, biobanks must be able to cover their expenses and attract investments in order to develop their activities (Auria Biobank 2013). Biobanks are often multimillion dollar operations, yet it seems that the economics and the role of business in these operations are not well understood (Vaught, Rogers, Carolin & Compton 2011b, 24).

Biobanks engage in business endeavours as quite large amounts of financial resources are being exchanged for samples by pharmaceutical companies (Salminen-Mankonen 2014). To investigate the possibilities of the field, Tekes (the Finnish Funding Agency for Innovation) has published a report concerning business opportunities of biobanks (see Biopankkien liiketoimintamahdollisuudet FINAL 2014), and according to Minna Hendolin, director of social and healthcare services in Tekes, they are expected to arise significantly. She believes that the activities eventually create business opportunities and revenue, as via accomplishments and new product development, global investments will follow. (Biopankkien liiketoimintamahdollisuudet 2014.)

Considering that Finnish biobanks are at the moment in their introductory phase, it seems vital to organize biobanking activities clearly and visibly to abide by legalities and to avoid public confusion concerning ethical treatment of the samples. It is also important that biobanks start creating business plans to visualize the network in which they operate, attract investments and can create value for one another (Girod 2008, 16.). Being able to fulfill the scientific requirements whilst developing profitable business makes sense in long-term planning of the organization (Salminen-Mankonen 2014). This kind of well-run biobank creates economic welfare mainly by affecting developing start-ups, attracting global investments, securing the success of Finnish research groups and thus guaranteeing international cooperation and resources, as well as improving the quality of national health care (Biopankkien liiketoimintamahdollisuudet 2014). These are widely acknowledged areas in the development of biobanks in Finland, yet there is little research concerning these elements. This study on its part strives to shed light on these possibilities. Particularly the elements vital to business model creation will be further examined in the following chapter, which outlines the objective and structure of the study.

1.3 The objective and structure of the study

There has been relatively little research on business models of biobanking and even less that concentrate on Finnish biobanks. The focus on the commercial side of biobanks has mainly been on the cost calculation side to ensure the overall maintenance and survival of the organization. Even though the business planning has largely been limited to calculation of costs, there seems to be a change in shift towards extra-organizational activities amongst biobanks around the world. Due to this change, it seems meaningful to examine the commercial opportunities and obstacles for business model development in Finland as well. In addition, it is important to study business model creation in order to reveal the expectations of stakeholders, and consequently develop activities to a more consumer-oriented direction. The potential value created by biobanks to themselves and stakeholders should be addressed more now in the early phases of activities when there is much potential, but the organizations are still molding and finding their operational models.

This thesis aims to develop a suitable business model for optimal value creation for biobanks. The sub-objectives of this thesis are to

- analyze biobanks' commercial potential through product innovations, as well
- to map the barriers for creating a business model

The study approaches the subject from a theoretical point of view of business model creation. As stated above, the primary economic approach to studying biobanks has been from the viewpoint of cost accounting and different cost calculation methods. Therefore, this study is limited to business model creation with particular emphasis on value creation. Nevertheless, previous studies are taken into account especially when examining the earlier empirical research on the economics of biobanking.

In the current discussion within the healthcare industry, the possibilities of biobanking and potential future products and services are widely reflected, which is also emphasized in the chosen theories. The theoretical framework takes into account a few select business model theories, which in their pervasiveness fit to studying new organizations like biobanks. The chosen theories are well-round and take into account different aspects of business models. However, certain areas have risen in the media discussion of commercialization of biobanks, including issues of pricing potential products, which are brought our more clearly in the analysis of different models.

The study consists of six main chapters. The introduction illustrates the importance of the subject of study, as well as the objectives and structure of the research. Chapter two focuses on biobanking activities in Finland and the revenue logic behind biobanking. In addition, it illustrates how biobanks create value within its network, and sheds light on the earlier empirical research on the economics of biobanking. The theoretical framework of this study is depicted in chapter three through selected business model theories, which

are integrated into a suitable business model synthesis for biobanks. The fourth chapter reflects the methodological choices and validity of the study, and finally, the empirical findings of the study are explored in chapter five. The study concludes in chapter six, where the decisive findings are explored in regard to managerial implication and possible future research.

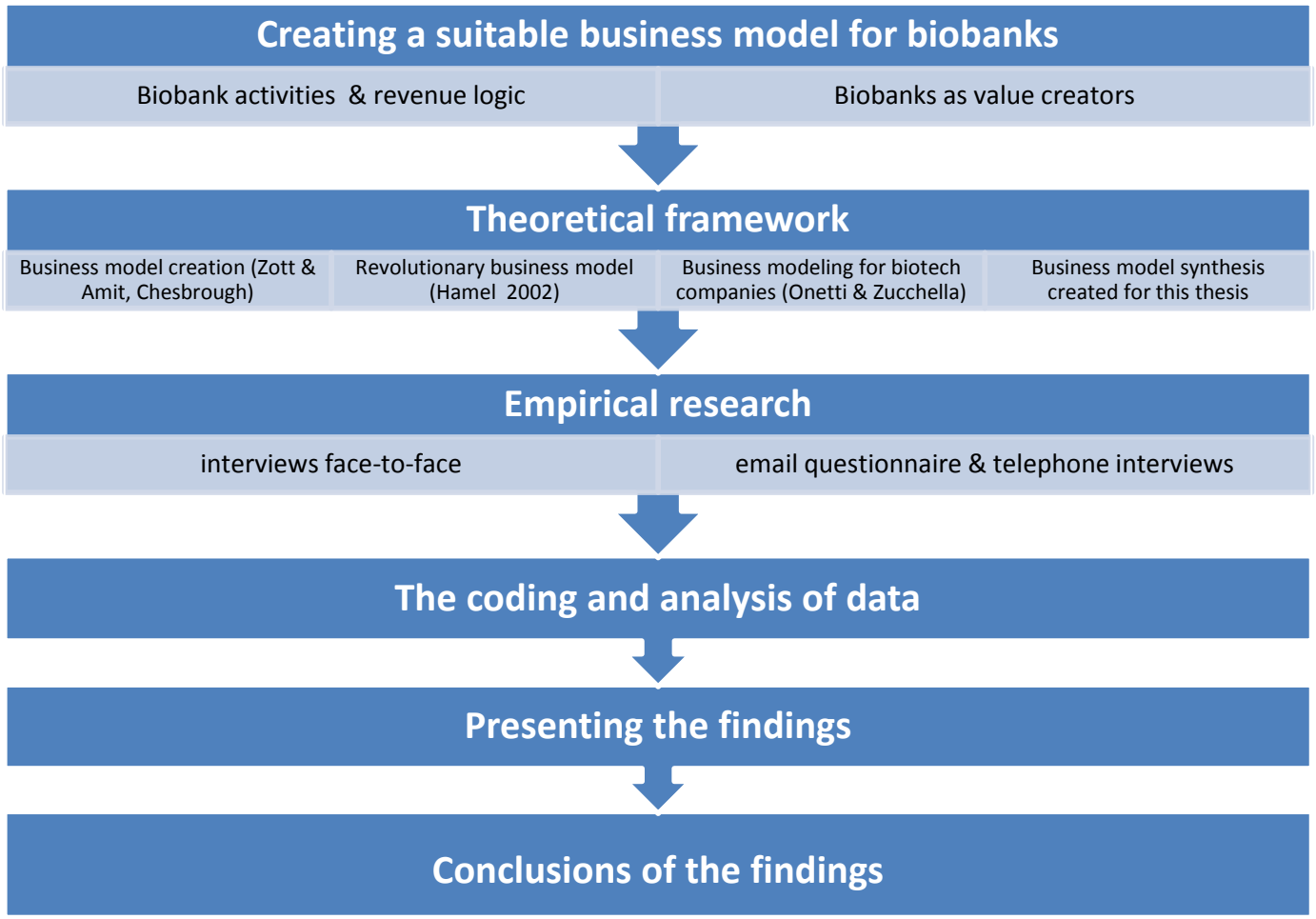

Figure 1 Structure of the study

Studying biobanks is challenging as many procedures and activities revolving them are not yet established in Finland. These organizations are currently forming their operational modes, and striving to regularize their activities in lack of tradition and previous experience, which gives a certain "tabula rasa" air to the subject. Due to the novelty of biobanks, there are natural limitations to conducting this study: much of the studies conducted of biobanks are extremely tentative, and most of them concentrate on the medical point of view, legal issues and some on the economics of biobanking. The data available in Finland is scarce and scattered, and the theoretical framework is

challenging to assemble, as there are applicable points as well as non-essential ones in most business model theories. However, the strength of studying such a subject lies in expert interviews, which in the most optimal case, delivers a diverse discussion of a relatively unknown topic. Concentrating on adapting a suitable business model for Finnish biobanks − regardless of how the topic of choice limits the theoretical framework and data available in conducting the study – is essential in revealing the future commercial potential.

2 BIOBANKS IN THE FINNISH SOCIETY

2.1 Activities and resources of biobanks

Everyday activities, different actors and unique resources define a biobank's outline. The interaction of these features is essential for successful communication within a business network (Ford, Gadde, Håkansson, Snehota & Waluszewski 2010, 98). One way to analyze this entity is through the "ARA model" by Håkansson and Johanson (1992), which studies actors, resources and activities as the key ingredients of networks. This framework also helps in comprehending the operational environment and networks of a biobank. In this chapter the activities of biobanks are briefly presented first, following an overview on the resources of biobanks from the viewpoint of value creation, and concluding with a description on the actors and stakeholder environment in the following subchapter. This order presents the internal activities of biobanks completing with a description on the external environment.

Activities of biobanks are heavily influenced by national institutions and legislation. In Finland, biobanks are monitored by Valvira, the National Supervisory Authority for National Welfare and Health, and their existence and activities are regulated by the Biobank Act. Valvira currently maintains a biobank register where all the information concerning the administrator of a biobank, as well as availability and storage of samples among other unrestricted information, is held. (Valvira 2014.) Defined by the Biobank Act and the biobanks' operating plans, achieving better medical practices, treatments and eventually preventing diseases are the main objectives of biobanks. This goal is gradually achieved by sets of activities that compile everyday routines. The basis for all operation lies in samples that are collected during a medical examination, and information regarding the donor. (BBMRI 2015.) The samples can be taken in exchange for the patient's consent: for example extracting tissue during surgery or taking a blood sample in a medical examination.

As suggested by the activities-resources-actors model by Håkansson and Johanson (1992), there is a core activity within all operations. In this case, the basic core activity process is circular, as it begins from the patient (who gives their consent for the utilization of the removed sample and other related information), and via research and possible discoveries ends in benefiting the same or other patients with similar medical conditions (Pajusola 2014). These samples usually require special storage, where samples are cooled and preserved in sub-zero temperatures. They can be stored in single refrigerators or larger warehouses, and they are most often maintained by universities, hospitals, pharmaceutical companies, ranging from profit to non-profit organizations. (Huttin & Liebman 2013, 184.) These everyday activities aim at collecting and combining two types

of information, one deriving from the sample and other from the information regarding the patients' environment and lifestyle. This creates a basis for disease prevention programmes that benefits also on a national level. (BBMRI-ERIC 2014.) The centralized databank also facilitates the work of many researchers, who do not necessarily have to gather data from the beginning, but they can turn to the supply of biobanks to see, whether appropriate samples can already be found there (THL 2014).

Biobanks operate within the health care industry, which alters the mentality of gaining economic profit and sets different revenue requirements compared to companies working in other industries. There are many researchers who take into consideration these environments, and propose business model frameworks for such organizations, who need to emphasize societal values relatively more than an average company. They focus on creating business models that lead to societal wealth improvements, such as reducing poverty and human suffering, in which instance the value that is created may refer to different forms of value, such as societal, psychological or economic value (see e.g. Thompson & MacMillan 2010, 291−293).

As suggested by the activities-resources-actors model by Håkansson and Johanson (1992), activities harness the valuable *resources* of an organization to create the desired outcome. Defining the most valuable resources of a company has become increasingly important in today's highly competitive market economy, and there are numerous different interpretations on what kinds of resources create substantial value to the firm and its stakeholders. Nevertheless, most scholars agree that resource is often perceived as valuable when it is scarce, novel and hard to imitate or substitute by others (Amit & Zott 2001, 497). Value is highly subjective; it is defined by customers's view on the product's usefulness (Bowman & Ambrosini 2000, 4; Grönroos & Voima 2011, 135) and it can only be estimated in relation to a specific market environment (Amit & Schoemaker 1993, 39). Studying value creation of organizations, one has to turn to newer business model theories to complement the ARA –framework, as it is limited to identifying the three elements without much emphasis on other related issues.

The value of a biobank, as any given organization, can be studied in relation to its network; that is, assessing how and for whom value is created. According to resource-based view, a firm can achieve sustained competitive advantage, when it possesses valuable, rare and inimitable resources and capabilities (Kraaijenbrink, Spender & Groen 2010, 350). Globally examined, biobanks are unique pioneers within the health care industry, as they explore unprecedented biological information in the pursuit of creating a larger biodata bank, and provide services accordingly. From the RBV point of view, biobanks fulfill the criterion for possessing those rare capabilities, which are needed in order to create sustained value. In value creation, essential is also mapping the actors who have a stake in the firm's operations, or are in some notable way affected by a firm's (business) activities, i.e. stakeholders (Phillips 1997, 52).

Resources of the six established biobanks differ from each other due to the nature of the gathered data. For instance, Auria biobank holds a large number of cancer samples gathered over decades, whereas FHRB concentrates mostly on hematologic research and HUB on the research and treatment of urological cancer. THL on the other hand promotes the welfare and health of the population due to its ample population studies. (BBMRI 2015.) Academic Medical Center Helsinki, emphasizes translational research with a wide area of medical expertise, and the data gathered by the newcomer of biobanks, Northern Finland Biobank Borealis, lies within the homogenous population, which is valuable for research. The correct use of the resources defines the success of a biobank: biobanks must excel scientifically, and the data has to be applicable for the development of potential biobank products (Ranki-Pesonen & Soppi 2014, 2). These unique resources, combined with in-depth analyses on relative strengths and proactive identification of industry partners, determine the successful commercial exploitation of a biobank (Lindpaintner 2014, 2). This can happen in two ways: the value can be captured as a one-time transaction, for instance as an individual purchase, or through value creation, which is a longer-term approach based upon managerial action and the transfer of capabilities (Angwin, & Meadows 2014, 2). For instance, biobanks may engage in simple transaction of selling certain samples for pharmaceutical companies for their own research purposes, or instead commit to a long-term partnership of joint research by sharing resources.

Equally relevant for a firm is the downside to capturing value: not all value that is generated by the firm's activities is harnessed into tangible action and creating revenue. Therefore, firms create business models as a necessary tool for capturing value, since "a company that cannot earn a profit from some portion of its activities cannot sustain those activities over time" (Chesbrough 2007, 12). Consequently, this study aims to create a business model for biobanks that minimizes this kind of value loss for the biobank. In conclusion, the resources and activities of biobanks are strongly linked to each other, and they are also a subject to differing resources of biobanks. When these work in unison, value is created to biobanks and to the stakeholder environment, which is depicted with more detail the following chapter.

2.2 Stakeholder environment

According to the model of Håkansson and Johanson (1992), resources and activities need *actors* who perform the tangible operations, or alternatively are essentially linked to the organization, i.e. stakeholders. Subsequently, there has been a noticeable shift within business organization literature from internal processes towards the organization–environment interface and the importance of stakeholders within the last decade (Håkansson & Snehota 2006, 257). Focus on external factors has become more and more

relevant in this acceleratingly intertwined world, and enterprises study themselves as a part of a bigger entity; network and relationships between different actors of the industry (as well as cooperation between parties of different industries) is crucial in estimating a firm's value creation (Chesbrough 2007, 12). Economic activities are all the more diverse and less and less tied to specific industries, which has led to the emergence of "business ecosystems", where different stakeholders are in contact with each other in a more realistic and dynamic way (Moore 2006, 32). Stakeholder approach is self-evident for nonprofit organizations, whose motivation is to serve a larger group of actors. Biobanks, which are nonprofit organizations by regulation, have a social and juridical responsibility as an actor within the health care industry, to take into account its stakeholders.

Stakeholder theory emphasizes the importance of networks when conducting business, and it is equally relevant when designing suitable business models. According to Romme (2003,570) organizations are putting more and more focus on external elements (stakeholders, partners etc.) of a firm as opposed to internal ones, which creates a competitive edge. Biobanks are highly linked to external public and private parties, and they are therefore subject to similar viewing: creating a business model for biobanks should crucially take into account their stakeholders, especially in the context of Finnish health care industry, where biobanks are not as privatized as in many other countries.

According to Simeon-Dubach and Watson (2014, 301) biobanking has evolved through different phases starting from a more quantity-based approach, which focused on biospecimen and person related data, eventually developing into a more quality-intensive approach, whose focus shifted towards biospecimen related data. The authors refer to these first stages as Biobanking 1.0 and Biobanking 2.0. However, the authors highlight the generally recognized era of modern biobanking, which relies on the importance of external stakeholders. Håkansson and Johanson (1992) brought up the importance of actors already more than two decades ago, and since the stakeholder point of view has established an even stronger foothold within the study of organizations in general, and respectively in studies related biobanking.

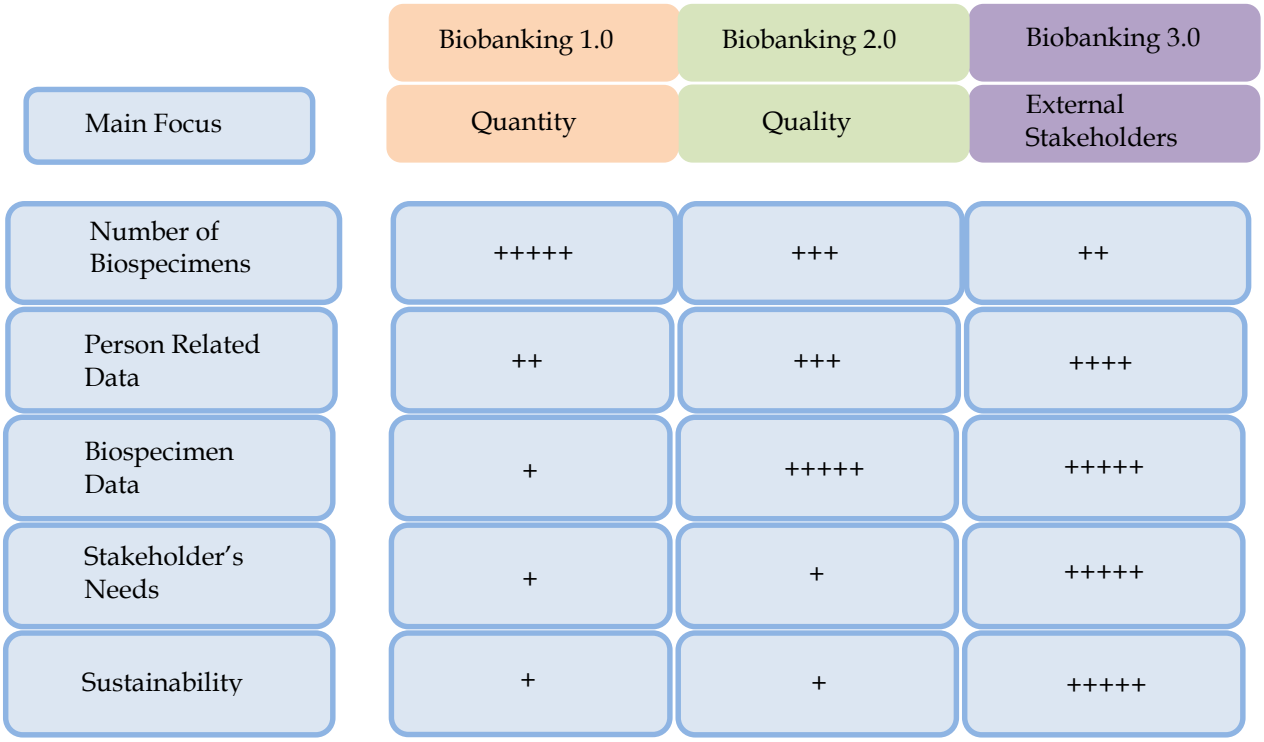

Figure 2 Different stages of biobanking (Simeon-Dubach & Watson 2014, 301)

Figure 2 illustrates the shift of focus during the different stages of biobanking. The earlier studies of biobanks have emphasized the quantity of samples and inner activities of organization, whereas the latter phase 2.0 takes on the importance of stakeholders and extra-organizational elements. The importance of data related to the samples has changed rapidly to one of the most core topics in biobanking, even to the point where experts are stating that samples themselves are useless without the derived data. The first stages of biobanking concentrated on establishing the operations and surviving day-to-day activities, whereas biobanking 2.0 takes into consideration sustainability and long-term planning. This view has gotten an increasingly important role in biobanking.

The rapid growth of biobanking has brought about debates over the ethical treatment of patient information, and hence set off many jurisdictions dealing specifically with stakeholder issues (see e.g. Vaught, Caboux & Hainaut 2010; Widdows & Cordell 2011). To respond to these demands, there has been an increase in creating best practice guidelines for biobanks, where different actors within the biobank's networks are taken into account (see e.g. Hallmans & Vaught 2011; Vaught & Lockhart 2012).

Actors of biobanks within the organization (for example the researchers and personnel) are crucial when creating substantial value for the stakeholders. Biobanks relate to a number of external stakeholders, including donors, other researchers and institutions, regulatory bodies, funders, and many other societal actors. (Bjugn & Casati 2012, 239.)

The operational environment in Finland is similarly vast and it interconnects different actors within different industries. Biobanks operate within (or in tight cooperation with) at least six large fields: resources and capabilities, infrastructures, networks, legislation, market demand and finance within R&D. (Sitra 2014.) A sound strategy for external stakeholder engagement is considered essential in project management and organization theory (Bjugn & Casati 2012, 239), and it has equal importance in achieving long-term financial sustainability of biobank infrastructures (Simeon-Dubach & Watson 2014, 300).

According to Lenney and Easton (2009, 559), continuous and dynamic interaction between different actors is defined by the level of commitment, which takes place between these organizations. These relationships link the resources and activities of one party to another in an often complex and way, and instead of happening through discrete transactions, they take place over time (Håkansson & Snehota 2006, 260). Respectively, the evolvement of commitment between biobanks and stakeholders is particularly interesting from the viewpoint of this study. Analyzing this evolvement plays a key role in the construction of value for stakeholders (Ford et al. 2010, 99), which is further analyzed in the results of the study. This is depicted particularly in the experts' opinions of important issues for different stakeholders.

2.3 Revenue logic in biobanking

Health care industry sets certain boundaries in the "revenue mentality" due to the nature and objectives of work. There is often conflict of interest with nonprofit organizations generating profit. This has subjected biobanks around the world under examination and even critique, as many individuals scrutinize the ethics of commercialization. (see e.g. Cambon-Thomsen, Rial-Sebbag & Knoppers 2007; Evers, Forsberg & Hansson 2012; Steinsbekk, Ursin, Skolbekken & Solberg 2013). One of the greatest concerns among donors is samples being sold overseas. However, there are equally donors, who perceive this a necessity in order to gain better results. (Tupasela & Snell 2012, 435.) Biobanks as nonprofit organizations must maintain their ethical integrity, while facing the economic reality of having to generate return on investment. Nevertheless, many find that utilizing biobank's resources for commercial pursuits is not at all in conflict with ethical behavior, as commercialization provides opportunities in developing research, making it completely aligned with the objectives of biobanking. Commerce in biobanking is believed to enable much larger resources in providing more extensively information for individual participants. (Lindpaintner 2014, 3.)

Biobanks are large operations that require extensive funding, as there are lots of expenses that need covering in an operation of such magnitude. Most biobanks assess their costs following a value chain approach, mapping the costs in all the main steps from

sample collection to final use (such would include storage, transport, distribution, information management etc.) (Huttin & Liebman 2013, 186). Finding the resources to initiate a biobanking project usually begins with the aid of public finance. For example, in its founding phase, Auria attracted most of its funding from the government, the University of Turku and the hospital districts of Southwest Finland, as well as Tekes (the Finnish Funding Agency for Innovation) and EU programs (Auria Biobank 2015). Also THL Biobank co-funds its operations with the Academy of Finland, Tekes, EU projects and government funds (THL 2014). However, after the initiation phase, there becomes a need for a more sustainable approach in minimizing costs – and subsequently generating profit. The goal for Auria is to be able to cover the activities through its own profits generated by usage fees and project profits (Auria 2014).

Biobanks have been under increasing cost pressure in recent years, since direct grant sources are more and more difficult to secure, and generates reduced financial support, compared to previous years (McDonald, Sommerkamp, Egan-Palmer, Kharasch & Holtschlag 2012, 421; Vaught, Rogers, Carolin & Compton 2011b, 24). One way to ease the financial pressure is to establish a fee-for-service model (Lindpaintner 2014, 4-5; McDonald et al. 2012, 423).

Biobanks usually comply with a cost price model covering the production and related costs by selling specimen. These are so called commodity-based revenues for biobanks. (Vaught et al. 2011b, 29.) Basing the revenue logic solely on a cost price model can be construed as a threat towards the development of business activities (Ranki-Pesonen & Soppi 2014, 38). Studies have shown that there is a need to go further: a well-defined fee-per-service model based on cost information is perceived a more lucrative option for value creation (Gonzalez-Sanchez, Lopez-Valeiras, Morente & Fernandez Lago 2013, 272). Vaught et al. (2011b) present, that commodity-based revenue should be complemented by fee-for-services, which could include offering datasets, genotyping, sequencing, or offering training and education on biospecimen/biorepository management.

Implementing a sustainable financial model, in which the value of fee-for-services and the generated revenue combined with non-fee-for-service money (i.e. grants) should at least equal the expenses involved. A good fee-for-service schedule helps to meet this standard, while also providing customers a sense of fairness and value. Fee-for-service model has to be properly measured to cover operational costs while still offering competitive value to users. In this model, customers are never charged for the biospecimens themselves, but rather for the laboratory services associated with them. (McDonald et al. 2012, 422.) Nevertheless, this kind of service model is best implemented in the early phases of setting up a biobank operation having the future customer base already to some extent in mind (Lindpaintner 2014, 4).

2.4 Earlier empirical research on the economics of biobanking

Globally, the empirical research on the business dimension of biobanks has evolved from the emphasis on economics and financial issues of biobanking (see. e.g. Vaught et al. 2011a; Vaught et al. 2011b) to best practices of biobanking (Vaught & Lockhart 2012) and therefrom to taking into account more and more external issues as the industry has evolved (see e.g. Bjugn & Casati 2012; Macheiner, Huppertz & Sargsyan 2013; Simeon-Dubach & Watson 2014).

There has been some earlier empirical research on the economics of biobanking in general, but less research on business models of biobanking, and even fewer that concentrate on Finnish biobanks. Cost models and calculation methods for biobanks have been studied more vastly than business model creation (see e.g. Gonzalez-Sanchez et al. 2013; Huttin & Liebman 2013). The first groundbreaking publications on creating a proper business model for biobanks were conducted by Vaught, Rogers, Carolin and Compton. Their two publications (Vaught et al. 2011a; Vaught et al. 2011b) concentrate on creating taxonomy to define the economic benefits of biobanks, and forming a sustainable business model for them. The authors refer to this area of research as "biobanconomics". Even though these publications have a strong emphasis on economics and cost management, they do assess other areas of biobanking as well, including critical factors in the value chain.

Few select publications were studied more extensively in outlining this study (see table 1). Vaught et al. (2011b) highlight the managing of biobanks' value chain in a successful business model. They emphasize a few critical areas of the value chain; collection of data, processing of tissues, management of storage, distribution of samples and infrastructure and administration. According to Vaught et al. (2011b) Total Life Cycle Cost of Ownership (TLCO) model may be developed to estimate costs and assessing other biobanking initiatives. Also Huttin and Liebman (2013) emphasize the importance of TLCO, however adding other possible cost models alongside.

Table 1 Earlier research on the economics of biobanking

PUBLICATION	CONTEXT	KEY FINDINGS
Vaught, Rogers, Carolin & Compton (2011a)	Economic benefits within translational medicine in cancer research	• Importance of standardized centralized human biobank • Benefits framework
Vaught, Rogers, Carolin & Compton (2011b)	Business model creation in cancer research	• TLCO • Value chain framework • Fee-for-service model

Huttin & Liebman (2013)	Economic models for adaptive knowledge intensive biobanks (breast cancer)	• Main types of cost models: 1. TLCO 2. Recovery models 3. Adaptive knowledge platforms
Gonzalez-Sanchez, Lopez-Valeiras, Morente & Fernandez Lago (2013)	Cost model for biobanks (Spanish National Biobank Network)	• Economic and technical management of biobanks complicated due to high maintenance costs ➢ Unique cost model including six stages and four cost objects
McDonald, Sommerkamp, Egan-Palmer, Kharasch & Holtschlag (2012)	Fee-for-service as a Business Model (The Academic Biobank Experience)	• Increasing cost pressure ➢ Fee-for-service model ➢ Value assessment & creation

These previous publications were studied in order to create a more profound understanding on the subject. Certain research gaps emerge from these studies: for instance, Vaught et al. (2011a, 32) highlight the importance of studying in the future the broad perspective of business models, especially understanding the far-reaching influence that biobanks truly have on the stakeholders within the domestic economy. Huttin and Liebman (2013, 188−189) conclude with remarks that developing economic models and financial sustainability requires debating strategic options between different biobanks' managers in issues concerning repurposing or networking, which is essential in stakeholder engagement. Gonzales et al. (2013, 276) on the other hand conclude, that providing the biobank managers with more professionalism in the decision-making process fosters cooperation and mutual learning opportunities between different institutions, deserves more attention in the future research. McDonald et al. (2012, 421) depict the possibilities of fee-for-service models and emphasize that these models work only when communication practices, proper assessment of value and implementation of best practices are in order, and there is a sound business plan. This study strives to take these previously detected gaps into consideration when creating business models.

3 VALUE CREATION THROUGH BUSINESS MODEL

3.1 Business model concept

The business model concept is widely recognized as a slightly blurry term, as scholars do not agree on its accurate definition. The interpretation of the concept varies from scholar to scholar according to the phenomenon of interest, in which the term is being studied. (Zott, Amit & Massa 2011, 1019.) In the absence of a common definition of the term, scholars are more unanimous on what a business model is *not*; most importantly that it is not the same as product market strategy, and it does not involve a straightforward, linear, mechanism for value creation from suppliers to the firm to its customers (Zott et al. 2011, 1031).

A business model of a company can simply be referred to as an interpretation of its business logic, that is, what companies offer their customers, through which resources and partners they reach them and how they make profit doing all this (Syeedun & Ravichandran 2013, 92; Osterwalder & Pigneur 2005, 2−3). Business models have also been referred to as the architecture of the product, service and information flows (Timmers 1998, 4), a heuristic logic that connects technical potential with realization of economic value (Chesbrough & Rosenbloom 2002, 532−534), a conceptual tool or model (Osterwalder et al. 2005, 3) as well as a reflection of the firm's realized strategy (Casadesus-Masanell & Ricart 2010, 42). Euchner and Ganguly (2014, 33) summarize a business model as "the means by which a firm creates and sustains margins or growth". Nevertheless, there is consensus amongst scholars concerning certain facets around which business model revolves. Nenonen and Storbacka (2009, 4) have summarized the core elements of business model definition of which the majority of scholars agree on: customer value creation, earnings logic, value network, resources and capabilities, and strategic choices. However, these elements appear in business model literature with different names in different contexts (for instance customer value creation can be referred to as "value design", earnings logic as "profit formula", value network as "links to external stakeholders" or resources and capabilities as "core competency"). Despite the abundance of vocabulary, logic remains the same behind the conceptualization of a business model. In this research, business models are studied as an entity, which consists of customer value creation, earnings logic, value network, resources and capabilities, and strategic choices, as they are generally the characteristics scholars agree on.

The academic research concerning value creation derives from the 80's, when the term "value chain" was first introduces and its mechanism studied by Michael Porter (1985). Since Porter's groundbreaking research, value creation has been perceived a core issue in business model development. A business model's greatest strengths as a tool for planning

activities, is considered to be the attention on the "elements of the system"; how they fit into a working practice as an entity, and especially how perceived value is created (Davey, Brennan, Meenan & McAdam 2010, 24). According to Zott et al. (2011, 1038) business model is theoretically an underdeveloped and overloaded concept, and therefore may raise doubts in regard to its practical usefulness. However, the idea of a business model being a source of sustenance and a key to better performance largely prevails in literature (Syeedun & Ravichandran 2013, 97). Zott et al. (2011, 1029) emphasize value creation and capture through business model, stating that value is created "in concert by a firm and a plethora of partners, for multiple users", most often having economic or social objectives. Just as with defining what business models are, researchers have different ideas on how value can be created through these models. Current researchers assess value creation through standardized markers, whereas some prefer so called revolutionary business models, such Gary Hamel's research, which redefines the traditional concepts of value creation through business model. Some have gone as far as abandoning the term business model when studying value creation, replacing it with alternatives, such as "business ecosystem" (see e.g. Clarysse, Wright, Bruneel & Mahajan 2014; Moore 2006). Yet a crucial distinction must be made with the two concepts: an ecosystem is not tied to a specific firm; different firms can share the same ecosystem, whilst having very different business models (Zott & Amit 2013, 407).

Some scholars see business model as an embodiment of top management and result of organizational performance (see e.g. Patzelt, Knyphausen-Aufseb & Nikol 2008). Barriers and conflicts may also exist when the connection between the two is tight: establishing a new and innovative business model might not please the more traditional organizations' managers, who might resist experimentation. Therefore, it is wise for the managers to assess what kind of an approach suits the organization best, whether it is a more proactive and practical experimentation, or perhaps a less committed approach of mapping the alternative underlying processes of the new business model. (Chesbrough 2010, 358−359.) In the interest of long-term success, sustained value creation is a facet which managers need to ensure. Many companies fail in relying on previously successful methods and neglect to adapt their business model to its dynamic and competitive environment. (Achtenhagen, Melin & Naldi 2013, 427.)

The business model entity, which consists of customer value creation, earnings logic, value network, resources and capabilities, and strategic choices are the areas, which strongly emerge in the theories illustrated in the following subchapters. As stated above, value creation and capture through business model takes place between the firm and its multiple partners and users. The chosen theories emphasize the stakeholder approach, which is relevant in this particular context. The theoretical framework also takes into

account the previously mentioned hindrances of business models, such as the possible barriers to developing innovative solutions.

3.2 Composition of the theoretical framework

As previously stated, there are numerous frameworks through which to examine business models and the value that is created. On grounds of studying an organization that is relatively new in Finland, and whose modus operandi is far from set, the theories chosen are relatively loose in order to be applicable in this context. Therefore, the suitable frameworks are narrowed down to a handful of theories: Zott and Amit's views on business model creation, Hamel's revolutionary business model and Onetti and Zucchella's business model creation for biotech companies. These theories are illustrated in dialogue with other studies, which concentrate on other relevant aspects of stakeholder engagement, such as networks, alliances and clusters. Studying their specific features and thoughts on value creation give the reader a general idea on what are the main issues considering this area of study, and gives insight to the theme when later on studying biobanks in specific. The chapter concludes with a business model synthesis, in which the most relevant aspects of the theories are merged to apply for biobanks. When conducting the interviews, this synthesis acts as a base for the interview questions.

3.2.1 Business model – a tool for strategic analysis

Pioneers of the business model literature, Zott and Amit have extensively studied business models to portray their role in the more and more complex and interconnected world. As a result of the widely diverse interpretations that prevail in literature, Zott and Amit have aimed at unifying the conceptualization of a business model. In addition, their numerous researchers prove, that the design of a business model is indeed central to value creation (Zott & Amit 2013, 404). Their research indicates that in today's world, a business model is a whole new unit of analysis with boundaries wider than the firm itself; it is a mirror of how the firm engages in business, explaining both value creation and capture (Zott & Amit 2011, 1019).

According to Zott and Amit (2013, 403−406), business models can create value through efficiency, novelty, complementarities, and lock-in (Zott & Amit 2012, 403−404; 2013, 45−46). These value-creating assets are a strategic tool, which a firm should take into account when devising a lucrative and sustainable business model. In the case of biobanks, efficiency is measured based on transaction cost theory: efficiency creates

value when the transaction costs of a biobank are low. It is also stated, that a smooth information flow within a network reduces transaction costs (Dyer 1997, 552). This requires closer observation, when planning the cooperation between the pending biobanks' activities with the currently operative biobanks. The researchers also argue, that a viable business model is dependent on novelty (innovation) that derives from the classic Schumpeterian cycle of "creative destruction" (Zott & Amit 2013, 404). According to Chesbrough, "a better business model often will beat a better idea or technology" (Chesbrough 2007, 12), which suggests that he is also basing his views on value creation in the Schumpeterian theory of evolution of innovation.

Business models that emphasize novelty and are coupled with either differentiation or cost leadership can have a positive impact on the firm's performance (Zott, Amit & Massa 2011, 1030). So far, in the biobank context, novelty and differentiation seem to be the primary assets when creating a long-term business model. Bundling resources and capabilities results in products or services (or a combination of the two), which are offered to customers in addition of the core service a firm. These complementarities may not be relevant in the early phases of an organization such as biobanks, but will probably become a topic of interest as the core activities are established. Complementarities alike often result in efficiency, at least, from the customer's point of view.

The researchers' fourth pillar in value creation is lock-in, which prevents the migration of customers and strategic partners to competitors. (Zott & Amit 2001, 505−506.) As there are currently less than a handful of biobanks in Finland, there is little fear of competition in the traditional market economy sense. Nevertheless, biobanks must not overlook lock-in as redundant, since loyalty amongst different stakeholders have an impact on a myriad of things, such as reputation, general contentment. Patients who lose faith in the overall activities of biobanks has an effect on word of mouth concerning the organization. It is essential to analyze (and hopefully lock-in) the possible stakeholders in order to make lucrative and sustainable choices in the future. Zott and Amit emphasize that all these elements are important for creating and maintaining proper business models, because according to the researchers, business model is in fact "a common language between the stakeholders" (Zott & Amit 2013, 404).

As opposed to Zott and Amit's holistic and thematic approach to value creation, Chesbrough studies business models in a more proactive and detailed way. Nevertheless, these two views are in no way contradicting each other, simply observing the issue from slightly different perspectives. Chesbrough argues that there are six essential functions of a business model: 1) identifying the value proposition 2) identifying the market segment 3) defining the value chain and complementary assets 4) specifying the revenue logic 5) positioning the firm by identifying its stakeholders and 6) formulating a competitive strategy. Both Chesbrough and Zott & Amit ask similar questions: what can we offer our customers that is more valuable than what our competitors are offering? How do we

generate revenue? Who are our stakeholders and how do we position ourselves within our network? Chesbrough states that it is important for a firm to know what is truly valuable for customers, who these customers are, how the firm is to distribute the offering, and especially knowing who are the linking suppliers, customers and competitors. (Chesbrough 2007, 13.)

Compared to Zott and Amit's research on business models, Chesbrough presents a slightly more instructive model, which has many similarities to revolutionary business models, such as Gary Hamel's model (2002). Zott and Amit view the business model in larger entities, whereas Chesbrough and Hamel have aimed at dividing the concept into more individual and tangible step-by-step pieces. In relation to biobanks, the most relevant parts of the business model theory by Zott and Amit are efficiency, novelty, complementarities and lock-in, which will be integrated into the framework used in this study.

3.2.2 Components of the business model

As noted by Zott et al. (2011), value can be created and captured efficiently through so called revolutionary business models, which are more adaptable to modern firms that operate in highly competitive and dynamic environments. Some researchers have aimed at simplifying the business model concept due to its complexity, e.g. McGrath (2010), who has stripped down the concept, stating that a business model consists of only two core components: the basic 'unit of business' and 'key metrics' of process or operational advantages for delivering superior performance. Another acclaimed revolutionary business model has been proposed by Gary Hamel in Leading the Revolution (2002), which acts as an exemplary case in this research as well.

Networks are integral parts of business models, and their importance are emphasized in both global and local context; especially the latter linkages are important for raising capital (Gertler & Levitte 2005, 504). In the case of biobanks this is a relevant point, as their funding is based on mostly domestic capital. According to Hamel (2002), companies adapt and develop new business models, in which value is created within a network of, for instance, suppliers, partners, distributors, and other coalitions extending outside the firm's boundaries. He has divided a business concept into four most essential components: 1) customer interface 2) core strategy 3) strategic resources and 4) value network.

All of the components of the business model include subcomponents that specify the ingredients of a bigger "box" (see figure 4). These components are intertwined with each other in order to create a functional entity. This means, that the components are linked to each other with a certain intermediary, which portrays the most relevant aspect between

the components; in this case configuration of activities, customer benefits and company boundaries. (Hamel 2002, 86−95.)

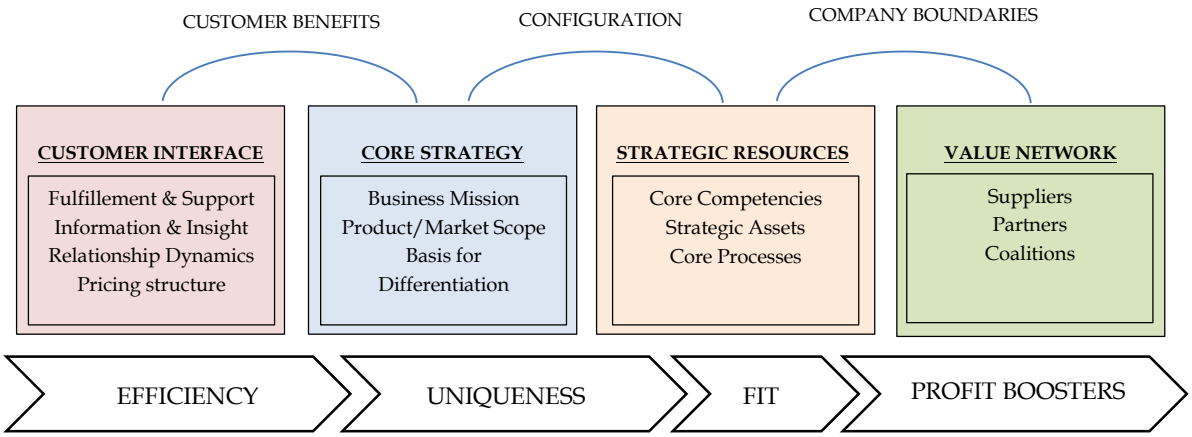

Figure 4 Unpacking the business model (Hamel 2002, 92)

Hamel's most essential business components make a comprehensive framework, but the importance of the components or subcomponents vary from industry to industry, and therefore need to be adapted to the focal company. For instance, customer interface entails issues like how to reach customers, how the knowledge is collected from and utilized on behalf of customers and what kind of interaction there is between producer and customer (Hamel 2002, 80−86). When studying biobanks, the fulfillment and support (how to reach customers) is relevant as the rate of participation is extremely high, and there are many critical ethical issues concerning patient consent practices. Information and insight, meaning the knowledge that is collected and utilized, is crucial for biobanks, as it is the main activity of the operation. From the viewpoint of business, the pricing structure is a very essential aspect of this particular customer interface component. Questions like what to charge for, how much and whether to do it directly or indirectly will be included in the synthesis. This will also be emphasized more in the empirical findings.

Biobanks in Finland operate in a very small market niche and they are highly differentiated organizations with a set mission, therefore the most essential components to study within the core strategy, are product scope and differentiation. In which product segments biobanks compete, or will compete in the future, are of interest from this thesis' perspective. It is equally relevant to study, whether a biobank should specialize in the research of a specific disease or remain a general information data bank in order to be cost efficient or innovative. From the strategic resources –box, the strategic assets of a

biobank will be taken into closer consideration in the synthesis of the theoretical framework, as it is relevant to assess the infrastructure, the potential use of customer data in product and brand creation. Less importance in this case is set on the processes and competencies of biobanks, as in the early phases of biobanks, there is relatively little of both.

The focus of this thesis is the creation of a suitable business model that offers considerable value to its stakeholders, therefore, value network component is crucial. Firms' networks are dynamic relationships between many parties, and they often include different kinds of partnerships and cooperation. Firms may for instance decide to enter into an alliance, which can be recognized in terms of its motivation to exploit either existing capability or to explore new opportunities, which in turn affects new product development. (Rothaermel & Deeds 2004, 202.) The potential cooperation between biobanks and other parties within the industry (pharmaceuticals, biotech companies etc.) as well as inter-industry partners, is of interest in the thesis. Suppliers and possible partners amongst other important stakeholder groups will be emphasized in the synthesis.

According to Hamel (2002, 71), what determines the profit potential of a business model are four underpinning factors: efficiency, uniqueness, fit and profit booster, which are linked between the different components. To summarize, this means that a good business model (no matter which components are stressed), is efficient, unique and creates and enhances profits, and it should be internally consistent, so that all its parts work together towards a common goal (Hamel 2002, 96).

The framework that Hamel has created demonstrates the vital components of a business model in a complete, yet simple fashion. The most crucial elements within the business model components, information and insight, pricing structure, fulfillment and support, product scope and value network in whole, are integrated in the synthesis. These elements are subsequently combined with Zott and Amit's views as a basis for the questionnaire for interviewees.

3.2.3 Business modeling for biotech companies

Hamel, Zott and Amit, Chesbrough and many other scholars have vastly studied business model creation and its conceptualization. The models previously presented in this thesis should have given the reader a brief overview on the subject and its most pressing issues. From the perspective of this thesis, it also seems relevant to implement a business model

to the theoretical framework, which is particularly composed for biotech companies and studying life sciences[1] , as this includes biobanks.

Onetti and Zucchella present their own business model for life science and biotech companies, which aims at creating value and competitive advantage with the "milestone bridge", a simple and effective business-modeling tool (Onetti & Zucchella 2014, 1). Alike the scholars mentioned before, Onetti and Zucchella derive growth and development from innovation, which they find to be the key driver of competitive advantage. They present a managerial tool, which concentrates on three key decisions: *focus* (strategic relevance), *locus* (geographical location) and *modus* (method of operation). These three elements are in the core of what the authors call "the milestone bridge". The milestone bridge joins these three elements with different activities of the firm and assembles them into a matrix, which helps the management to ask the three strategic questions concerning their business activities.

Table 2 Overview of the Milestone Bridge (Onetti & Zucchella 2014, 37)

	Activity list	Focus (strategic importance)	Locus (location of activity)	Modus (mode of execution)
Activity A	Which activities are required?	How much to allocate?	Where?	In-House or third parties? Capital or labor-intensive? How tech-intensive?
Activity B				
Activity C				
…				

Onetti and Zucchella approach the subject of business models from a slightly different perspective than the previously mentioned researchers. Hamel, Zott, Amit and Chesbrough have composed frameworks to be implemented in the business organizational and structural level, whereas Onetti and Zucchella propose to implement these guidelines on the activity level. This means, that the business model is efficient, when these three questions are properly assessed in every important activity within the organization.

[1] Life sciences are a field of science, which studies living organisms, such as plants, animals and human beings.

Where to invest additional resources and from where to divest them, is important to assess when carrying out activities. This prioritization is the key decision in focus, and represents similar elements as Zott and Amit's views on revenue generation and Hamel's core strategy and strategic resources. It also delves into issues of funding and lock-in of investors. According to Onetti and Zucchella, executives must decide the geographical location (locus) or the industrial clusters where the bio company's value-adding activities occur, as well as the method of operation (modus) based on the company's core competencies and cost efficiency. Biotech firms benefit from situating within a cluster due to high innovation density (Coenen, Moodysson & Asheim 2004, 1014). Innovation on its part transforms knowledge into novel wealth-creating technologies, products and services through processes of learning from other members of the cluster (Cooke 2002, 133). This kind of knowledge-transfer is essential when studying biobanks, which often are located in bioclusters. In Finland, most biobanks are also physically within or nearby a university. This is an opportune location, since commercializing knowledge requires information transfer from discovering scientists to those who will develop it commercially. With biotech companies the close proximity to universities supports these objectives (Zucker, Darby & Armstrong 2002, 138).

These dimensions, locus and modus, are deeply interlinked, since they delve into the issue of outsourcing. (Onetti & Zucchella 2014, 39−44.) The decisions to outsource is a strategic one in creating a suitable business model for a company, which entails weighing the cost efficiency of managing an activity in-house as opposed to outsourcing (see e.g. Miller, Schindehutte & Allen 2005, Weerakkody & Irani 2010). Authors Onetti and Zucchella have aimed at creating a framework that helps the management to make this decision as well by categorizing the different activities. The term 'bridge' refers to the objective of the executives: connecting effectively business activities to achieve successive milestones, that "signal value creation for all the company's stakeholders – especially investors" (Onetti & Zucchella 2014, 2), thus linking the model with both, the dialogue of value creation and stakeholders.

In the theoretical framework of this study, all three elements, focus, locus and modus are accounted for. From the point of view of this thesis, questions concerning the investment and divestment of resources, outsourcing of activities and knowledge-transfer are the most relevant when forming the synthesis. These issues are stressed in the questionnaire for the conducted interviews.

3.3 Theoretical framework for studying the business model of a biobank

The business models that have been presented above share partial similarities and differences considering value creation. However, there are equally relevant elements in all of the theories, which be disassembled and combined to apply for biobanks. The integration of the aforementioned business models acts as a theoretical framework and basis for the interview questions.

In this thesis, the combined business model, through which biobanks are studied combines the most relevant parts of the business model theory by Zott and Amit, Hamel and Onetti and Zucchella as follows.

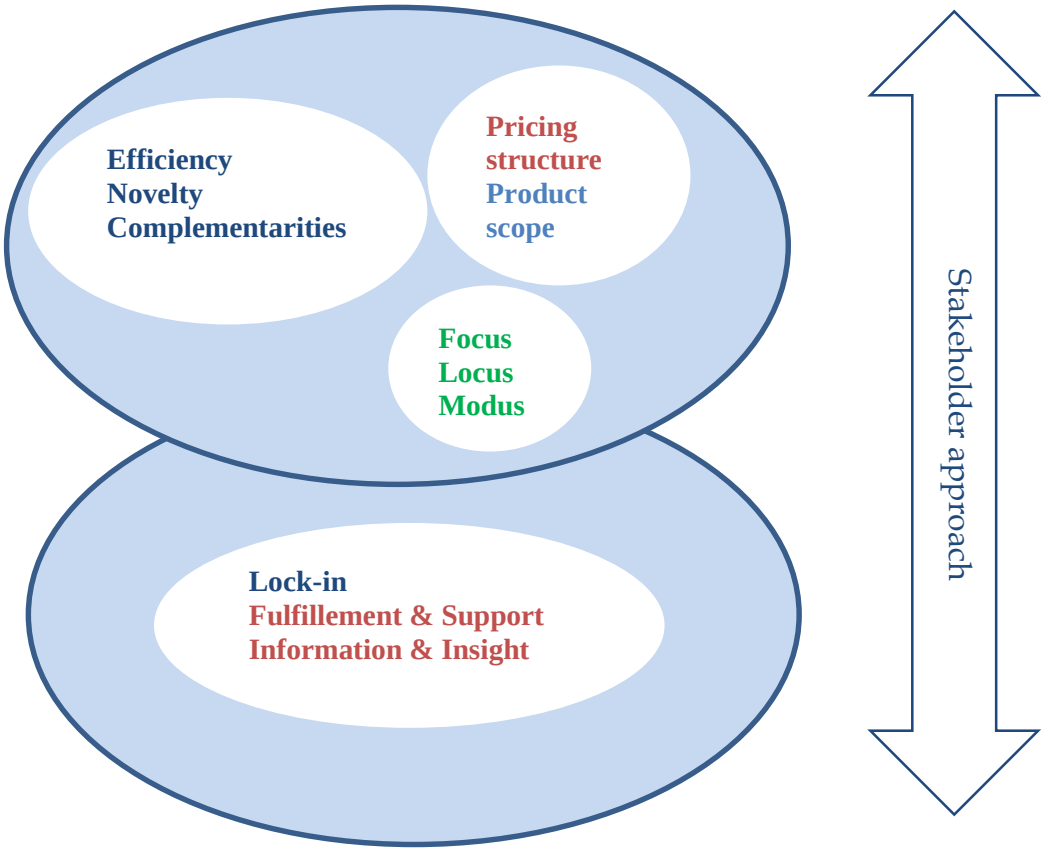

Figure 5 Business model synthesis

Chapter 3.2.1 through 3.2.3 consisted of the illustration of three essential theories and their most relevant aspects considering biobanks. In figure 4, these elements are brought together to form a suitable business model for studying biobanks. The first component unifies the similar aspects concerning the offering and tangible issues of business modelling brought out in the theories by Zott and Amit (blue), Hamel (red) and Onetti and Zucchella (green). The second component of the business model explores less

tangible aspects, including how to maintain the trust of stakeholders and what are the most crucial issues of communication between biobanks and the public. When conducting interviews, these areas are emphasized, and stakeholder approach is highlighted throughout each section.

In the interviews, novelty, product scope and complementarities are discussed in the form of potential products and services mainly through consumer genomics, which is a newly emerged consumer-oriented field of products and services based on genetics. Issues of efficiency and pricing are also depicted according to the interviewees' views, as well as thoughts on location and outsourcing. Lock-in, fulfillment and support, as well as information and insight are assessed in the findings, mostly in the latter part related to the barriers of business model creation.

In the following chapter, the research design of this study is presented. This includes an assessment of the research approach, as well an outline of the data collection and coding. In addition, the chapter analyses the trustworthiness of the study.

4 RESEARCH DESIGN

4.1 Research approach

Choosing a suitable research approach is an essential decision, which should reflect the nature of the research problem and the objectives of the study (Eskola & Suoranta 1998, 14). Within ambiguous contexts, conducting research which addresses many complex and dynamic factors, it is common to use qualitative approach as opposed to quantitative approach. In particular, studying phenomenology, case studies and narratives, in which the objective is to form interpretations of data, qualitative approach is often the most fitting choice. (Creswell 2003, 19.) Respectively, when the research problem calls for drawing causalities between the studied subjects, it is often more purposeful to use quantitative approach. However, these approaches are not mutually exclusive, and can be used in triangulation forming a mixed methods –study (see e.g. Tashakkori & Teddlie 2010).

The purpose of this study is to understand the key elements concerning biobanks' commercial opportunities by forming a suitable business model, and shed light on stakeholders' expectations. This kind of research angle, whose objective is to seek understanding often requires a qualitative approach (see e.g. Stake 1995), where the role of interpretation, flexibility and subjectivity is emphasized (Chakhovic 2013; Cassell & Simon 1994). In this case, qualitative research approach seemed natural, as it suited to study the focal organizations and enabled embedding information in a creative manor into the research. The nature of the study has been mostly descriptive, yet it has a slightly normative approach due to the development ideas presented in the findings and conclusions.

According to Hirsjärvi, Remes and Sajavaara (1997, 165), qualitative research approach aims at gathering information in natural surroundings, supports data collection through individuals, and usually applies an inductive approach. It was essential that interviews were conducted in natural settings for the interviewees, where the individuals could provide natural and uninhibited information regarding their personal experiences. In addition, the goal was to discover and combine new information instead of testing previously set hypotheses, which meets the qualitative approach criteria. Hirsjärvi et al. (1997, 165) also state, that qualitative research is conducted via qualitative methods using carefully select individuals instead of random sampling, and aims at analyzing unique instances instead of generalizing information. The primary method in conducting the study was interviewing beforehand carefully selected experts, who represented different organizations. The feedback they provided was crucial to a creating a holistic perception on the subject, where also individual, and at times divergent, impressions were taken into

account. It is also common for qualitative research that the project process can be quite sporadic and may change courses even to the extent where the research plan changes (Hirsjärvi et al. 1997, 165). Despite a set focus, new potential research objectives and participants may emerge during the process (Marshall & Rossman 1999, 25). Similarly, the research process for this thesis was very dynamic, and it evolved partially according to the findings, and in some cases the lack of findings. This constant cycle of inquiry defined the research problem further.

As illustrated in chapter 2.4, much of the research concerning biobanks' commercial opportunities has emphasized economics and cost accounting, which often relies on quantitative measures. Therefore, the need for a more qualitative approach felt necessary, as it delves deeper in the more intangible aspects of business models. By bringing together the information provided by experts within the industry and combining their insight into business model creation leaves scope for interpretation and subjectivity. Therefore, qualitative research approach seemed most suitable in forming this thesis.

4.2 Data collection and analysis

The research approach of this study was qualitative, as it fitted the research problem and the overall nature of the study. The aim of the research was to include the thoughts of as many biobanks' representatives as possible to assess the business potential of biobanks, and examine the stakeholders' expectations on potential future cooperation. This kind of research approach often requires a qualitative study, especially in cases where there has been little empiric research on the subject, and when the studied phenomenon is topical (Eriksson & Koistinen 2005, 5). Business model creation for biobanks is equally a relatively recent and under-researched topic, which makes it opportune for a qualitative study. In this thesis, the data collection consists of expert interviews, and the findings are their conjecture on the subject. In addition to the biobanks' representatives, substantial emphasis has been put on stakeholders to create a more well-round assessment on the situation. This sort of slightly scattered and complex approach also dictates the research method.

Research method, a set of tools or procedures to form data in practice, sets to answer the larger and theoretical background, methodology (Wahyuni 2012, 72). There many different sources in conducting qualitative research, for instance observations, databases, physical artefacts and surveys (Yin 2003, 83–106; Malterud 2001, 5). In this case however, interviews were chosen as the main source for data collection, as it enabled a more in-depth understanding of the participants' unique thoughts and experiences. The interviewees were chosen to represent one of the three target areas: current biobanks, pending biobanks and external experts or stakeholder group representatives.

It is often essential to conduct expert interviews for gathering high-quality information. These experts are usually deliberately chosen due to their expertise and position within the organization of interest (Muskat, Blackman & Muskat 2012, 11). The interviewees chosen for this thesis represented organizations, whose input was important for the content of the study. The participants' proficiency and knowledge of the field was equally crucial, and their personal contacts furthered the process by adding a few interviewees, who were not thought of beforehand, but whose expertise added considerable value to the thesis. It is suggested that using highly knowledgeable informants who view the phenomenon from different perspectives reduces bias and therefore increases reliability of a study (Eisenhardt & Graebner 2007, 28), which accounts for the number and differing background of the interviewees.

The interviews took place face-to-face and via telephone. Seven face-to-face interviews were conducted, four in Turku and three in Helsinki, between October the 28th 2014 (the pilot interview) and 28th of April 2015. Interviews took place within premises chosen by the interviewee, mostly in work offices, one at a home office and two at restaurants. The face-to-face interview environments were mainly peaceful and the interviews were not disturbed. Two interviews were conducted by telephone, the other being a telephone conference of three participants. Both telephone interviews were insightful, but unfortunately slightly hindered by technical difficulties. Due to these difficulties, the latter interview was not recordable. In addition to face-to-face and telephone interviews, e-mails were sent out to the representatives of biobank initiatives and a representative of Sitra (The Finnish Innovation Fund), to gain information from a larger scope of stakeholders. Two representatives wished to remain anonymous, and are therefore excluded from the table. Altogether, 15 participants' expertise and knowledge were taken into account when collecting data for this study.

Table 3 Table of participants

	Interviewee			Interview	
	Name	**Organization**	**Position in Organization**	**Date and place**	**Length and language**
Face-to-face	Heli Salminen-Mankonen	Auria Biobank	Director	28.10.2014 Office in Turku	38 min Finnish
	Perttu Terho	Auria Biobank	IT engineer	19.2.2015 Office in Turku	24 min Finnish

	Sirpa Soini	THL Biobank	Executive Director	30.3.2015 Company cafeteria in Helsinki	34 min Finnish
	Marjut Ranki-Pesonen	M.I.T. Consulting	Senior consultant	31.3.2015 Home office in Helsinki	42 min Finnish
	Kalervo Väänänen	The University of Turku	Rector	10.4.2015 Office in Turku	15 min Finnish
	Petri Lehto	MSD	Director of policy and communication	17.4.2015 Conference room in Helsinki	50 min Finnish
	Jari Forsström	Abomics Oy	CEO	28.4.2015 Company cafeteria in Turku	55 min Finnish
Telephone	Minna Hendolin	Tekes	Executive director of health and well-being	26.3.2015	27 min Finnish
	Tarja Jalava	Bayer AG	Head of clinical project management (medicine oncology)	15.4.2015	~ 30 min (not recorded) English
	Arndt Schmitz	Bayer AG	Head of research, biobank Bayer		
e-mail response	Tuula Tiihonen	Sitra	Business development director		
	Hanna Tuhkanen	Biobank of Eastern Finland (initiative)	Research Coordinator		
	Teijo Kuopio	Central Finland biobank project	Professor		

The interviews followed a general interview guide approach, which is a common method for data collection, and also known as a semi-structured interview (Hirsjärvi & Hurme 2002, 47). The questions addressed in the interview were mainly semi-structured, complying with the theoretical framework of this thesis (see operationalization of the study in table four; interview structure as appendix). Expert interviews are especially common within semi-structured interviews (Muskat, Blackman & Muskat 2012, 11). This study adopted a non-standardized interview approach, which is a hybrid of open theme interviews with less rigid structure (Wahyuni 2012, 74). The semi-structured questionnaire acted as a framework, which allowed the conversations to develop in a flexible manor without excluding insightful stories or information. Follow-up questions were also made during the interviews mainly to clarify or get more details on the subject. Collecting and processing data happened through a partially deductive and partially abductive manor: the business model theories presented by Zott and Amit (2013), Hamel (2002), Onetti and Zucchella (2014) served as bases for questionnaire. The connection between these elements is presented below in the operationalization table.

Table 4 Operationalization table

Research Objective	Themes	Questions for the interview
Business model creation	Commercial possibilities	How prepared are biobanks for commercial activities? What are the challenges in commercialization? Is specialization beneficial for a biobank's success? Are biobanks cost-efficient organizations?
	Potential offering of biobanks, revenue logic	What kind of products are biobanks offering for patients/customers at the moment? In the future? How do biobanks price their services/products? Has there been conducted market research concerning commercial possibilities? What kind of infrastructure does a biobank have?
		What activities should be outsourced concerning commercial activity? (modus)
		Are there available any complementarities/by-products (e.g. e-services)? What are future possibilities for complementarities? Do future Finnish biobanks have an impact on the others' cost efficiency?
	Lock-in of stakeholders	Who are the most important stakeholders of a biobank? Are there any partnerships between biobanks and stakeholders?
		Is international cooperation between biobanks and stakeholders probable? Examples? (locus)

All the interviews were transcribed into a more comprehensible frame, and the transcriptions were afterwards coded to match the theoretical frameworks. Coding of the

data is often used by researchers, and it can be either open, axial or selective coding (Boeije 2010, 15).) In this study, processing the data followed the open coded path: the material was read through several times, after which labels were created to stand for different themes. To help myself categorize the material, I used simple open coding by "pinning" certain sets or initials of words to thematize the material (e.g. in the parts of transcriptions where the interviewee talked about the potential services provided by biobanks, I added "BP_PALV" [BB_SERV] in brackets after the related chapters). This method is based on what naturally emerges from the data, instead of grounding it into the existing theory. In addition, it also facilitated combining similar answers of the interviewees, which corresponded to the same research questions. However, coding or transcribing is not in any way compulsory in studying qualitative data, yet it is a very common method for analyzing an interview (Hirsjärvi et al. 2001).

Even though the main research approach of this study is qualitative, there are elements of triangulation especially concerning data collection. Secondary sources, such as company websites, were used as well for illustrating company characteristics and financial information, and complementing the findings of the interviews. Pluralism in research methods and triangulation on theory is found to give a more extensive view on information in organizational activity (Hoque, Covaleski & Gooneratne 2013, 1171; Morgan 1988), which was also valid in portraying the biobanks' complex activities and environment.

Processing the information happened more or less simultaneously with reading theory and articles, which modified the learning process into a more interactive one of existing theory and new material. The data collection process was therefore partially abductive (or retroductive), as it combined the use of theory and material (Zachariadis, Scott & Barrett 2013, 855). Some researchers believe that it is the missing link between induction and deduction, where "novelty, innovation and creativity enter the scientific method" (Mingers 2012, 860). This dialogue between theory and existing knowledge of biobanks and the material provided by the interviews resulted in overlapping integration of all sources. The analysis process of the study complied with the model presented by Hirsjärvi et al. (2001), where the analysis process takes place when an explanation or conclusion of the material is presented. In this case, the material provided by the primary and secondary sources were described and combined to answer the research questions. During this process, the material was constantly categorized to facilitate the final steps, where the conclusions were refined.

4.3 Evaluation of the research

It is said, that both quantitative and qualitative approaches have different strengths and weaknesses. According to Lund (2012, 156), implementing qualitative methods creates a more in-depth analysis compared to quantitative methods, whereas quantitative methods may result in better objectivity and generalizability than qualitative ones. Similarly interview as a method for collecting data has its benefits and disadvantages. The great advantage of interviews when comparing to other data collecting methods is the flexibility to monitor and adapt to the situation in the way it requires. However, it can be time-consuming, requires a lot of planning and can include misconceptions and inaccuracies from both the interviewer and interviewee's side. (Hirsjärvi, Remes & Sajavaara 2001, 192−193.)

According to Guba and Lincoln (1998), the evaluation of research and assessing its trustworthiness can be studied through certain parameters: credibility, transferability, dependability and conformability. There are other frameworks for evaluation, and many of them differ depending on the nature of the research method. For instance, quantitative research is often studied with similar factors, yet with an emphasis on external validity: how the outcome can be generalized from a smaller population into a larger one. However, in qualitative research, much emphasis is put on internal validity and reliability.

According to Guba and Lincoln (1998), *credibility* of the research means that the results gathered are equivalent to reality. The interviewees of this study were chosen due to their professional knowledge and extensive information concerning biobanks, which contributes to the credibility of the material. They provided credible information on the subject and the material was ample for analyzing the topic. That said, the credibility of the answers can partially be derived from the neutral presentation of the questions. Another facet of trustworthiness, *transferability* of a work, refers to the generalization of the findings, and its ability to transfer into other settings (Zachariadis, Scott & Barrett 2013, 860). It also refers to the likeness to other pieces of research, and its functional and conceptual equivalence to other pieces of research on the subject (Sinkovics, Elfriede & Ghauri 2008, 696). In this case, studying the statements of other health care professionals and comparing their thoughts to the answers of the interviewees, clear resemblance and transferability can be found. The transferability also emerges when comparing the different interviews of this study; experts working in completely different settings were in many respects unanimous concerning certain issues, especially the challenges of biobanks' commercial opportunities and their barriers. However, as biobanks are newly established and rare organizations in Finland, they are partially studied as cases in this research, and much like many case studies, they are not unequivocally transferable to other cases (Stake 1998). The outcomes of this study are dependent on very unique research targets, which makes the generalization of some of the results fruitless. Even

though there are many similarities between biobanks in Finland, they operate in different settings and there are many local and implicit characteristics which should be taken into account when making assumptions.

Studying theory and background resulted in forming the research questions and conducting the interview. The primary and secondary material provided was fused together as well as to the existing theory, and enabled the analysis and conclusion of the study; all in all, the research process progressed logically. The sources used are listed in the references, and the questions and interviews are also archived and therefore traceable, which guarantees the *dependability* of the study. In addition, all the results are based on the material provided by the interviewees or data published by biobanks and institutions, such as the Finnish Funding Agency for Innovation, the EU and the National Supervisory Authority for Welfare and Health, as well as other relevant health care industry actors. This *conformability* of a research means that the results are derived from the material available instead of being a product of the imagination. (Guba & Lincoln 1998, 213−214; Zachariadis et al. 2013, 860−861.)

Most of the interview environments were opportune, as they guaranteed privacy. Subjectively, the interviews progressed smoothly without outside disturbances, with the exception of a few technical problems of telephone interviews. The interviewees were forthcoming and communicative and the relaxed communication ensured a more extensive content, than solely answering to the questions would have provided. All in all, the interviews followed a logical and clear path. Nevertheless, there are factors, which can be criticized to have had a potentially negative impact on the quality of the interviews.

Even though the course of the interviews was effortless and even enthusiastic, at times both the interviewer and the interviewee delving into the interesting topics talked past subject, which can have a negative impact on the quality. Also, at times the conversations reflected even strong individual sentiments. However, the role of a researcher as "faceless" and neutral participant is much under debate as well, and many a researcher acknowledges that none of us are "tabula rasa"; we all have a frame of reference in life, and many even suggest, that disclosing ourselves into a truthful and subjective discourse enables us to learn from the interviewee more, as well as ourselves (Fontana & Frey 1994, 373–374). Even though some of the information was slightly beside the focus, it helped me as a researcher understand several implicit matters I would not have acknowledged under a more structured interview situation. Some scholars refer to research as a construction called 'bricolage', which is constructed by the researcher, the so called 'bricoleur'. This means that a research constantly evolves during the research process, and cannot be fully planned beforehand. What makes a good qualitative research, is the ability of the researcher to create flexible and adaptive conjecture. (Eriksson & Koistinen 2005.) Conducting a study which had not been reflected much before in this context, required this kind of versatile approach and an unrestricted interview environment.

Perhaps one of the most confrontational aspect of conducting the interviews was the broad spectrum of interviewees. As some of the interviewees worked in a biobank as opposed to other interviewees who presented stakeholders, questions had to be adapted accordingly, as naturally the interviewees had different degrees of knowledge concerning biobanks' activities. This might to some extent affect the internal validity of the study. However, adapting slightly the questionnaire was necessary in order to conduct a logical and coherent interview, where the most important issues were included, and respectively less valid aspects (for examples questions the interviewee would not be able to answer due to differing backgrounds) were excluded. Internal validity may also be affected by the participants' strong individual perceptions on the issues and natural bias. However, the same quality ensures the deep and diverse insights concerning the subject.

A researcher's own personal knowledge on the subject affects the trustworthiness of the study immensely. When collecting useful data for research purposes, it is necessary for the researcher to develop as much their own expertise concerning relevant topic areas as possible in order to ask informed questions (Qu & Dumay 2011, 239). In introspection, I strived to take my time during the preliminary phase of the study, and get as much acquainted with the material as possible before jumping into the data collection. Aiming for the most reliable results, I wished to have gotten even deeper within the subject when collecting the data for the thesis. However, when the results start to show saturation, as they did, researcher has to finish collecting material and start analysing it to avoid wasting resources. In the following chapter, these analyses are presented according to the research problems.

5 BUSINESS MODELING FOR FINNISH BIOBANKS

5.1 The future of Finnish biobanks

The pharmaceutical industry is going through substantial changes. It is more and more challenging to develop medicines with traditional means and the standards are increasingly higher. Biobanks and genome informatics are expected to provide new solutions for personalized, highly individual, healthcare. However, biobanks are new organizations, who have yet to realize their commercial potential.

Concerning the preconditions of creating viable business models for biobanks, the interviewees concur with many of the points brought out in the literature review in chapters one through three. For instance, globally examined, the participants find the Finnish bio- and IT know-how and the healthcare network one of the greatest advantages in forming secure environment for biobanks. More particularly, the perseverant long-term collection of high-quality health records, their linkage to clinical patient data, and the collection and analysis of samples are seen as the most crucial requirements for well-functioning activities in Finnish biobanks, without which commercial opportunities would be non-existent.

A general optimism prevails in the discussion concerning potential business activities of biobanks. However, the interviewees cautiously address the hype around biobanks and their business potential.

> *We are not yet fully prepared for commercial activities; however, I believe that with considered actions we have the potential to engage in significant business in due time.*

Alike, most of the interviewees agree that the general preparedness of Finnish biobanks is not advanced enough to engage in actual business endeavours. Some attribute this to the lack of business orientation in the traditions of academic circles. However, there is a growing approval for such activities among scientists, as many have come to realize the importance of cooperation with the pharmaceutical industry and other collaborators.

The interviewees unanimously feel, that the most crucial factor underlying all possible business activity, is the unique trust and cooperation of the citizens. Globally, people are far more sceptic towards the government collecting personal data, and the participation rates are low. In Finland however, people are relatively open-minded towards medical cooperation, which is the foundation for all biobanking activities. It is also the prerequisite for potential commercial activity as well. One interviewee expressed their concern of the

commercialization, stating that "'commercialization of biobanks' is an unclear definition and troublesome in terms of image. By profiling themselves as commercial actors, there is a fear of losing the patients' conformity, which biobanks cannot afford to do. It is more relevant to study biobanks as pillars for universities and for national research and innovation systems, instead of seeing them as independent actors in business life". Another interviewee agrees by pointing out, that maintaining the trust of the public is the biggest challenge for the development of biobanks. If overlooked, it would be detrimental to all biobank activities, and hope for generating business would be completely lost in the process.

In retrospect, the hospital systems have been introvert and withholding of data; now the emergence of modern e-solutions for prescriptions and patient systems enable more realistically a comprehensive biobanking system. According to the interviewees, business activities of biobanks have a lot of potential due to the long-term national health record collections combined with the data gathered by biobanks, which accumulates into a rich material pool. This constitutes a good backbone for developing personalized medicine with tailored treatments and products for patients.

5.2 Commercial potential of biobanks

5.2.1 Novelty and focus of biobanks

The *novelty* of biobanks, in other words their innovation value, has generated general hopefulness concerning future success of biobanks. Interviewees concur nearly unanimously, that innovation is the foundation for value creation and a baseline for the development of products and services. However, there are many unresolved question marks concerning biobanks' activities and possibilities to conduct business, as the biobanks have been operating a relatively short period of time.

According to the interviewees, the only realistic sources of profits are samples and particularly the related data. The potential products and services are based on samples, which are refined in biobanks. Biobanks may gain profit derived from samples in three ways: by selling the sample itself, the analysis or data based on the sample, or alternatively both. Several of the interviewees state, that commerce of data is the key to future biobanking success. Most participants emphasize, that a more appropriate name for biobanks would be "bioinfobanks" or "biodatabanks", considering the importance of the research data. A participant mentions, that:

> *business is the selling of refined information, not tinkering samples. Of course it is important, that the samples are appropriately processed, but it is not business. Business is taking the specimen with all the related attachments and creating something new of it.*

Participants share this view, and accentuate, that information is the leverage within the industry, and a source for long-term success. Based on the interviews, commercial activities of biobanks can be categorized into individual transactions, or long-term "commercial" partnerships – a division brought up in the literature review as value capture or value creation. Value capture is a onetime, transaction-related event, involving shifting value from previous shareholders/stakeholders to the acquiring firm's stakeholders. For example, selling individual sets of samples or data to a pharmaceutical company is a one-time transaction without further commitment to a business relationship, whereas value creation is a longer-term approach where parties commit to having a longer relationship with several transaction of assets. This view is based upon managerial action and the transfer of capabilities between firms through mechanisms of resource sharing, functional skills transfer and general management capability. For instance, the cooperation between biobanks and pharmaceuticals to commit to a common research project, may take long periods and include countless and continuous transfers of assets. In reality, however, most business activities will probably fall into both categories in the future, where biobanks gain from individual business deals and simultaneously engage in long-term partnerships.

Value capture, individual transactions in layman's terms, is however perceived by most interviewees as a less sustainable option for developing business in the long-term.

> *Marketing simply "specimens-for-sale" can be seen as slightly short-sighted business model, which eventually will create very little value for the biobank.*

When developing a business model, it is essential to decide on which markets to enter and which product segments to choose, i.e. specify the *focus* of activities. Generally in economics, specialization is favoured in boosting economic activity and cost-efficiency. In this instance, several interviewees state, that it is irrelevant to assess whether biobanks should specialize in the research of certain diseases, or to remain general biobanks. They believe, that often these decisions are subconscious, as the environment dictates the orientation of the biobank, and the biobanks evolves around what comes naturally from the university's research background. Some on the other hand disagree and find it relevant in creating comprehensive medical knowledge. These participants state, that when providing holistic treatment, it is important that there are biobanks with broader research

areas, as well as those with a certain specialty complementing one another. A participant feels, that specializing completely in the analysis of one specific disease, reduces market opportunities, and it is natural to specialize in a certain area, if there is substantial existing knowledge or possibly on-going research within the network of a particular biobank. However, this may restrict the infrastructure, which is disadvantageous for the biobank.

> *The two options are in no way mutually exclusive. From the viewpoint of research and potential commercial possibilities, I prefer the general clinical biobank concept, as it enables combining information in a much inclusive manor, and it facilitates the acquisition of new information.*

Most interviewees share this similar view, that the two can, and should, coexist and complement each other. A participant states, that from purely business view, specialization limits the customer base. On the other hand, if you decide to remain a general clinical biobank, you must see to it, that when you offer everything, you have to have the expertise to cover all areas; you must be prepared to answer the patients' questions and concerns. A few of the participants mention, that from a purely commercial point of view, specializing in cancer research might be the most profitable mode of operation. What supports this view, is the uncommon Finnish disease heritage, meaning that there are many rare hereditary diseases, which are clearly more prevalent in Finland than anywhere else in the world (The Family Federation of Finland 2015). An interviewee stresses, that biobanks are in a key position in the research of these rare diseases, as we can more easily gather data concerning them. The population of Finland has been very isolated compared to many other countries, which has created a more homogeneous genetic heritage. From the international business point of view, the situation has an upside: if researchers, pharmaceuticals or even a foreign government wishes to understand and develop treatments to the diseases caused by these gene mutations, they can for instance ask for a population sample of a hundred from Finnish biobanks, as opposed to a sample of a thousand that they would have to get from some other country with more diverse genetics. Nevertheless, it is very feasible to deepen the knowledge concerning these uncommon diseases without particularly revolving all activities and reputation around them, adds an interviewee.

An interviewee emphasizes, that the most critical issue is for every biobank to have their own clear strategy, which is based on individual strengths – a principle, which applies to all business. Without these kinds of "information clusters" it is challenging to fund all biobanking activities. Another interviewee shifts the focus to the core issue, by stating that

> *the important thing is, that there is a comprehensive amount of high-quality samples, which are sensibly structured and well linked with the continuously cumulative data.*

Those interviewees who believe, that specializing is a more profitable option, specify that representatives of pharmaceutical companies have clearly emphasized the importance of chronic diseases, which strain the public health as a channel for developing potential products or services. It is profitable for pharmaceutical companies to focus on mass diseases like diabetes and cardiovascular diseases, and by developing more preventive services, pharmaceuticals could change their whole revenue logic.

An interviewee suggests, that this is a question of IT-infrastructure, which can either enable the smart cooperation between all biobanks, or let them alternatively remain inefficiently separate.

> *In a country this small, it would be smart to have access to all information. There should be access points, otherwise the spectrum is too wide. It could work so, that biobanks could specialize in certain areas, but the samples and data would be accessible to all. Biobank information system could be general, while the individual biobanks could be specialized.*

Overall, the interviewees seem to feel, that the question is not crucial, as the orientation of the biobank comes naturally based on comparative advantage of research and the background of universities. However, it seems worth noticing, that opinions vary vastly within a relatively small field, of what constitutes a good basis for business models of biobanks.

5.2.2 Efficiency and pricing-related considerations

The literature review summarized, that when creating a long-term business model, novelty coupled with either differentiation or cost leadership is essential. Starting out, Finnish biobanks are dealing with the same issues of funding, costs and profits. *Efficiency* is measured based on transaction cost theory: efficiency creates value when the transaction costs of a biobank are low. The interviewees ponder over efficiency-related issues, through the different possibilities of sample pricing to outsourcing.

The principle revenue flow comes from selling the samples or related information to another authorized party. The law requires transparent and equal *pricing*, which most likely will reflect the original cost price, and adapt to the principles of a non-profit organizations. Profits from samples are used to keep the activities rolling and funding

research projects. Currently, the sample volume is seen relatively small, which in practice makes the large-scale commercial activity too expensive. An interviewee states that simplistically, 300 samples would be 300 times cheaper than one. As long as the volume is some twenty samples per month, the price is high. Generally speaking, if the sample volume was high systematically, it would cost basically nothing and the benefits would be high.

A participant feels, that pricing is a substantial issue in many publicly funded organizations, who ponder over productization. Currently, public pricing mechanism includes bidding in order to remove possible illegalities. Developing the commercial aspects of biobanks and entering free markets could create a need for creating new systems and changes in the whole pricing process. The participant believes, that public organizations might not be ready for that kind of innovation.

Another participant, according to whom many experts dismiss too quickly the opportunities commercialization presents, adds that the healthcare industry is sometimes too afraid of commercial possibilities. The interviewee points out, that the outcome should be appropriately priced, in order to make it appealing for top researchers to become involved, and get funding for their research projects. When this is done properly, all parties benefit.

Yet, there is much to be developed within the financial planning of biobanks in the long run. Several interviewees pinpoint, that one of the most essential part is establishing a solid pricing structure, which could differ from the current cost pricing, or at least include markup for small profit. A participant adds, that it should also be taken into account from everyday activities to long-term financial business planning, that the resources differ vastly from one another; some biobanks can afford to be more flexible than others.

There are many other aspects which should be taken into account when creating a cost efficient business model. For example, a few of the interviewees underline, that biobanks which are located within or close to hospital premises obtain synergy gains and cost-efficiency, which is crucial in developing a business model in the long-term.

> *Having nearby the required equipment and personnel, and agreeing to use sources of both organizations to mutual advantage, is a possibility that detached biobanks do not have.*

In practice, synergies are gained when for instance patients attending the laboratory are taken an additional biobank sample enabling the biobank to save in sampling infrastructure costs. Even though the location does not pose a substantial issue for the business planning of Finnish biobanks – as all current and pending biobanks are situated within or close to hospital premises – possibilities of the synergies of coexisting is valid

to think beforehand. Moreover, it is reasonable to take into account, that many synergies cannot be recognized before the actual activities start taking place.

5.2.3 Products of consumer genomics

When creating a business model, molding the core strategy, including deciding on the *product scope* and market segments, is essential. The starting point for Finnish biobanks seems, that currently there is very little innovative business activity. At this point the general idea of how biobanks will engage in business in the upcoming years is processing and selling the data based on samples. However, there are differing ideas on what the services or products in practice will be. There is much speculation of different products or services (or a combination of the two), which are offered to customers in addition of the core service a firm, i.e. *complementarities*, which can be anything from e-services to home-delivered DNA-kits. This chapter conjectures especially the latter possibility mirroring it to a similar innovation in the USA.

Many of the interviewees bring up the possibilities offered by a relatively new field called consumer genomics, where individual consumers are offered gene tests and related services. Consumer genomic services can be offered directly to the consumer or through an intermediary like a pharmacy. They can also be offered with assistance of healthcare professionals, who together with the customer, would go through the results. Some interviewees contemplate DNA services similar to the American company called 23andMe, who offers individual customers health and ancestry reports, which helps them understand their own genetic information. 2 A few of the interviewees estimate that in a few years, these kinds of services will become routine in the health care scene, and by taking into account the increasing interest of the public concerning their heritage, biobanks could become a forerunner in the field. A participant reflects on the possibilities of the concept:

> *The patient could be informed of the possibilities of further DNA services along with the biobank concept. Emphasizing the possibility of receiving more personalized medicine, the patient could be offered a*

[2] 23andMe works as a partial self-service concept, where the customer orders a DNA kit, takes their own saliva sample and sends it back to the company for analysis. Afterwards, the customer can access their home page for genetic information including a general overview on the individual's genetics, as well as information concerning DNA relatives and ancestry. (23andMe, 2015.)

> *pharmacogenomics panel, which takes into consideration the individual's genetic variation in relation to the treatment or the medicine. The panel would be processed in a company like ours, the data would be downloaded and analyzed, and finally offered to the patient, for instance in a mobile application form. The thought is not far off, as it is already been done in the States.*

The interviewee adds, that this could be a stepping stone for other business activity that cannot be yet realized, including innovations within the diagnostics and medical industry, as well as application development. Regardless, there are many sensitive areas legally and from the viewpoint of health care, if such projects were launched in the Finnish markets.

The first version of 23andMe was shelved due to concerns of the officials, and similar concerns would probably be voiced in Finland. Few of the interviewees state, that it is problematic to find, where to draw the line between information which can be safely disclosed to the patient, and which cannot; unclear procedures concerning sensitive information is threat to the development of such services. Launching similar DNA services based on the biobanks' information requires a thorough examination of the Biobank Act, and particularly the patient's right to receive information regarding their health.

> *This is about finding the right and safe practices. It is important not to divulge information, which can be harmful to the individual's health or the treatment. --- I believe that it is only a matter of time when these services start appearing - at a reasonable price.*

Interviewees emphasize, that there is a growing interest of individualized genomics among citizens. People are more and more aware of the new possibilities of attaining genetic information which, however, may result in under-the-counter action, as happened in the US before approving the concept. Interviewees flash the thought of perhaps instead of – or concurrently with – analyzing highly delicate issues like the heredity of cancer, the service could be modified to address less delicate issues. People are interested in knowing what kind of people there are in their family trees; whether there have been musical talents, whether they are the only red heads in the family, or how they have inherited their eye colouring. There is definitely a growing market for such services, but so far few to produce them. Even though pharmaceuticals are perceived as most potential business partners due to their market power, interviewees also emphasize that biobanks should 'think outside the box', and consider more innovations from the perspective of the actual consumer. An interviewee sees much potential with combining biobanks'

resources with the know-how of, for example, health centers' doctors. This could provide surprising innovations for patients.

The bundling of resources and capabilities results in new products and services (or a combination of the two), which are offered to customers in addition of the core service a firm. The interviewees feel, that these complementarities have not been relevant in the early phases, but will become increasingly a topic of interest as the core activities are established. Complementarities alike often result in efficiency, at least, from the customer's point of view. However, it is still a challenge to figure out, what exactly are the possibilities of biobanks and what kind of services can be offered in the future. Most of the interviewees concur, that consumer genomics has its possibilities in the Finnish markets, but there are many challenges, which can even overthrow business opportunities for biobanks.

5.2.4 Location and mode of operation

Outsourcing is a crucial matter in business model creation and it is equally relevant for biobanks. The decision of where different activities are located and the decision of whether perform the activities themselves, or turn to a third partner sets the mode of operation for biobanks. These cooperation opportunities continuously come up in interviews, and participants brainstorm of different kinds of partnerships. The aforementioned views in previous chapters have mainly revolved around the discussion of samples versus data as a source of business activity. Furthermore, two other operation modes are brought up in the interviews: project-based mode and rental mode, through which samples or information can be shared.

A project-centred view is a natural option for biobanks due to the nature of medical research. Salminen-Mankonen, the director of Auria biobank, states that for now the goal for the biobank has not been acquiring licenses, but mostly developing collaborative projects. Auria announced its commencing cooperation with Bayer Pharma AG in cancer research in April 2015, with the goal to increase knowledge of cancer cells and develop more efficient treatments. Similar cooperation opportunities are emphasized in all interviews: working together with different stakeholders affects vitally all areas of business model creation.

> *It is important at the moment, that we understand the business opportunities presented by partnerships, especially in recognizing the mechanisms of diseases. By cooperating, we can for example trade expertise: one offers gene sequencing services and the other samples and*

> *knowledge. Without this step, it is hard to develop tangible consumer products or services.*

Zucker, Darby and Armstrong (2002, 21) state, that new knowledge tends to be developed in tacit form, which often leads to joint research. This allows tacit information to be better captured in team production by scientists. An interviewee feels, that there is a lot of tacit information within biobanks' network, and now when the activities are still molding, joint research would support the development.

Interviewees underline, that decisions from what to produce and how to price it, how to be cost efficient and what to outsource to the quality of the service or product outcome, are all affected by cooperation. Cooperation opportunities can present themselves in different forms. Several interviewees contemplate the possibilities of 'contract research', a strategic partenership between the biobank, a pharmaceutical company and a research group. The research group would bring the added value, as renowned scientists and first-rate research goups increase the project's reputation and consequently its value in the market. However, another cooperation possibility could be 'record research', in which the pharmaceutical company would be offered access to anonymous data bases. This would exclude the need for a research group.

Several interviewees reflect on the possible cooperation between biobanks, pharmaceuticals and biobank-spawned start-ups. In case the pharmaceutical was only interested in the results, the analysis know-how could be provided by an analysis start-up. In addition to the benefits it provides the biobank and the partner, such cooperation could create demand for a new kind of core competence. Nevertheless, both straight forward cooperation or via intermediary (be it either a big pharmaceutical or a start-up), are seen viable options for business activity. A few of the interviewees also bring up the option of a so called 'rental mode', which refers to the possibility for the partner to acquire information or samples sporadically when needed. This way, the partner can turn to a biobank in a looser manor for individual data or sets of samples. The option can however be seen as additional service, which can be realized alongside a project, as issues may arise spontaneously during a project. Nonetheless, without precedence of such a model, an interviewee finds it challenging to assess beforehand how convenient this option would be in practise. The participant contemplates, that a rental option is more ambiguous than other options from a legal point of view.

Outsourcing of certain activities is perceived generally prudent for business development. An interviewee highlights, that biobanks should concentrate only on the core activities, and use genome consultants for further services. The consultant firms are able to integrate the biobank data into the technological systems and form, for example, strategies of how to sequence the genome data for everyone's benefit. The interviewee stresses, that consultants could link the biobank to the right contacts, projects and

products. The participant adds, that they might even have an outsider's slightly more objective perspective on what should not be focused on, what projects are out of date. DNA isolation and sequencing are mentioned as the most suitable activities for outsourcing by several interviewees. Outsourcing or collaborating regarding these areas with close-by hospitals create synergies; yet, a participant stresses, that with the current vague understanding of the biobank's own agendas, outsourcing is fruitless. The participant adds, that outsourcing too is a matter of financial resources, and biobanks should first and foremost stabilize their needs, before thinking about cooperation opportunities.

In addition to commercial partnerships, business development is perceived contingent upon the cooperation between biobanks themselves. This aspect is emphasized strongly in most interviews: the participants feel, that without working well together, the value of an individual biobank is nearly insignificant. An interviewee sees cooperation willingness between a biobank and a commercial partner notably easier to find, than between biobanks themselves. Another participant adds, that when there is the possibility of making profit, organizations are naturally willing to cooperate; yet, much more crucial and challenging would be to get the biobanks cooperating with each other.

Tightening the cooperation of biobanks will facilitate creating for example e-services. Several interviewees feel, that the first scenario could be the integration of biobank information with current electronic portals. If biobanks had access points to each other's data, they could integrate their information concerning a patient, and combine it with the information in the e-service My Kanta, a portal for medical records and electronic prescriptions.3 This could be developed into a comprehensive bank of medical records combined with genetic and lifestyle information, and the records concerning how and where the samples and related data have been handled. In practice however, these applications pose many juridical issues, and require extensive sorting through before any kinds of implementation can take place. Nevertheless, without the cooperation between biobanks, the possibility for innovation is severely limited, and Finnish biobanks will not meet even the current expectations or "hype" around them.

The importance of value network, including cooperation and partnerships with other organizations and between biobanks, distinctly emerges as a green leaf for biobanking business opportunities. The interviewees nearly unanimously feel, that without developing a collective agenda between biobanks, and enhancing the general positive atmosphere towards collaboration, the possibilities for creating long-term commercial relationships will remain limited.

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[3] [3] My Kanta is a portal of electronic prescriptions and medical records collected from both public and private healthcare. (Kansallinen Terveysarkisto (Kanta) 2015)

5.3 Barriers for developing business models

5.3.1 Lack of established procedures

Particularly three major barriers related to establishing actual business activities come up in the interviews: the lack of business orientation and the lack of marketing and information channels. These issues also comply with the latter part of the theoretical framework, which consists of information and insight, lock-in, as well as fulfilment and support. Business activities of biobanks are still taking baby steps and many issues are unclear; however it seems, that the barriers for developing business are clearer at this point. The challenges and limitations are constantly emphasized in the interviews, and most of the interviewees feel, that without clearing up these barriers that are already generally acknowledged, it is futile to think of business innovations. Therefore, the most important barriers are discussed in this chapter, in order to understand what issues lie behind the previously discussed possibilities.

The most compelling shortcoming seems the lack of experience in this new field: there is very little understanding currently of all the business possibilities without actual established procedures. A participant stresses the fact that many people working in key positions within biobanks are overloaded with tasks, and have taken on the biobank activities on the side of other jobs.

> *There is a million things to do, and no one is fully taking responsibility of the business development. We should understand commercial requirements, sniff around the markets and really comprehend the needs of the pharmaceutical industry. We should realize our niche, and the added value we offer. We are lacking a strategy.*

Few others concur, stating that currently commercial opportunities are a haze, and there should be a clearer division between the business entity, legal entity, and other activities. There also needs to be clearer assessments of the ownership structure and public-private partnerships. The biobank concept is new and therefore founded a bit problematic from the point of view of customers. To develop business activities, biobanks have to find out the needs of customers, which is even more problematic when the organizations themselves do not know what they want out of the project. However, a participant supposes this will get easier as the customers become more aware of the possibilities offered by consumer genomics.

Information and insight, which refers to the knowledge that is collected and utilized, is a core issue for biobanks at the moment. The interviewees find the most tangible

deficiency to be the lack of a common IT infrastructure between biobanks, which would enable a smooth information flow between biobanks. Generally, the integration of data between biobanks is perceived crucial for all individual biobanks, and the whole network. Especially the sharing of best practices, including what the more advanced biobanks have realized to be important, and moreover, what are the pitfalls of activities. A participant finds it extremely cost-inefficient, that biobanks have their own personnel for developing their own systems, and many stress, how a smooth information flow within the network would reduce transaction costs. Nonetheless, a participant accentuates, that the integration is not so simply done, and many things cannot "copy-pasted" to other biobanks, due to many structural differences. Even though integrating the IT systems will be challenging, it is essential especially in studying rare diseases, as the amount of samples per individual biobank might not suffice, another participant adds. Transforming all documents and forms into electronic form is also mentioned as essential for the integration of information systems.

> *The national biobank network [BBMRI] is working on establishing common procedures and information databases for all biobanks. In the beginning, it is crucial to have processed/ harmonized information regarding samples and have a common database of available data for researchers. In addition, it is important to develop consistent quality system practices.*

The interviewees also emphasize the importance of a much larger IT infrastructures between different biobanks and potentially other stakeholders, which would enable the sharing of commensurate numbers and information from all organizations resulting in cost-efficiency. An interviewee considers that, for example, launching a cooperative society could enable maximal benefits by sharing data between hospital districts, universities and other parties. In reality, combining IT resources will probably prove to be challenging: researchers need to have access, a channel, to utilize the information without compromising patient confidentiality. Nevertheless, it is generally acknowledged, that the IT interface should be opened up for integration – a vision advocated also by the recently published national genome strategy. The most recently founded biobank, Academic Medical Center Helsinki Biobank, has taken this integral step into account by building the infrastructure from the start compatible with the other Finnish biobanks.

Information channels are linked with the *lock-in* of stakeholders, as without a properly functioning information sharing system, it is difficult to ensure people's loyalty and good thought of the organization. It is essential to communicate to all stakeholders from patients to investors in a transparent way, as commercialization of biobanks raises very

divergent attitudes. This so called good thought of the organization is vulnerable at the moment according to a few of the interviewees, who bring up certain attitude-related issues, which hinder the development of the integration of information systems, and business activities in a larger sense. Several participants express their worry concerning the cooperation between biobanks and note, that there is a certain amount of self-absorption, which they find toxic for collaboration. A participant refers to the current mindset of biobanks as playing around in one's own sandpit kicking away the other children, who would like to borrow a play shovel. Another interviewee finds it natural for biobanks wanting to "guard their secrets", but highlights, that they are in no way compromised even if the cooperation would get tighter. A participant accentuates, that

> *at the moment biobanks are pursuing their own agendas and forget the importance of cooperation, which is natural due to incentives. They should be changed in order for each biobank to be able to gain from sharing information. If biobanks start to isolate in any way, they will lose their chance.*

Regardless the differences of mindset, the publishing of the national genome strategy is expected to have a positive impact in creating a more optimistic state towards cooperation and even commitment to the same goals. A few of the participants emphasize, that they have felt the collaboration evolving constantly towards a better state.

Developing a business model for biobanks faces prejudice: some interviewees feel, that there is a deep aversion towards all commercialization amongst researchers and doctors. Some feel, that there is a primitive reaction: no to all commercial! An interviewee criticizes people for forgetting, that before the medicines can be purchased from a pharmacy, there is a long product development process before that, in which biobanks could have an integral part. Naturally, there is a wide spectrum of attitudes: one participant mentions receiving strong criticism as a result from active participation with commercial actors, another however has received much support and encouragement from peers, but admits, that the reserved attitude is very common. Another participant adds, that it is not so much as the lack of business orientation in the traditions of academic circles, but more the fear and lack of courage to be the first to do things right in this field. Another interviewee agrees, stating that in Finland we are often in a holding pattern, waiting for the rest of the world to show us how these things are done, after which we try to copy them and certainly are left behind. All in all, it seems that all of the important decisions are a question of whether we have the courage to invest in them, and the decisions come from higher up, because biobanks are mainly publicly funded, highlights one participant.

One interviewee wonders, why people in this industry are so scared of the word ‘business’, stating that it is like a swear word in some circles. Another participant adds, that it should be understood that collaboration with commercial partners benefits everyone from the organizations to researchers and particularly patients. Interviewees summarize, that there is a definite lack of strategic marketing due to the absent business orientation and partially the lack of resources. In addition, a few of the interviewees emphasize prudence around the general enthusiasm around biobanks. They state, there is much a so called “hype” around them, but biobanks are still in an elementary phase.

> *Indicators for measuring health advantages should be developed more actively. There is much talk about improving people’s health, but I am missing the dialogue concerning actual health economic evaluation.*

Another related aspect brought up in the interviews, is the lack of information channels. How to reach customers is at the core of *fulfillment and support* –component of the theoretical framework. At the moment, the participation rate of patients is high, but biobanks wish for increasingly more participation from the citizens. Biobanks revolve around delicate, personal issues and therefore maintaining the trust of patients is crucial. There are many critical ethical issues concerning patient consent practices, which are often discussed in the general biobank discussion.

Even though Finns are internationally compared willing to cooperate in medical studies and donating samples, people tend to get more sceptical when business activities become involved, and even more so when there is talk of international business. A participant accentuates, that the citizens should be actively informed of the activities to maintain their trust, and convince them that the samples are not sold cheaply to international big pharmaceuticals. This would be beneficial for the information and support elements of the business model, which would in turn reflect on the lock-in stakeholders. In commercial activities communication may prove to be a bottleneck; the researchers, companies and citizens should be informed of what biobanks can offer, but campaigning is naturally challenging without resources.

> *We need more commercial know-how to complement the current medical and research knowledge. There is also much to develop in communication: biobanks could use people with stakeholder expertise, as it is difficult to view things from an outsider’s perspective.*

Altogether, interviewees feel that information and marketing channels should be actively developed, and most feel, that biobanks should resource more experts to deal with the business entity of biobanks. The interviewees state, that whether individual

biobanks develop their own business entities or there will be one central business unit, remains to be seen.

5.3.2 Juridical barriers for developing the product scope

The interviewees are mostly very satisfied with the Finnish Biobank Act and find it advanced compared to many other biobanking laws and regulations around the world. In practice, there are some barriers, which come up in the conversations as hindering elements towards developing consumer genomic services and products.

Information security is perceived as the biggest challenge in everyday activities, and particularly in creating services and products. According to the interviewees, there is no room for error, when it comes to patient information. Some concern regarding e-services and online consumer products' information security is raised in the conversations. The data stored in biobanks is highly sensitive, and therefore it is a likely candidate for hacking. A participant emphasizes the importance of building reliable databases and properly investing in their upkeep, as the likelihood of these unpleasant situations appearing will increase in time.

Even though the participants praise the Biobank Act itself, some find other legislation a slowing element for biobanking activities. The information security should be taken seriously, but there is a worry, that if the regulations get tighter, the bureaucracy will increase and stifle the innovation development. A few of the interviewees feel, that Finns are too eager to regulate organizational activities, making it difficult for a newcomer to build a business from scratch. In addition, an interviewee mentions that in Finland there is a detailed Biobank Act, but the officials and the Ethics Committee interpret it very differently. The participant adds, that these parties should give biobanks more time to mould their activities, without jumping in with ethical guidelines. Especially the Finnish registrar legislation is a target of frustration of several interviewees; it is very likely that when decisions have to be made, the Biobanks Act can be in contradiction, for instance, with the Social Insurance Institution of Finland (Kela). Consequently, the processes will be lengthy and thus repel potential big pharmaceuticals, who are fast-paced in their activities.

From a juridical point of view, some interviewees find the current form of patient consent malfunctioning. They underline, that there should be no patient consents, which are bound to individual biobanks, but the consents should be applicable on a national level to all other Finnish biobanks. Currently, if a patient gives their consent to a local biobank and moves to another part of Finland, the information is in away "left behind", or at least it is not handily recovered. Several interviewees reprehend the system, stating that it does not serve any purposes. A participant forms their thoughts adamantly: either the patient

wants to be all in, or completely out, which means that a willing patient should give their consent to all biobanks simultaneously in order to receive the best possible treatment. Regardless, a few of the critics comprehend, that this juridical problem may well be sorted out if a national IT system is taken into use between biobanks.

Many of the participants consider the biobanks' success to be contingent upon the functionality of Finnish politics and decision-making on a higher level. There is some reprimand towards the operational environment of biobanks: participants emphasize that encouragement from the government is needed and particularly predictability concerning the biobanks' activities and jurisdiction. It is seen important from the point of view of companies and especially foreign partners and investors. An interviewee finds it crucial to have a clearly established operational environment for biobanks, since it will decrease risk of losing companies and investors to other countries' biobanking systems, which they might find more stable.

5.3.3 Challenges of international partnerships as a mode of operation

A particular aspect related to the *location* and *mode* of operation distinguishes itself from the discussion: the partnerships between biobanks and international pharmaceutical companies. They are seen as one of the most potential collaboration forms, yet it undisputedly needs development in order to function. Nevertheless, interviewees find international business opportunities increasingly realistic for biobanks, and most emphasize, that some amount of international business activity will take place shortly in the form of individual research partnerships, but large-scale international business planning is absent for the being time.

Interviewees unanimously underline the importance of creating a "one window" principle for big pharmaceuticals. This means opening up access points to Finnish biobanks for information transfer and enhancing cooperation between them. In practice, this could be enabled with a common IT infrastructure, which is currently lacking. This intertwines the discussion back to the *information and insight* of a business model, yet with an international perspective.

An interviewee's concern is that currently, when a foreign partner or investor looks at the Finnish biobanking system, they will find it too scattered and most will not be interested in collaborating with individual biobanks, which naturally does not promote the *lock-in* of international partners. The interviewee adds, that generally, companies are looking for national-wide solutions when it comes to biobanking. Another participant reinforces the view stating that

> *we should have one portal, like a phone number, behind which we have stored all the offering of Finnish biobanks. In practice, this means harmonized information systems, practices and policies, and preferably systematic marketing of biobanks as integral part of Finnish know-how.*

If a "one window" principle was introduced in Finland, it would facilitate the lock-in of potential international partners, i.e. prevent the migration of customers and strategic partners to competitors. In this case, the threat is to lose potential partners to other Nordic biobanks. An interviewee considers the "one window" principle the most essential part in international business creation, stating that cooperation will most probably take place through the bigger biobanks, to which the smaller biobanks are linked purposefully, according to the area of study. The interviewee also states, that sprinkling public resources sporadically to all biobanks is a waste, which the country cannot afford to do. Another interviewee agrees by stating, that some of the smaller biobanks cannot take responsibility, with the exception of certain narrow fields of research, and pharmaceuticals probably will turn to those biobanks with ample resources and coverage of population.

This view is supported by the so called hub-and-spoke model, which is advocated in many industries to increase efficiency and simplify the network. The core idea in hub-and-spoke is to arrange the system to have units linked to a central hub by spokes, forming a wheel. In this scenario, all Finnish biobanks would be linked, most likely through a common IT infrastructure, to a central unit, where collected samples would be sent for analysis and storage. This model is implemented in biobanks around the world from Netherlands to South-Africa (see e.g. Bruinenberg, Frey, Napier & Summers 2014). Ultimately, it seems that the decision comes down to finding a way to introduce a common information infrastructure between biobanks.

There are several other hindering elements the participants list, including foreign countries' legislation. An interviewee mentions, that adjusting a Finnish biobank's activities to an industrial customer's domestic legislation is a highly sensitive area; the regulations can be much tighter in other countries, and the differences should therefore be taken into account beforehand. Another interviewee adds, that even though it is self-evident that legislations of different countries differ from each other, the business potential can be completely stifled in certain areas, which should accordingly be excluded from the target market agenda of Finnish biobanks.

Even though the uncommon genetic Finnish heritage makes the domestic biobanks likely to be sought after in the research of rare diseases, there are much larger databases around the world, which is one of the reasons, why the importance of marketing is constantly emphasized in the interviews. A few of the interviewees contemplate, that properly investing in marketing and communications is overlooked in the public sector,

or there just is not enough resources to begin with. In addition, a few of the interviewees voices their concern towards the business mentality in Finland. A participant states, that

> *big pharmas proceed quickly in their activities. They move along like a train: the pace is fast, yet consistent. Finland's great handicap is that we have so few, who have relevant experience regarding the business culture of international pharmaceutical companies.*

Several participants suggest caution when promoting biobanks and some even reprimand exuberant advertising, which has partially taken place in the media. An interviewee points out, that Finns have a tendency to start basking in their success when something develops in a positive manor, and they forget to evolve, when others will eventually pass by. Another interviewee adds, that few realize, that there is a competition situation taking place, as the other Nordic countries are equally developing their biobanking systems.

Nevertheless, the Finnish biobank Act appears to have certain elements favouring it to other Nordic countries' biobanks solutions, based on NordForsk's report (2014). From the point of view of international collaboration, delivering samples and information abroad is self-evidently important. However, Iceland, Sweden and Norway are subject to stricter regulations concerning delivery of samples and data abroad for research purposes (no record of Denmark in this criterion). In Sweden, delivering abroad samples requires an application and an ethical review, and similarly in Iceland and Norway, an approval needs to be submitted; whereas in Finland the initial consent by the patient allows cross-border cooperation. This would suggest, that other Nordic countries currently face a lengthier process than Finnish biobanks, when wanting to develop international opportunities in biobanking.

Overall, the participants feel that pursuing actively international opportunities is justified after the activities are established in the domestic markets, and the other critical barriers for business activity more or less removed. However, there is some resistance towards this kind of subtle approach: a few of the interviewees feel that there should be an idea or a preliminary strategy prepared concerning future market areas and cooperation, and at least some feeling about the international opportunities. The national genome strategy is believed to advance the situation; nevertheless, the interviewees feel that more should be done, especially regarding the common information infrastructure, and investing in marketing and commercial expertise.

6 CONCLUSIONS

6.1 Connecting the theoretical framework with the empiria

The aim of this thesis was to develop a suitable business model for optimal value creation for biobanks. In order to combine a suitable framework for biobanks, different business model theories applicable for this research topic were used as a basis of the framework. The most important elements of these theories were selected and combined for the theoretical framework for business model creation of biobanks.

The business model framework for biobanks suggests, that there are two relevant components when studying biobanks: a more tangible component, which covers mainly the product (or service) scope and related internal issues, and a less tangible component with more external elements, including communication with stakeholders.

In the empirical findings, the novelty and focus -related discussion is mainly brainstorming of the interviewees of how biobanks should engage in business. This element of the business model is one of the most blurry ones to depict, as it seems that participants have divergent views on the actual business potential of biobanks and decisions like whether or not to specialize in the research of certain diseases. The pricing and efficiency of biobanks has stronger roots in existing regulation set by the government for biobanks, and therefore there is less speculation on the topic. On the other hand, decisions of location and mode of operation stirred more discussion, and especially the possibilities of different kinds of partnerships and outsourcing possibilities were discussed.

The sub-objectives of the thesis takes into a closer focus the previously mentioned product scope, as the innovations which stem from consumer genomics are the most potential sources of future revenue for biobanks, as well as barriers which affect the business model throughout. These barriers are discussed from the viewpoint of theoretical framework's latter component, which consists of lock-in, information and insight, as well as support and fulfilment.

Consumer genomics and potential products, services and complementarities are discussed mostly through an example of a US-based company's DNA service, in the lack of similar one in the domestic markets. The purpose of the example is to show the possibilities of innovations in the biotechnology industry, and extend the thought play to Finnish markets. The findings suggest, that there is a growing interest among citizens for such services, but there are perhaps more hindering elements in practice, including unclear legal issues regarding the launching of such services. In addition to legal obstacles, the findings conclude that lock-in of stakeholders is severely limited due to the

lack of a common IT infrastructure, as well as the lack of marketing know-how within biobanks.

There is an endless amount of considerations when forming a business model, therefore it is safe to say, that some relevant aspects may have been overlooked in this thesis. Because biobanks are new organizations and there is relatively little research regarding them, the bridging of theory to empiria was slightly challenging. Nevertheless, the interviews and e-mail answers provided by experts working in the field indicates, that the elements brought out in the findings are in fact hot topics within the current biobank discussion, and therefore need to be emphasized clearly in the findings as separate issues. The lack of previous research or theories should not be seen as a downside, but rather a challenge for future researchers. The different issues discussed by the interviewees can act as a supportive element in the discussion for developing biobanks' business in the future.

Regardless of the theoretical framework, the focus of the study slightly shifts towards practical implications, as the interviewees had numerous development suggestions for biobanks in practice. The next chapter concludes the practical implications and these further suggestions for future research.

6.2 The practical implications and suggestions for further study

The interviews showed clear enthusiasm of the subject of the study, but there is much uncertainty and doubt around the business potential of biobanks. The interviewees emphasize mostly practical suggestions for further development by underlining current handicaps of biobanks, which the biobanks' management should take into account when developing long-term business plans for biobanks.

The most essential improvement which stands out, is creating a national information transfer system between biobanks. This is crucial in order to meet the biobanks' most important objectives: provide best possible treatment to patients and develop research. Being the most potential business partners, international pharmaceuticals should see Finland as a unity instead of individual dispersed biobank units. By sharing information between biobanks in an efficient and extensive way, sharing a common IT system or finding other ways to seamlessly transfer samples and data, this is best enabled. Also sharing best practices is seen important for the cooperation between biobanks. Understanding the cooperation opportunities within and outside of the industry is also vital for the development of biobanks: besides pharmaceuticals, smaller start-ups, offering diagnostics, technological and consulting services perceived as potential partners.

A need for more commercial expertise and business know-how derives from the discussions, and especially marketing and communication specialists. Also with the exception of a few individuals, stakeholder-savvy key personnel are lacking in biobanks. Nevertheless, even more significant barriers for creating sustainable business models seem to be juridical issues and differences of attitudes and priorities amongst biobanks and individuals. There is dissatisfaction towards the general entrepreneurial and innovative atmosphere, which is affected by the Finnish legislation, as well as contradicting registries and ethical committees. Participants hope for a freer atmosphere surrounding biobanks in order to let them mould their activities and find a natural balance. In addition, there are set ideals within the academic community regarding the integrity of researchers and biobanks, which some even find hostile towards individuals, who are more inclined to map the commercial possibilities of biobanks. Therefore, participants stress a holistic understanding of the benefits that could be generated, and hope for a better dialogue between biobanks and stakeholders. A tight collaboration between biobanks is unanimously hoped for; yet it seems that there is more incentive to ensure personal gain instead of developing a common agenda. However, this is seen to have improved, partially due to the national genome strategy, and will be emphasized more in the newer biobanks' modes of operation.

Biobanks' potential to become an engine for the Finnish medical industry has been taken seriously and it has received much positive attention. Despite the general enthusiasm, some participants advice caution, as it is crucial to act fast and consistently.

> *Someone said that biobanks are a gold mine. A fellow of mine said, that they are like a pile of ore; worthless without refinement and enrichment. Becoming a pioneer is determined by our ability to act quickly.*

In addition to purely business model development, the scope of research could be expanded into other areas as a cross-department study. This could offer insight to the individual handicaps of certain areas in biobanking, which are currently seen so strongly. Integrating for example information technology research or a juridical study with the commercial development side of biobanks would be beneficial for a holistic understanding of the situation.

Regardless of the theoretical aspects, the findings suggest, that cross-industrial understanding is inevitable if biobanks wish to develop their activities and reach their own goals. Currently biobanks want to develop cooperation between each other, but the information sharing is underdeveloped. This clearly suggests, that the organizations' management need to consult a third party IT-provider to start developing an efficient channel for communication, or alternatively establish a common IT unit. Similarly, this

study suggests, that there is a need for a marketing unit (whether a common one or not) to substantially improve the communication between biobanks and their stakeholders.

7 SUMMARY

Biobanks stir currently much discussion in the Finnish media due their original operations and innovation value within the healthcare industry. There is much enthusiasm – even hype – revolving around the potential of biobanks, but also critique and scepticism towards certain practical obstacles, which are seen as threats for the development of biobanks.

Currently the product scope of biobanks is severely limited, yet there are visions of what kinds of products and services biobanks can offer in the near future, which include mainly e-services integrated into the databases of national archives and the data gathered by other biobanks. Further in the future, the possibilities of consumer genomics is seen potential in Finland as well: consumer-oriented genome services including self-service DNA-kits with attached diagnostic services are reality in today's healthcare scene in the States. There is a growing interest among the Finnish population for similar services, which suggests, that further research on the subject is valid.

Regardless of the potential of biobanks, there is much discussion on the barriers for biobank development, and many improvement suggestions, most essential being the lack of a national information transfer system between biobanks. In addition to the importance of information sharing and synergy gains for biobanks, this is crucial from the viewpoint of international business, as the international pharmaceuticals should see Finland as a unity instead of current individual dispersed biobank units. Another equally important challenge lies within the lack of marketing and communication know-how. Maintaining the trust of the citizens is a core issue regarding the overall biobanking activity. Informing them regularly and transparently of biobanks' activities, especially the ones related to commercial activities is crucial. Also other stakeholder groups should be included in this communication. A need for a marketing entity clearly stands out in the findings of the study. However, the lack of public resources and market-orientation severely limits these commercial needs.

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Appendix

Appendix 1: Interview questions

1. How prepared our biobanks for commercial possibilities?
    a. What are the challenges posed by commercialization?
    b. Has there been sufficient market research concerning business opportunities?

2. What are the characteristics of a well-functioning biobanks?

3. Are biobanks currently cost-efficient organizations?
    a. Is it more profitable to specialize in the research of an individual disease or remain a general databank?
    b. What is the impact of establishing new biobanks to the existing ones in terms of efficiency?

4. What are the potential services/products biobanks offer?
    a. What are the possible e-services biobanks may offer in the future?
    b. How do biobanks price their samples?

5. What kind of infrastructure does a biobank have?

6. What are the possible cooperation and outsourcing possibilities of biobanks' activities?

7. What are biobanks' most important stakeholders?
    a. Do biobanks have (tight) international cooperation with other biobanks and stakeholders?

8. What are the most essential barriers for the business development of biobanks?

9. Other feedback