Creating Shared Value through Strategic Biobanking

Public-Private Partnerships in Healthcare

TROLLE VON SYDOW YLENIUS

ANTON AGERBERG
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Anton Agerberg
Trolle von Sydow Yllénius

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SE-100 44 STOCKHOLM
Gemensamt värdeskapande genom strageisk biobankning

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Anton Agerberg
Trolle von Sydow Ylleenius
Abstract
Societies are plagued by growing healthcare expenditures and budgetary constraints. The strategy for solving the issue has been heavily debated, with proposed solutions such as Value-based healthcare (VBHC), Public-Private Partnerships (PPP) and improved medical treatments. A novel concept that aims to improve medical treatment is strategic biobanking. Strategic biobanking is the act of saving biological samples and clinical data for future research. Access to strategic samples can speed up future clinical trials and studies, provide researchers with more useful research material, enable more thorough analyses of biomarkers, facilitate faster drug development, and increase the power of both retrospective analyses and precision medicine.

This thesis studies the shared value effects of a strategic biobanking PPP by drawing on the theoretical fields of VBHC, PPP and Creating Shared Value (CSV).

Specifically, the effects of hospital organisational structure, regulatory framework and public interest on strategic biobanking PPPs was studied.

The research was carried out through a single holistic case study of Karolinska University Hospital in Stockholm, Sweden and multiple pharmaceutical companies, and data was collected through semi-structured interviews. Data analysis was carried out in accordance with the grounded theory framework.

The researchers find that regulatory structure can limit the options when crafting the business model and the industry value proposition for a strategic biobanking PPP. Some strategies on how to deal with these restraints are outlined.

Furthermore, the research highlights the importance of longitudinal data-sets and how a hospital organised according to the VBHC principles is more suitable for implementation of longitudinal sampling routines.

Finally, the research shows that that the concept of CSV can act as guidance for private partner decision making to increase public interest. By adopting principles of transparency regarding financial incentives and motivations, an industry partner can garner increased trust with the general public as well as their public partner. The shared value effects are pronounced, and the study finds that a strategic biobanking PPP moves the boundary for what is scientifically possible for all stakeholders in the healthcare domain.

Key-words
Creating shared value, Strategic CSR, Public-private Partnerships, Value based healthcare, Biobanking
Sammanfattning

Samhällen plågas av skenande sjukvårdskostnader och budgetåtstramningar. Vilken strategi som kan lösa problemet har debatterats flitigt. Lösningar så som Value-based Healthcare (VBHC), Public-Private Partnerships (PPPs) och mer avancerad vård har alla föreslagits som alternativ. Ett nytt koncept som ämnar att förbättra sjukvården är strategisk biobankning. Strategisk biobankning innebär att spara biologiska prover och klinisk data inför framtiden. Detta kan snabba på framtida kliniska prövnings- och studier, förse forskare med mer användbart forskningsmaterial, möjliggöra mer grundliga analyser av biomarkörer, snabbare utveckling av mediciner, samt öka potensen hos både retrospektiva studier och precision medicine.

Denna uppsats studerar gemensamma värdeeffekter hos ett PPP inom strategisk biobanking genom att använda sig av de teoretiska fälten VBHC, PPP och Creating Shared Value (CSV).

Mer specifikt studeras hur PPP inom strategisk biobanking påverkas av sjukhusets organisationsstruktur, rådande regelverk och allmänintresse.


Forskarna finner även att rådande regelverk begränsar möjligheten för utveckling av affärsmodell och värdebjudande gentemot privata partners. Några strategier för att hantera dessa begränsningar tas upp i uppsatsen.

Vidare belyses vikten av longitudinella dataset, och att ett sjukhus vars organisation är strukturierad enligt VBHC-principer är mer lämpligt för implementation av longitudinell provsamlings.

Slutligen finner forskarna att privata CSV-conceptet utgör bra vägledning för privata partners för att skapa allmänintresse. Genom att anamma principer som premierar transparans gentemot sina ekonomiska och strategiska incitament så kan förtroende byggas gentemot allmänheten. De gemensamma värdeeffekterna är tydliga, och forskarna finner att tillgång till en strategisk biobank flyttar gränsen för vad som är vetenskapligt möjligt för alla aktörer i det sjukvårdsrelaterade ekosystemet.

Nyckelord

Creating shared value, Strategic CSR, Public-private Partnerships, Value based healthcare, Biobanking
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Nomenclature

CSR  Corporate Social Responsibility
CSV  Creating shared value
IPU  Integrated practice unit
p2p  Peer-to-peer
PPP  Public-private Partnerships
PR   Public Relations
R&D  Research & Development
SCC  Stockholm County Council
SMB  Stockholm Medical Biobank
VBHC Value-based Health Care
Chapter 1

Introduction

The introduction chapter of this thesis is comprised of two sections. In section 1.1 the reader is provided with the background surrounding the problem handled in the thesis, starting with the broad issue of racing health expenditures and ending with the issue of Public-Private Partnerships (PPP) in healthcare. In section 1.2 the problem statement for the thesis is made, describing e.g. how PPPs in healthcare is under-researched. In section 1.3, the purpose of the thesis as related to the problem statement is specified. In section 1.4 the main research question and sub-questions are stated and motivated. Section 1.5 details the delimitation of the thesis, specifying the scope of the research. Section 1.6 lists definitions and explanations of terms and concepts commonly used in the thesis.

1.1 Background

Rapidly growing healthcare expenditures are major problems in many nations around the world. According to OECD (2015), many nations have experienced healthcare expenditure growth outpacing their GDP growth. OECD fears that the share of GDP spent on healthcare will reach 9% by 2030 and 14% by 2060. According to OECD (2015) and Torchia et al. (2015), this increase is due to four main factors:

1. New technologies, enabling more expensive medical procedures and Research and Development (R&D).

2. Higher income, resulting in greater expectations on high quality care for patients.

3. Population ageing, resulting in more age-related illnesses.

4. Policy changes, increasing the requirements of healthcare services.

These trends are both ubiquitous and undeniable, and it is likely that these trends are unavoidable as societies develop around the world. Ruling out the possibility of changing any of these trends, the issue of rising healthcare expenditure has to be tackled in another manner. In academia, this issue has sparked both debate and research, with researchers from different academic fields weighing in on the topic.

Firstly, researchers studying PPPs have noted that due to these trends—along with budgetary constraints—the public sector can not solve the problem on its own,
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and has been forced to seek the help of the private sector (Roehrich et al., 2014; Torchia et al., 2015; Hofman et al., 2014).

Secondly, solutions have been proposed from researchers within the field of economics. According to Porter and Teisberg (2006), the healthcare system can only succeed if it is reformed and adopts a strategy they call Value-based Healthcare (VBHC). Important steps towards this reformation include: Reorganising healthcare providers, systematically measuring healthcare costs and outcomes, and changing how healthcare providers are compensated for their services (Porter and Thomas H. Lee, 2013). Similar reforms focusing on the healthcare sector’s incentive structure have proven effective in containing healthcare expenditures (OECD, 2015). This kind of reform has been implemented at Karolinska University Hospital in Solna, Sweden. The implementation of VBHC has been highly debated in contemporary Swedish media, with critics stating that costs are too high while the quality is lacking. Critics note that contract arrangement has been unsatisfactory, stemming from public sector inexperience.

The concepts of VBHC and PPP intersect in an interesting way. The value-focused organisational structure presents a possibility for PPPs. While private enterprises have been forced by the capitalist market to provide maximum value, that has not necessarily been the case for public actors. By implementing a value-based model, the goals of public and private actors are more congruent which, in turn, facilitates partnerships (Roehrich et al., 2014).

PPPs involving biobanking is an especially interesting area of study, seeing as how the collection of biomaterial is of large strategic importance to medical research, and efficient PPPs are necessary for public biobanks to be sustainable and competitive (Hofman et al., 2014).

The case to be analysed in this thesis is a PPP—with Karolinska University Hospital as the public partner—which output is the development of a strategic biobank. Strategic biobanking is a novel concept and a subset of biobanking. The focus of strategic biobanking is on storage of biological samples for a long time in preparation for future research. This separates strategic biobanking PPPs from other biobanking PPPs, where research can commence shortly after sample storage.

1.2 Problem Statement

The concept of strategic biobanking is nascent and not thoroughly researched. Experts in the area—interviewed in this thesis—state that strategic biobanking is important for streamlining future medical research and speeding up drug development. However, the incentive for the PPP parties is less direct when samples are saved for an unpredictable future. This creates unique incentives and benefits from strategic biobanking PPPs, but it also requires different strategies and new knowledge.

Moreover, while the potential upsides for PPPs are many, some researchers contend the actual effectiveness of currents PPPs, stating that evidence that puts it into question has been conveniently overlooked (Hsiao, 1994). Thus it is meaningful to explore the prospective effectiveness of a PPP in a strategic biobanking context.

Furthermore, according to a literature review conducted by Torchia et al. (2015), there are important dimensions of healthcare PPPs that are under-researched. These include several factors that influence the synergies between the public and private
partner, such as regulatory structure, public interest, contract arrangement and stakeholder involvement (Torchia et al., 2015).

1.3 Purpose

Firstly, to further explore the under-researched areas indentified by Torchia et al. (2015), the authors have elected to study regulatory structure and public interest, to further describe how these factors interact with synergies and obstacles within healthcare PPPs.

Secondly, in order to explore the contextuality of PPPs, the impact of organisational structure of the public party on PPPs is analysed. Because of Karolinska University Hospital’s organisational structure, the VBHC framework is employed to understand the nature of this interaction.

Finally, in order to study the factor of public interest, a lens from the field of Corporate Social Responsibility (CSR) is applied. Due to the indirect incentives inherent to strategic biobanking, it is meaningful to study indirect long-term value effects across the profit/non-profit boundary through a CSR lens. According to Reich (2002), a PPP can be a powerful tool in a company’s CSR toolbox. Furthermore, Matinheikki et al. (2016) specifically encourages further research to explore the potential of Creating Shared Value (CSV)—a subset of CSR with focus on transparency and strategy—in public and private healthcare collaborations.

Figure 1.1: Strategic biobanking studied in the intersection of three theoretical lenses.

1.4 Research Questions

In order to explore the aforementioned research problem—and to guide the research process—a main research question is formulated:
MRQ: How is shared value attained in strategic biobanking PPPs?

An answer to the main research question is attained by first answering three sub-questions. The sub-questions are as follows:

**RQ1:** What synergistic effects drive shared value creation in a strategic biobanking PPP?

**RQ2:** What obstacles impede shared value creation in a strategic biobanking PPP?

**RQ3:** What contextual factors shape the shared value creation processes of a strategic biobanking PPP?

The first question intends to explore the processes that create tangible shared value in a strategic biobanking PPP. The tangible shared value is the projected practical output of the PPP.

The second question is motivated by the fact that many PPPs do not perform to their full potential because of a number of obstacles that impede satisfactory implementation, and that these obstacles are not sufficiently understood (Torchia et al., 2015).

The third question is important because strategic biobanking PPPs, like all PPPs, are heavily context dependent. Hofman et al. (2014) identify a number of common roadblocks for biobank PPP implementation. However, they are researched without a specific context in mind, and the information regarding their interaction is limited.

Finally, while synergistic effects, obstacles, and contextual factors are partly explored within the field of healthcare PPPs (Roehrich et al., 2014), strategic biobanking PPPs differ in terms of incentive structure, benefits and tangible output. This can, in turn, affect the relevant synergistic effects, obstacles and contextual factors and how they interact with a PPP.

### 1.5 Delimitation

Legal aspects are taken into consideration for practical purposes, but they are not treated at a theoretical level in the thesis. While the authors have access to legal counsel, they do not possess the knowledge to carry out an analysis of legal implications in a meaningful way.

The results of the PPP will not be evaluated. This is due to the time frame of the research, which does not encompass the actual implementation of the proposed PPP case studied in the thesis.

PPP is assumed to be an appropriate approach for Karolinska University Hospital in the case study. The thesis will not evaluate nor compare other options. The authors recognise that PPP might not be the most appropriate solution. It has been recommended that managers make such comparisons to ensure that a PPP is an appropriate approach to any specific problem (Torchia et al., 2015).

When studying the interaction of regulatory effects, only Swedish regulatory structure is studied. This is due to limitation in case availability. This reduces the external validity of the study. However, the effect is mitigated by the fact that the
interaction is described qualitatively, in rich detail (Cook and Campbell, 1979). The reader is provided with information, not just on how Swedish regulations interact with PPPs in healthcare, but on the nature of this interaction in general.

1.6 Definitions

Some of the concepts used in this thesis do not have one agreed upon definition. For the purpose of this thesis, concepts are briefly defined in Table 1.1 to clarify how they are used.

<table>
<thead>
<tr>
<th>Concept</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPP</td>
<td>A partnership where one party is part of the public sector and another is part of the private sector. (For more information, see section 3.1)</td>
</tr>
<tr>
<td>CSR</td>
<td>CSR refers to “...the obligations of businessmen to pursue those policies, to make those decisions, or to follow those lines of action which are desirable in terms of the objectives and values of our society” (Bowen et al., 1953, p.6) (For more information, see section 3.2)</td>
</tr>
<tr>
<td>CSV</td>
<td>A corporate strategy that realises that economic profit and social value are intimately connected, allowing businesses and society to work in symbiosis (Porter and Kramer, 2011). (For more information, see subsection 3.2.1)</td>
</tr>
<tr>
<td>VBHC</td>
<td>A management principle that describes how to organise the healthcare sector to incentivise its actors to compete on patient value, thereby lowering costs and rewarding excellence (Porter and Teisberg, 2006).</td>
</tr>
<tr>
<td>Patient value</td>
<td>A measure of healthcare efficiency, defined by Porter and Teisberg (2006) as: $\text{Patient value} = \frac{\text{Patient health outcomes}}{\text{Dollars spent}}$</td>
</tr>
<tr>
<td>IPU</td>
<td>An organisational unit of a healthcare provider that is based around the patient medical need rather than physician expertise (Porter and Lee, 2013). (For more information, see section 3.3)</td>
</tr>
<tr>
<td>Strategic Biobanking</td>
<td>The act of inductively collecting data (clinical or biological samples) that is not motivated by the research question of a current clinical study, but is instead saved for future research. (For more information, see section 4.2)</td>
</tr>
<tr>
<td>Retrospective analyses</td>
<td>Retrospective analyses are used when the outcome of the studied event is known. Retrospective analyses make use of previously collected historical data to arrive at conclusions. (For more information, see section 4.2.6)</td>
</tr>
<tr>
<td>Prospective analyses</td>
<td>Prospective analyses are used when the outcome of the studied event is not known. Prospective analyses make use of newly collected data to arrive at conclusions. (For more information, see section 4.2.6)</td>
</tr>
<tr>
<td>Longitudinal data</td>
<td>Data regarding the same variables at multiple points in time. For instance, data collected from the same patient at multiple points in time. (For more information, see subsection 4.2.4)</td>
</tr>
<tr>
<td>Informed consent</td>
<td>A consent that has to be given by the patient in order for their sample to be used for any purpose. The patient should be properly informed regarding the implications of consenting before being prompted to do so.</td>
</tr>
<tr>
<td>Biomarker</td>
<td>A measurable state of some biological substance. Biomarkers are used in multiple fields, and are essential to improve diagnoses, prognosis and predictive treatment in the healthcare sector (Hofman et al., 2014).</td>
</tr>
<tr>
<td>Diagnosis group</td>
<td>A diagnosis group is a group of patients that are diagnosed with a condition that belongs to a specific set of diagnoses. The set might consist of a number of diagnoses, or it might consist of one. Karolinska University Hospital structures its IPUs around diagnosis groups. (For more information, see section 4.1)</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>Studies made in clinical research in order to assess behavioural and bio-medical factors. Clinical Trials are necessary to answer certain questions regarding novel drugs, and are required in order to launch a new drug on the Swedish market.</td>
</tr>
</tbody>
</table>

Table 1.1: Definition of concepts.
Chapter 2

Methodology

This chapter begins, in section 2.1, with a brief philosophy of science meta discussion describing the fundamental assumptions for the conducted research. Grounded in the assumptions, the research design and the choice of methods are subsequently presented in section 2.2. In section 2.3, the empirical context in which data collection took place is described. Details regarding data collection are then further elaborated on in section 2.4, while section 2.5 explains how the collected data were analysed. Finally, reports concerning the quality of the conducted research are provided in section 2.6, and ethical considerations are clarified in section 2.7.

2.1 Fundamental Assumptions

In order to identify appropriate methods that are conducive to answering the research questions posed in section 1.4, it is meaningful to determine the fundamental assumptions supporting the research. The philosophical discourse emanates from assumptions regarding: (i) The objectivity of the empirical world and the extent of its dependency on perturbations from humans (ontology) (Halaweh et al., 2008). (ii) Assumptions on how knowledge is created and evaluated (epistemology) (Halaweh et al., 2008).

Morgan and Smircich (1980) provide a framework for mapping philosophical assumptions underpinning research endeavours, within the realm of social sciences, but on a subjectivist-objectivist scale (see Figure 2.1). Using this framework, the core ontological assumption, as well as the basic epistemological stance, were identified to be close to the middle, but with a slight tendency toward objectivism.

More specifically, this thesis explores the complex interaction between multiple stakeholders in the highly contextual field of strategic biobanking PPPs. In order to understand the potential opportunities and obstacles for such an endeavour, a core ontological assumption on reality as a contextual field of information is appropriate. The high contextuality has implications on the core epistemological stance as well. In this thesis, knowledge is created primarily by mapping contexts, and by studying systems, process, and change (Morgan and Smircich, 1980, p.492).
However, it is also important to understand how the social world interacts with the PPP phenomenon. The stakeholders of a PPP have different presuppositions, interests, cultures, and perspectives. The intrinsic dynamics of this interaction was deemed meaningful to explore. Thus, a need for interpretivist and constructionist perspectives were identified as well (Bryman, 2012).

Considering the aforementioned assumptions, and alluding to the issue that the number of studied variables are more numerous than the sources of data, qualitative methods for data collection and data analysis—such as case studies—were deemed conducive (Yin, 1994).

### 2.2 Research Design

The phenomenon under study is a strategic biobanking PPP. The interaction between the social organisations inherent to PPPs constitutes the single unit of analysis of this study. While there are a few recent examples of research in biobank PPPs—see e.g. Hofman et al. (2014)—strategic sampling through a PPP is a novel arrangement.

In Figure 2.2, the overarching research design is depicted. Noteworthy is the dichotomisation of the exploratory and explanatory phases. This is also reflected in the research questions defined in section 1.4. The main research question is a 'how' question and thus aims to explain, while the sub-questions are ‘what’ questions and thus aim to explore (Yin, 1994).

In order to completely understand the research design, and certain concepts like interpretive p2p (peer-to-peer) triangulation, readers are encouraged to revisit Figure 2.2 during the course of reading, and after finishing the chapter.

### 2.2.1 Case Study Research

In this thesis, case study research methods are used as a means to define and frame the main research question, and to guide the choice of the empirical context. Grounding the main research question and the empirical context in the theory of case study research is appropriate as the method copes with situations in which there will be many more variables of interest than data points (Yin, 1994).

Due to the novelty of PPP arrangements in strategic biobanking, a single, holistic case study design was considered ideal for designing the empirical context. This
rationale is supported by Yin (1994). He claims that the single case study design is particularly powerful for documenting unique cases and exploring novel phenomena in social sciences. The single case study design is thus analogous to single exploratory experiments in natural sciences with unique and/or novel character (Yin, 1994).

### 2.2.2 Grounded Theory

In this thesis, grounded theory is used as a general method for conducting qualitative research. Grounded theory is appropriate as it seeks to uncover relevant conditions, as well as to determine how actors respond to changing conditions (Corbin and Strauss, 1990). This resonates with the high contextuality advocated for in section 2.1, and the novelty of the phenomenon advocated for in subsection 2.2.1.

Moreover, due to the aforementioned novelty in studying strategic biobanking PPPs, the data collection and data analysis will commence in an exploratory fashion initially, and theory will be generated inductively from the data analysis (Saunders et al., 2009).

Additionally, the study aims to explain the findings in relation to a deduced theoretical framework. The main literature review will be conducted after the final inductive data analysis, according to Figure 2.2. The data will subsequently be analysed anew through a lens derived from both the literature review and previous data analysis. Analysing the data in this manner is useful to achieve explanatory power (Saunders et al., 2009).

More specifically, Strauss’ approach to grounded theory was followed as it is more structured than Glaser’s approach, and more compatible with abductive (inductive-deductive) methods (Halaweh et al., 2008).
2.2.3 Infusing Grounded Theory in Case Study Research

The combination of Strauss’ grounded theory and case study research aligns with the fundamental assumptions in section 2.1, where a need to encompass multiple epistemological and ontological viewpoints were identified.

The notion that grounded theory and case study research are compatible is supported by the methodological development made by Halaweh et al. (2008). In their paper, they find that Strauss’ approach to grounded theory under interpretive and constructionist assumptions is compatible with case study research.

2.3 Empirical Context

In this section, the empirical context in which the research takes place is described and motivated. See chapter 4 for the detailed empirical case.

Data collection in this single holistic case study takes place in two empirical domains. Namely, the two organisational entities inherent to PPP arrangements: (i) The public party. (ii) The private party. Karolinska University Hospital constitutes the public party, and pharmaceutical companies constitute the private party.

The specific empirical context was decided on after consulting with two experts:

Lena Brynne Director of Stockholm Medical Biobank at Stockholm County Council.

Martin Ingels Head of Industry Collaboration at the Karolinska University Hospital Innovation Center.

Lena Brynne and Martin Ingels provided the authors with guidance and expert input continuously throughout the research process. They also helped arrange the interviews with experts in the two aforementioned empirical domains. Data was collected separately in two phases, one for each empirical domain.

Phase 1: Karolinska University Hospital

It was decided for data collection to commence in the healthcare sector, at Karolinska University Hospital. In the VBHC organisational model at Karolinska University Hospital, similar diagnoses have been aggregated into patient groups → patient flows → themes, where themes constitute the highest hierarchical level. Data collection took place by interviewing two managing chief physicians in two different themes. Consequently, differences, similarities, and generalisability between different themes in the hospital’s organisation could be assessed. The following two themes and chief physicians were contacted and accepted an invitation to participate:

Cancer Theme One of seven themes at Karolinska University Hospital. Interviewee: Anders Ullén, Chief Physician and Managing Director for the Pelvis Cancer Patient Flow at the Karolinska University Hospital. Associate Professor at the Karolinska Institute.
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**Cardiovascular Theme** One of seven themes at Karolinska University Hospital. Interviewee: John Pernow, Chief Physician and R&D Manager at the Cardiovascular Theme at the Karolinska University Hospital. Professor at the Karolinska Institute.

**Phase 2: Pharmaceutical Companies**

Data collection subsequently continued with interviews in the private party domain. The purpose was to understand the private party’s perspective on the prospect of a strategic biobanking PPP. In the healthcare sector interviews, the authors enquired on which competencies, and which kinds of companies, the chief physicians thought were interesting to collaborate with in a hypothetical strategic biobanking PPP. The interviewed companies were selected based on the general recommendations from the chief physicians. The following companies were contacted and accepted an invitation to participate:

**Merck & Co. (MSD)** A USA based multinational pharmaceutical company with approximately 69,000 employees (2018). Interviewees: Magnus Lejelöv, Strategic Accounts Head at MSD in Stockholm; Jennifer Olovson, Associate Director Regional Account Lead at MSD in Stockholm; Åsa Egelstedt, Biobank expert at MSD in Stockholm.

**Astra Zeneca** A British and Swedish multinational pharmaceutical company with 61,100 employees (2019). Interviewees: Karin Gedda, Associate Director at Astra Zeneca in Gothenburg; Joachim Reischl, VP, Head Diagnostic Sciences at Astra Zeneca in Gothenburg.

**Bayer** A German multinational pharmaceutical company with 110,838 employees (2018). Interviewee: Gunnar Brobert, Director in Epidemiology at Bayer in Stockholm. PhD Associate Professor.

By interviewing multiple companies, differences, similarities, and generalisability between the companies, as well as between the public and private, could be assessed.

**NOTE:** Statements made by interviewees are not representative of their respective organisations.

**2.4 Data Collection**

The primary data in this thesis were collected through interviews conducted in the two domains specified in section 2.3. See Table 2.1 for an overview over the conducted interviews. Moreover, the primary data was also complemented by secondary data consisting of data from interviews and workshops, and archival data.

**Primary Data**

Interviews are a highly efficient method to gather rich empirical qualitative data (Eisenhardt and Graebner, 2007). Moreover, according to Corbin and Strauss
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(1990), and Yin (1994), interviews as a method for data collection is appropriate. This agreement on data collection methods between case study researchers and grounded theory researchers further supports the notion that the two methods are compatible.

<table>
<thead>
<tr>
<th>Interview</th>
<th>Type</th>
<th>Interviewees</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer Theme</td>
<td>Vis-à-vis</td>
<td>1</td>
<td>60 minutes</td>
</tr>
<tr>
<td>Cardiovascular Theme</td>
<td>Vis-à-vis</td>
<td>1</td>
<td>90 minutes</td>
</tr>
<tr>
<td>MSD</td>
<td>Vis-à-vis</td>
<td>3</td>
<td>90 minutes</td>
</tr>
<tr>
<td>Astra Zeneca</td>
<td>Teleconference</td>
<td>2</td>
<td>90 minutes</td>
</tr>
<tr>
<td>Bayer</td>
<td>Vis-à-vis</td>
<td>1</td>
<td>90 minutes</td>
</tr>
</tbody>
</table>

Table 2.1: Interviews listed in chronological order with associated information.

Furthermore, it is preferred that the informants have a context-specific expertise regarding the structure of their respective organisation and the nature of different managerial decisions. Not only to collect data regarding which key decision-factors and mechanisms in the interaction between the stakeholders to explore further, but also to mitigate some hazards of data collection through interviews. According to Eisenhardt and Graebner (2007), highly knowledgable informants are less prone to biases such as impression management and retrospective sense-making. Consequently, the interviews were conducted exclusively with individuals in management positions and/or experts—within healthcare and the pharmaceutical industry—as described in section 2.3.

The data collection, as shown in Figure 2.2, belongs to the exploratory part of the research process. In order to facilitate exploration, the interviews were conducted using in-depth methods. In-depth interviews with open-ended questions are appropriate when it is desired that the interviewees build on their responses, talk freely, and are allowed to expand on questions (Saunders et al., 2009).

Allotting 60-90 minutes for each interview allowed the interviewers to mix elements of unstructured and structured interview techniques. A semi-structured approach allows the use of a question frame. This frame can be based on previously collected data, which is in accordance with grounded theory (Corbin and Strauss, 1990). While a pre-written question frame was used, interesting themes that emerged were explored further with follow-up questions. Deviations from the question frame were encouraged and explored as this was deemed conducive to achieve a fuller exploration of the phenomena. However, the interviewers returned to the pre-written question frame when a certain topic was exhausted. The question frames that were used are available in the research database, which is reachable from section 2.6.

Secondary Data

Archival data (see research database), data from two workshops and four meetings with experts Lena Brynne and Martin Ingels (introduced in section 2.3), have assumed a supporting role as secondary data. More specifically, archival data, meetings, and workshops have been used to: (i) Understand regulations and processes related to biobank operations. (ii) To validate some of the findings in the interviews. Only primary data—i.e. data from interviews—were transcribed, coded, and
analysed according to the description in section 2.5.

### 2.5 Data Analysis

In order to understand—and inductively generate theory from—the unstructured interview data, the interviews were recorded, transcribed, and coded. The transcripts were coded according to the grounded theory method outlined by Corbin and Strauss (1990), and later elaborated on by Halaweh et al. (2008). In grounded theory, data analysis begins immediately after the initial data collection. Analysis is necessary from the start as it guides future interviews and observations (Corbin and Strauss, 1990; Cope, 2010; Halaweh et al., 2008).

Coding is done in three steps. Namely, *open coding*, *axial coding*, and *selective coding* (Corbin and Strauss, 1990).

1. **Open Coding**: In *open coding*, data are broken down analytically. The purpose of this step is to break through preconceived notions, subjectivity, and bias. Events, actions, and interactions are compared with others for similarities and differences, and subsequently grouped into categories and sub-categories (Corbin and Strauss, 1990).

2. **Axial Coding**: In *axial coding*, the broken up data from open coding is essentially reassembled (Halaweh et al., 2008). Categories and sub-categories are related and tested against the data, and the coder continues to look for indications of new categories (Corbin and Strauss, 1990).

3. **Selective Coding**: In *selective coding*, the categories are unified into a core category which represents the central phenomenon of the study (Corbin and Strauss, 1990). This process is not completely different to axial coding, but it is done at a higher level of abstraction (Halaweh et al., 2008). Selective coding often occurs in the later stages of studies (Corbin and Strauss, 1990).

Practically, each of these steps constituted its own coding iteration. For each interview, open coding and axial coding were done separately by the two authors. Subsequently, the findings were summarised individually. Readers are encouraged to follow the thought process of the authors by reading the coding memorandums found in the research database. Finally, the analysis and summaries were compared in order to find differences and similarities in how the data were interpreted. Colloquially, the authors refer to this process as *interpretive p2p triangulation*, and its place in the research flow is shown in Figure 2.2.

Having numerous coders independently code data the same way improves the reliability as a common interpretation of data entails agreement on its meaning (Cope, 2010). Conversely, deviations in data interpretation entails disagreement, which is meaningful to explore. When a deviation occurred, the two authors discussed which interpretation, if any, that would represent the combined thought process. The detailed result of the *interpretive p2p triangulation* is also found in the research database.

When the data collection, the exploratory analysis, and the final literature review concluded, a selective coding iteration on all interviews was conducted. In contrast to the exploratory phase of the research, the coding frame now consisted
of predetermined deductive codes grounded in the previous data analysis and the literature. The purpose of the explanatory phase is to verify theory, evaluate causal relationships and build further on the qualitative knowledge from the exploratory part. This final data analysis phase facilitates getting to the core of the main analytic idea of the phenomenon (Corbin and Strauss, 1990). Ideally, the findings can even be conceptualised into a few sentences (Corbin and Strauss, 1990), which is attempted in section 7.1 in the concluding chapter.

2.6 Quality of the Research

The quality of the conducted research was assessed according to a framework presented by Gibbert et al. (2008, p.1467). The framework is grounded in the four criteria for methodological rigour in social science research employed by e.g. Yin (1994) and Cook and Campbell (1979). The criteria are reliability, internal validity, construct validity, and external validity. In the following paragraphs, these criteria are succinctly defined, and the measures that were taken to preserve high research quality are described.

Reliability  The goal of reliability is to minimise errors and biases in case studies (Yin, 1994). In order to reach that goal, transparency and replication is key (Gibbert et al., 2008). High reliability ascertains that the same case study could be repeated in the same context, with the same methods, with the same results (Kidder et al., 1986; Yin, 1994).

Two measures were taken to preserve high reliability: (i) A case study database was set up for complete transparency and replicability. The case study database includes coding memorandums, transcripts, the interpretive p2p triangulation memorandum, archival data, and summarised data generated by archival data, meetings, and workshops. (ii) The participating organisations and the informant names are explicitly given.

Internal validity  Internal validity concerns the plausibility and logical reasoning underpinning arguments for causality (Gibbert et al., 2008). A study with high internal validity provides a compelling argument that the relationship between variables and outcomes are causal, and not spuriously caused by confounding variables (Gibbert et al., 2008; Yin, 1994; Kidder et al., 1986).

In order to preserve internal validity, three measures were taken: (i) Multiple theoretical lenses were used to achieve theory triangulation. The findings were studied in the intersection of PPP, VBHC, and CSV (see Figure 1.1). (ii) The final deductive coding phase (see selective coding in section 2.5) matches the observed patterns from the exploratory phase, with patterns from extant literature. (iii) The case study includes studying two different themes at Karolinska University Hospital, and three different pharmaceutical companies. While this strategy is not explicitly defined as a strategy to increase internal validity by (Gibbert et al., 2008), the authors argue that this strategy does increase internal validity as defined by Gibbert et al. (2008). By collecting data from both the public and the private domain, and

\[https://drive.google.com/drive/folders/1VdMLPKuSM1V5eW72AKbe0ted1raE7HA3?usp=sharing\]
by studying multiple actors within each domain, similarities and deviations can be assessed. Findings that were not consistently observed were discarded, reducing perturbations and spurious causality.

**Construct validity** A research quality criteria concerned with the establishment of correct operational measures for the studied concept (Kidder et al., 1986; Cook and Campbell, 1979). Colloquially, construct validity is the extent to which a study studies what it claims to be studying. According to Yin (1994), case studies are often criticised for inconsiderate operational measures, and for subjective judgements in data collection (Yin, 1994, p.34).

Construct validity was preserved through the following measures: (i) The interpre-tive p2p triangulation is arguably the most important measure taken to minimise the issue of subjective judgements mentioned by Yin (1994). However, converging interpretations between the two authors could, admittedly, also stem from similar subjective judgements. (ii) Data collection circumstances are clearly described and motivated in section 2.3 and section 2.4. (iii) The data analysis procedure is clearly described in section 2.5. Additionally, coding memorandums are available in the re-search database. The coding memorandums elucidate the complete thought process leading to the conclusions. (iv) Transcripts were reviewed by the informants. (v) Drafts were reviewed by the informants and by academic peers. (vi) When applicable, interview data were compared with archival data, and data from meetings and workshops with experts.

**External validity** A research quality criteria concerned with a case study’s generalisability to settings beyond the studied specific context (Yin, 1994). Case study generalisability relies on analytical generalisation, which is the act of analytically generalising qualitative data to some broader theory (Yin, 1994). A single holistic case study design studying a novel phenomenon is inherently ineffective for inferences on generalisability, as only one case in one context is studied. However, describing the case in rich detail, and providing a lucid rationale for the case study context preserves some external validity (Cook and Campbell, 1979).

External validity was preserved—to the extent it was possible with the methodo-logical choices of the research—through the following two measures: (i) A rationale for the choice of a single, holistic case study is provided in section 2.2. The rationale is also supported by the fundamental assumptions in section 2.1. (ii) The case study context is described in great detail. See section 2.3 and chapter 4.

### 2.7 Ethical Considerations

In order to protect the informants’ integrity, the thesis complies with the four ethical guidelines stipulated by the Swedish Research Council (Vetenskapsrådet, 2002). A succinct summary of their codex for ethics in social science research states that: (i) The informants must be well informed about the purpose of the research. (ii) The informants must give their informed consent to participate, based on the purpose of the research mediated by the researchers. (iii) The informants’ confidentiality and integrity must be protected to the extent that is possible. (iv) Gathered information may only be used for the purpose of the research mediated by the researchers.
However, the ethical discourse should also take reliability and transparency into consideration. If the informants are completely anonymous, the data have no agent and could be fabricated. Only through transparency is it possible for a researcher to convince the reader that there were no irregularities in the data collection and analyses. Such irregularities could be e.g. conscious omission or adulteration of data in the analysis, or skewed extrapolation from incomplete data to support some agenda or desired outcome.

Reliability as a case study research quality criteria is elaborated on in section 2.6. Preserving reliability according to the measures described in section 2.6 have implications on the anonymity of the informants. All informants have consented to the transcripts being publicly available. Additionally, the informants were given the opportunity to read and edit their transcripts, and influence the content of any part in the thesis and research database that concerns them, prior to publication.
Chapter 3

Theoretical Background

This chapter aims to give the reader an understanding of the theoretical fields and concepts on which the research gap is identified, the research questions are based, and the perspective of which the analysis is made. Section 3.1 describes PPPs, how the concept is defined, its obstacles and benefits, what current researchers focus on and what they do not focus on. The section subsequently expands on PPPs in biobanking specifically. Section 3.2 describes CSR in general, and goes on to describe CSV, a subset of CSR. Section 3.3 describes the concept of VBHC - how it came to be, what it implies and its effects when implemented.

3.1 Public-Private Partnerships

In recent years, governments have sought to involve the private sector when financing, developing and delivering public infrastructure and services (Roehrich et al., 2014). The resulting collaborations—PPPs—have gained worldwide popularity as a strategy to deliver these services efficiently and effectively (Torchia et al., 2015). Specifically, the popularity of PPPs for the financing, development and delivery of healthcare related services has seen a substantial increase (Barlow et al., 2013). There are several factors that contribute to this trend, e.g. insufficient cost containment for maintenance and renovation of public infrastructure and facilities, and budget constraints (Blanken and Dewulf, 2010). This, along with an increase in healthcare related expenses caused by ageing populations, medical and technological developments and policy changes, causes a great deal of urgency for governments all over the world (Torchia et al., 2015).

The nature of PPPs and what constitutes the boundaries between the public and private sector is topical and frequently discussed (Shleifer, 1998; Hart, 2003). The contentions regarding the nature of PPPs stems, in part, from the lack of a common definition (Hodge and Greve, 2007). While Kernaghan (1993) defines PPPs as a relationship based on cooperation and shared knowledge, information and objectives, it is also defined as a relationship based on shared risks and benefits (Lewis, 2001). Furthermore, Columbia (2003) goes on to define PPPs as not a relationship, but a legally binding contract that facilitates risk sharing of the public and private parties. In their systematic literature review, Torchia et al. (2015) identify seven properties of a PPP that they found were commonly brought up in extant literature: cooperation towards a common objective, shared value creation, long-term relationship and cooperation, and sharing of costs, risks, and benefits.
Beyond these properties, Zhang et al. (2009) suggest that a PPP distinguishes itself from other partnerships in three ways: (i) The partners differ in terms of ownership structure. One party is owned by public stakeholders, while the other is owned by private stakeholders. This has implications on strategic goals and objectives because of the different incentive structures in the public and private sector. (ii) The output of a PPP is public goods and services for the benefit of a third party, the general population. This is different from private partnerships, seeing as the recipient of the partnership output is not a direct client or supplier of either party. (iii) PPPs entail long-term commitment as the partnerships persist over a long period of time (Zhang et al., 2009).

The reason for the governmental inclination towards collaboration with the private sector is fueled by the proposed benefits of PPPs. Governments wish to capitalise on the superior business acumen of the private sector, and to circumvent budget constraints (Roehrich et al., 2014). Partnership with private businesses are seen as an opportunity to access more resources, new competence and higher degree of innovation (Kivleniece and Quelin, 2012). However, the reason for the rise in PPP popularity is in contention, with critics stating that it is used as a policy tool to circumvent budgetary constraints and to shift costs and leaving it to future governments (Winch, 2000).

In addition to an increased governmental desire for PPPs, private businesses have also understood the need for long-term partnerships in the healthcare sector. PPPs have been recognised as important for private businesses’ strategic, long-term objectives. It has also been recognised as a viable strategy to take social responsibility as a part of a corporate citizenship (Reich, 2002).

While the proposed benefits of PPPs are clear, there are a number of obstacles that arise due to the unique nature of the PPP. Lonsdale (2005) suggests that asymmetries of power and information are common in PPPs, and that the general business acumen of private businesses is superior. This causes public parties to assume sub-par roles in PPPs. While public actors seek relationships with private businesses explicitly for their superior expertise and skills, this asymmetry is noted as a problematic factor when evaluating PPPs (Ramiah and Reich, 2006; Akintoye et al., 2003; Dixon et al., 2005), and has to be taken into account during implementation.

In their systematic literature review, Torchia et al. (2015) identify six categories of research in the field of PPPs. These are effectiveness, benefits, public interest, country overview, efficiency and partners. For the purpose of theoretical relevance in this thesis, the state of three of these categories will be described in more detail, namely benefits, public interest and country overview. The reason for this choice is due to the fact that Torchia et al. (2015) highlight a need for further research on the subject of public interest and the impact of regulatory structure on PPPs, and that the study highlights how these factors affect the benefits of a PPP.

Benefits Benefits regarding PPPs are mainly results of synergies between partners. When each sector contributes their available resources and skills, the combination of these factors have the potential of creating better results than a single partner could create on their own (Torchia et al., 2015). The different properties that characterise the public and private sectors enable for a wider array of skills and resources, and consequently more pronounced synergistic effects (Roehrich et al., 2014).
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2014). While the private sector is rich in resources, business acumen and technology, the public sector is rich in infrastructure, public image and regulatory power (UNECE, 2008). PPPs also offer governments a new ability to tackle issues related to healthcare problems that disproportionately affect poor people, such as drug research and development. Targeting these issues would otherwise prove un lucrative (Buse and Waxman, 2001).

Public interest Public interest is important for any PPP, as the public is the recipient of partnership outcomes. The difference in objectives come into play when the issue of public interest is scrutinised. Because the economic incentive that drives the private sector is profit, it can not be assumed that they have public interest in mind (Friend, 2006). Johnston and Gudergan (2007) suggest that all PPPs can be placed along a spectrum, from commercial interest to public image policy and that, unfortunately, many partnerships exist towards the former end. According to Porter and Kramer (2011), this view of economic incentives and social value as polar opposites is not necessarily true, stating that, from strategic long-term perspective, they are one and the same (for more information regarding this, see subsection 3.2.1). Regardless, it is important that PPP implementation and policy development is done with societal welfare and public health in mind (Johnston and Gudergan, 2007).

Country overview Country overview provides important insights regarding how PPPs differ from country to country. Research has been undertaken regarding government organisation, PPP history, PPP efficiency, and current practice (Allard and Cheng, 2009; Vecchi et al., 2010). Research on contextual factors such as culture, population demographics, and regulatory systems is surprisingly scarce, however.

Public-Private Partnerships in Biobanking

Biobanks, or Biological Resource Centres, are repositories of—and suppliers of services related to—biological material such as cells of micro-organisms, plants, animals and humans. Furthermore, they can also contain plasmids, DNA-related information, viruses, genomes and clinical annotations (OECD, 2001).

Access to biological resources of this kind is important in order to better understand diseases and to discover new biomarkers in order to improve diagnostics and to better predict treatment response and are a key resource for the pharmaceutical industry (Mahan et al., 2004; Hofman et al., 2014).

It is generally accepted that biobanks are not completely self-sustainable on their own (Salvaterra and Corfield, 2017). This makes PPPs crucial in order to ensure their long-term sustainability (Riegman et al., 2008).

However, Hofman et al. (2014) identify four main hinderances to biobanking PPPs reaching their full potential. Out of these, only two seem to be unique to PPPs in biobanking, as the other two are also identified for the healthcare sector by Lonsdale (2005) and Zhang et al. (2009) (see section 3.1). The identified roadblocks are: Poor biobank organisation during PPP implementation, evaluation of the cost and value of human samples, asymmetry regarding experience in setting up contracts (also identified by Lonsdale (2005)), and the fact that public and private parties don’t share common objectives (also identified by (Zhang et al., 2009)).
3.2 Corporate Social Responsibility

Corporate social responsibility, CSR, has a rich history. While the discussion regarding the private firm’s responsibility towards society is centuries old, the first usage of CSR term in academic literature is in the 1950’s (Carroll, 1999). The idea of what constitutes CSR has changed over the years. In the 1950’s, Bowen et al. (1953, p.6) defined CSR, then called Social Responsibility: “It refers to the obligations of businessmen to pursue those policies, to make those decisions, or to follow those lines of action which are desirable in terms of the objectives and values of our society”. While the definition is old, it still captures the general idea behind CSR and could serve as a good definition for the reader to understand the theoretical framework as such.

In the modern day, CSR is defined by Sheehy (2015, p.1) as “a type of international private business self-regulation”, and might be considered one of the more general definitions, seeing as it is based in a literature review that studies the definition of CSR. To understand what constitutes CSR, it is interesting to note that today, it is defined in a number of different ways, corollary to the fact that the concept is present in a number of different academic fields. Sheehy (2015) identifies five different academic lenses on CSR: Economics, Business, Law, Political Science and Institutionalism. For the purpose of this thesis, the definitions made in the field of economics will be described in further detail.

In the field of economics, issues related to CSR have been frequently studied (Crifo and Forget, 2012). Despite this, the most common definition of CSR within the field of economics is sacrifice of profits (Reinhardt et al., 2008; McWilliams and Siegel, 2001). This definition is not shared by all economists however, as some argue that there are CSR decisions that actually enhance profits and economic value (Porter and Kramer, 2011, 2006; Crane et al., 2014).

In Milton Friedman’s influential article in New York Times Magazine (1970), he argues that businesses do not have a social responsibility, and that the only responsibility of businesses is to their shareholders (Friedman, 1970). According to later research, it seems that the two concepts are related, and that they are not necessarily dichotomous. Some evidence demonstrate a positive or neutral correlation (Cochran and Wood, 1984; Tang et al., 2012). In general, researchers are not in agreement regarding the impact of CSR on corporate financial performance (McWilliams and Siegel, 2000).

3.2.1 Creating Shared Value

CSV is a subset of the CSR field, and is developed as a response to existing ideas in the CSR field that considered economic value and societal value as exclusive and that they had to be prioritised between, although critics argue that these ideas were present in pre-existing subfields of CSR (Beschorner, 2013; Crane et al., 2014).

First introduced by Porter and Kramer (2006), CSV is a concept that assumes that companies can create economic value and societal or environmental value simultaneously. It is suggested that businesses can achieve this in three ways, namely: (i) By "reconceiving products and markets", i.e. by identifying social problems and finding innovative ways to serve consumers while simultaneously providing societal value (ii) By "redefining productivity in the value chain", i.e. by enhancing the
environmental, social, and economical capabilities of supply chain members. (iii) By “building supportive industry clusters at the company’s locations”, i.e. so that development of specific areas can be facilitated through cooperation with local organisations (Porter and Kramer, 2011, p.3).

For instance, a CSV decision could be to reduce energy consumption (Auld et al., 2008). This reduces environmental impact while also lowering costs for the business.

Unlike traditional CSR initiatives, CSV’s main focus is not on improving reputation. Instead, CSV initiatives distinctly aligns with the overarching corporate strategy. Thus, CSV aims to reconnect company growth and success with social progress and sustainability (Porter and Kramer, 2011).

The potential benefits of the CSV paradigm are debated. On the one hand, Crane et al. (2014) suggests that the CSV concept suffers from several weaknesses. Crane et al. (2014) argue that CSV falsely assumes the alignment between social and economic goals, naïveté about challenges in business compliance, and that its conception of the corporation’s role in society is shallow. Crane et al. (2014) do recognise strengths in the CSV concept as well; The CSV concept is popular among managers, practitioners and academics alike, and it clearly connects business strategy and social goals.

While the empirical evidence for the effectiveness of CSV is still scarce, a case study conducted in the Finnish healthcare sector concluded that a CSV collaboration between a private actor and its surrounding community resulted in improved business opportunities (Matinheikki et al., 2016).

## 3.3 Value-Based Healthcare

VBHC is a management concept introduced by Porter and Teisberg (2006). The concept is introduced as a response and an antidote to what Porter and Teisberg (2006) refer to as a failing healthcare system in USA. The management strategy is based on an idea in which healthcare providers organise around patient value and that the system must be structured so that providing patient value becomes the ultimate incentive for any business within the healthcare sector (Porter and Lee, 2013; Porter and Teisberg, 2006). Porter and Teisberg (2006) define patient value as:

\[
\text{Patient value} = \frac{\text{Patient health outcomes}}{\text{Dollars spent}}
\]

Porter and Thomas H. Lee (2013) suggest that the implementation of this requires three steps, namely:

(i) That hospitals organise into Integrated Practice Units (IPU). IPUs are units that treat patients in their whole cycle of care, from preventive medicine to post-illness rehabilitation. While traditionally, healthcare providers have structured their organisation around physician speciality, IPUs are organised around patient medical needs. IPUs are not only specialised in treating that particular disease, but also treat related conditions that commonly occur with it. This makes IPUs inherently more structured around the patient’s situation and reduces the need for patients to travel between units. (ii) Outcomes and costs for every patient must be systematically measured to ensure that the system can learn from the data and improve patient value. By measuring outcomes and cost over the whole cycle of care, a logical
incentive system arises, where a disease prevented through a less costly procedure is perceived as a better health outcome than a patient being treated after disease outbreak. (iii) If preventive treatment is to be seen as more valuable than expensive treatments, the healthcare providers have to be paid in terms of the whole cycle of care. That means that payment will no longer depend on the amount of treatments, the cost of treatments, or the length of treatment in any individual case. Instead, a price will be set on a certain diagnosis. This incentivises healthcare providers to provide maximum patient value. Smith et al. (2015) states that the concept of patient-centered shared value can prove as great guidance for practitioners when developing new strategies in healthcare.

As for empirical evidence for the effectiveness of VBHC, Nilsson et al. (2017b) find that VBHC principles acted as a trigger for initialising improvements related to treatments, measurements and patient health outcomes. Researchers have found that application of VBHC principles in healthcare have had desired outcomes. Ying et al. (2016) find that outcomes were improved and cost was reduced in the area of thyroid cancer. Similarly, van Deen et al. (2017) find that VBHC principle application to treatment of inflammatory bowel disease yielded fewer treatments, fewer required surgeries, fewer emergency visits, less drugs administered, and reduced cost. Both these cases pertain to healthcare providers that provide a specific and niche healthcare service. For providers of more diverse healthcare services, some research has been done (Nilsson et al., 2017a), but empirical evidence is scarce.
Chapter 4

The Empirical Case: Strategic Biobanking

This chapter describes the empirical case. It makes use of primary data and secondary data, as described in section 2.4. While this chapter could be viewed as a result, it is not directly conducive to answering the research questions. Instead, this chapter’s purpose is to give a thick description of the empirical context. Understanding this context is important in order to properly understand chapter 5. In section 4.1, the different stakeholder groups that have interests related to strategic biobanking PPPs are listed and described. In section 4.2, the strategic biobanking concept is explained. Finally, the chapter is wrapped up in section 4.3 where each stakeholder groups’ interest in strategic biobanking is specified.

4.1 Stakeholder Groups

In the empirical context, the two main stakeholder groups are the public healthcare sector and the private industry. These stakeholders represent the public and private parties in the PPP framework. Considering that one of the focal points of the research is on public interest, patients are an important stakeholder group. Stockholm Medical Biobank (SMB) is central with regards to logistical and legal activity. Additionally, SMB acts as a mediator between the healthcare actors and industry actors. The Swedish Ethics Committee (EPM) is an important public policy enforcer and a key actor in a number of obstacles outlined in chapter 5.

The Patient

The patient needs to be kept as the single most important stakeholder, and the patient’s health should be centerpiece for all decision-making. This notion is also supported by Nishtar (2004). She states that it is critical that the public and private partners in a PPP should focus on societal value rather than their own respective benefit. Unfortunately however, this is not always the case (Hellowell and Pollock, 2009).

From a legal standpoint, a patient always owns his/her own sample, and can thus withdraw consent at any time that he/she wishes. While the samples legally belong to the patient, some decisions could be overridden by a medical professional if they deem that a patient’s choice is counterproductive to that same patient’s well-being.
Public Healthcare

Karolinska University Hospital is a hospital owned by the Stockholm County Council (SCC). The hospital is the largest in Stockholm and one of the largest university hospitals in Europe. With locations in both Solna and Huddinge, Karolinska University Hospital has 1600 hospital beds and an annual revenue of around 18 billion SEK (approximately 1.7 billion EUR\(^1\)). Additionally, Karolinska University Hospital’s is a university hospital. Beyond providing healthcare, they are also a provider of education and academic research.

Karolinska University Hospital offers highly advanced medical care. Consequently, they have high expectations from the SCC to provide this. Not only to the citizens of Stockholm County, but also to citizens in other parts of Sweden and other countries where medical expertise is lacking.

Moreover, Karolinska University Hospital is organised with the philosophy of VBHC in mind. The organisation is organised around patient medical needs instead of around physician expertise. Specifically, they have organised in IPUs, where patients with a certain diagnosis are treated for the duration of their stay in the diagnosis group associated with their condition. However, patient health is unpredictable—while the IPUs are designed to treat the majority of conditions related to the diagnosis—there are cases where patients have to switch IPUs to get appropriate care.

The diagnosis groups of Karolinska University Hospital are structured into three hierarchical levels. The highest hierarchical level are themes. Karolinska University Hospital consists of seven themes: Ageing, Cancer, Children & Women’s health, Cardiovascular, Inflammation & Infection, Neuro, and Trauma & Reparative medicine. At the second level are patient flows. These, in turn, contain multiple patient groups. Karolinska is structured into 290 patient groups.

Private Industry

The private industry constitutes the private party in the PPP framework. After communicating with experts in the area, it was decided that companies specialised in pharmaceutical and diagnostics would be highly interesting to collaborate with in a strategic biobanking PPP. Firstly, these companies have a high interest in the actual samples. Secondly, they spend a considerable amount of resources on R&D to improve e.g. drugs and treatments. Finally, they have competencies that complement the public sector.

The Biobank

SMB is responsible for providing biobank services for the public, the industry, and all healthcare providers in the Stockholm County. Biobank services include sample storage, sample handling, and sample traceability services. SMBs overarching goal is to aid the progress of medical research and diagnostics optimisation. In extension, this creates new medical technology and treatments, which increases patient value. Hofman et al. (2014) categorises biobanks into two groups: (i) Bio repositories, which act as an interface between research and healthcare, stocking and delivering biospecimen. (ii) Integrated biobanks, which are more intimately linked to research.

\(^1\)Based on an exchange rate of 1 SEK 0.09 EUR (2019-06-01)
facilities, providing expertise and conducting their own research. SMB does not immediately fit into one of these categories. While SMB does not conduct research on its own, they provide expertise and services related to biobanking. Additionally, SMB also has the right to deny extradition requests at its own discretion.

**The Ethics Committee**

The mission of the ethics committee is to defend the patient in research. Ethical examinations are done for all research trials that involve humans, but also for research involving other biological material or personal information. The ethics committee ascertains that such research-related activities are conducted in accordance with ethical guidelines.

Thus, the ethics committee has to approve all sample extradition, sample routines, and clinical trials. The committee also ensures that the associated informed consent reflects the purpose of the research, and that it is complete, fair, and ethically sound.

**4.2 Strategic Biobanking**

Strategic biobanking is the act of collecting biological samples and clinical data for future use. This section covers the main properties of sampling methods, sample types, where in the treatment process sampling is carried out, whether sampling is done as a part of the regular treatment, data collection beyond biological samples, and methods for analysing biological samples and clinical data. Systematic strategic sampling in large scale is not currently performed at hospitals in Sweden.

**4.2.1 Deductive, Inductive and Strategic Sampling**

The researchers categorise sampling methods into three categories, namely deductive sampling, inductive sampling, and strategic sampling. It can be argued that strategic sampling is a subset of inductive methods. However, for the purpose of this thesis, the aforementioned taxonomy is used in order to clearly distinguish strategic sampling from general inductive methods.

**Deductive sampling**  When a clear, project specific, hypothesis exists, sampling is motivated in that it is needed in order to reject or confirm that hypothesis. This makes the motivation and potential upsides of the sampling clear. These samples are specific to the research questions of the specific study, and thus limited in their usability for other purposes.

**Inductive sampling**  When sampling is done in a broader sense—e.g. in a certain diagnosis group—and the purpose is to conduct inductive research on data from that patient population. This research is exploratory and data-driven. There is not a clear hypothesis that can be falsified or confirmed given some result. However, the researchers have a notion of what they wish to study before sampling takes place.
Strategic sampling  When samples are collected from a population where no hypothesis or study exists. The sampling is done to accommodate unknown future scientific needs. When future analysis is to be undertaken, samples collected through strategic sampling will be available for this purpose.

4.2.2 Sample Types

Two main types of biological samples were identified during data collection, namely blood samples and tissue samples. These two types are both subject to specific strengths and weaknesses (See Table 4.1). Additionally, urine and faeces samples were identified as a sample type that was increasingly useful, but they were only mentioned by informants as a viable alternative sporadically. Because of this, the researchers omitted this sample type from further analysis. For a more detailed description of the strength and weaknesses of blood and tissue samples, see Appendix A.

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<tr>
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<th>Blood</th>
<th>Tissue</th>
<th>Urine and faeces</th>
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<td>Strengths</td>
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<td>Analytically useful</td>
<td>Increasingly useful</td>
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<td></td>
<td>Low risk</td>
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<td>Invasive</td>
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Table 4.1: Strengths and weaknesses of different sample types.

4.2.3 In-routine or Out-routine Sampling

Sampling for strategic biobanking can either be done by taking additional samples when taking routine samples (in-routine), or it can be done through a separate procedure (out-routine). Sampling using a separate procedure is associated with more risk and higher costs, and are therefore difficult to motivate, both in terms of patient value and to the ethics committee.

On the contrary, drawing an additional vial of blood when drawing blood during routine care is comparatively cheap and safe. This is also true for tissue samples, provided that the additional sample does not require additional tissue to be removed from the patient.

4.2.4 Longitudinal Data-sets

Sampling longitudinally is the act of collecting data from the same patient at multiple points in time. According to healthcare informants, the most valuable moment for a new strategic sampling routine would be when the patient first arrives at
the hospital, preferably before any treatment has begun. The idea with the initial sample is to have it serve as a baseline sample, which subsequent samples can be compared against. Initial samples are already taken in today’s system to aid the cycle of care of specific patients. However, there is currently no standardised system for strategically biobanking these initial samples for research purposes. The samples are discarded if they have no further use in the patient’s treatment plan.

Similarly, the industry informants also appreciated the idea of having a baseline sample from patients when they first arrive at the hospital. However, it was also mentioned that an even stronger baseline are samples collected before the patient is ill altogether. Although, collecting the baseline sample out-routine is more costly than collecting from patients at the hospital.

Furthermore, it was suggested that subsequent samples—after the baseline sample—are collected for every new change in treatment, new diagnosis, or new step in a treatment plan. Longitudinally monitoring disease development over time is a powerful method for understanding diseases and fallout of various treatments.

Interestingly, longitudinal analyses can also be done on data-sets that are not inherently longitudinal at the patient level. If the data-set is longitudinal at the cohort level, highly standardised, and of high quality, longitudinal inferences can be drawn between individuals. However, it is difficult to achieve the level of standardisation that is required because it requires coordination between hospitals. Different hospitals may have different established sampling routines and different capabilities pertaining to sample quality.

According to industry informants, the current lack of longitudinal data-sets are holding back significant advances in healthcare-related research. The lack of longitudinal data-sets are an especially prevalent reverse salient in precision medicine (see subsection 4.2.6 for a more detailed description of precision medicine).

4.2.5 Clinical Annotations

Biological samples are not valuable if not coupled with clinical data. Peripheral knowledge about biological samples—such as detailed phenotype data—increases the value of samples a great deal. Clinical data are available through public Swedish registries. However, data on drinking habits, exercise habits, diet habits, other diseases, and other phenotype data are usually scarce. If these data are not available, the samples cannot be tied to these predictive factors and thus lose analytic value.

Data on sample quality is also important in order for the sample to be valuable. Data on sample quality include information about how the sample was taken, processed, and stored. Without detailed data regarding the sampling procedure, researchers can not be certain of the sample quality, which in turn makes the study outcomes uncertain. There are numerous error sources that can influence the validity of a sample, e.g. temperature fluctuations and processing procedures. These error sources are minimised when data on sample quality are detailed.

4.2.6 Medical Analysis Methods

Biobank samples and clinical data are used in a number of different medical analyses. Two of these methods were brought up in the interviews, namely precision medicine and retrospective analysis.
Precision Medicine

Precision medicine is a medical model where treatment is tailored to the unique situation of individual patients. By longitudinally monitoring biomarkers in a patient’s blood, disease trajectories, and the effectiveness of treatments can be monitored and understood. Studying biomarkers in blood and other biological material is a vital part in providing functioning and customised care, and can help researchers find out why some patients respond to a drug while others do not.

Cancer treatments in particular are highly expensive—making oncology a well studied area within precision medicine—where the effectiveness of a treatment can be evaluated in an early stage. This minimises unnecessary treatment and costs.

In order to identify important biomarkers for a condition in precision medicine, samples of healthy individuals—control material—is useful to control for which factors actually affect the outcome. The control material can be the samples collected before disease outbreak (discussed in subsection 4.2.4), or samples where the patient is incorrectly diagnosed. Additionally, there are other ways of collecting control material. For instance, biobank samples could be saved from blood donors.

Retrospective Analysis

A retrospective analysis is an analysis method that makes use of previously collected real world data. Hypotheses can be tested by comparing different groups through registry data. The effectiveness of retrospective analyses are contingent on the quality and standardisation of the real world data. Retrospective analyses are commonly used in epidemiology as it enables testing of hypotheses without having to collect data for decades.

In Sweden, plenty of registry data are available, but the retrospective analyses could be significantly improved if the registry data were accompanied by additional clinical data and biological samples. Retrospective analyses are proven to be a sufficient basis for a clinical trial. Although, while it is scientifically viable, authorities do not recognise it as such. Consequently, more expensive, prospective analyses are performed instead.

Retrospective analyses can also be done inductively by studying registries, finding correlations, and studying whether they are causal. Historically, epidemiologists utilised retrospective analysis methods to prove the unhealthy effects of smoking. By studying the correlation between smoking and other health indicators, they could prove that the correlation was causal.

4.2.7 The Case for Strategic Biobanking

Strategic biobanking is the act of strategically storing large amounts of biological material and clinical annotations for the future. Connecting this data to the extensive registries available in Sweden—see subsection 5.3.2—increases data quality and sophistication, and it enables future research to use already collected data. This can speed up clinical trials and studies, provide researchers with more useful research material, enable more thorough analyses of biomarkers, facilitate faster drug development, and increase the power of both retrospective analyses and precision medicine.
4.2.8 Further Reading

For more information regarding sample types and the main cost drivers associated with sampling, see Appendix A.

For more information regarding the establishment of new sampling routines, the extradition process of samples, and the establishment of new informed consent structures, see Appendix B.

4.3 Stakeholder Interest in Strategic Biobanking

Patient value  Patient value is increased when new and improved treatments are developed. Strategic biobanking contributes to medical development in a number of ways (for some impacts, see subsection 4.2.7). It is important to note that future patients may reap the benefits of scientific progress, and that the value for today’s patients is small when compared to the benefits for future generations (Fouchier et al., 2012).

Healthcare  Healthcare shares all the value effects with the patient, as their task is to treat patients in the best way possible. However, they also need to weigh outcome with cost in order to maximise value for tax payer money. Access to biobanked samples improves the quality of care, and lowers the cost for care through better diagnostics and more precise treatments (Hofman et al., 2014).

Industry value  Industry value is made through increased access to data in order to develop better drugs, diagnosis methods, and treatments. This data is not easily attainable without the aid of a public partner. Moreover, financing new sampling routines creates value for healthcare, patients, and society as a whole. This could have a positive impact on their reputation, and as a consequence, increase their financial performance (Cochran and Wood, 1984).

Society  Societies are struggling with financing healthcare (OECD, 2015). Strategic biobanking could alleviate some of the pressure of increasing healthcare expenses by allowing for better disease understanding. Consequently, more precise and effective treatments can be developed, thus avoiding treating patients ineffectively. The value is not only financial, however. To society, patient health is not just a means to an end, but an end in itself.
Chapter 5

Results and Analysis

This chapter presents the research results and analysis. While chapter 4 presented the contextual information needed to understand the case, this chapter presents information needed to answer the research questions. A section is dedicated to answer RQ1, RQ2 and RQ3, respectively. In section 5.1, the synergistic effects that constitute the benefits of the PPP in strategic biobanking are described, and answers RQ1. In section 5.2, obstacles that have to be overcome to ensure a successful and efficient PPP are described, answering RQ2. In section 5.3, contextual factors that shape the shared value creation process—and how these factors interact with the synergies and obstacles of a strategic biobanking PPP—is described, thus answering RQ3.

5.1 Synergistic Effects that Drive Shared Value Creation

This section describes the synergistic effects that affect the parties in a strategic biobanking PPP. In subsection 5.1.1, the mutual dependency and tight collaborative nature of industry and healthcare is described. In subsection 5.1.2, the shared value and complementary resources of the two parties are described.

5.1.1 The Mutual Dependency between Industry and Healthcare

The industry and healthcare are dependent on eachother. The symbiotic relationship between them is pronounced, collaboration is commonplace, and numerous private actors have moved to offices closer to the hospital to facilitate cooperation. Research-related collaborations are sometimes initiated by hypotheses generated from healthcare, and sometimes from the industry. Academic researchers in healthcare have better basic research, while the industry is better at identifying the future need in their respective niche fields. The industry invests significantly more money in identifying the future need compared to healthcare – they need to have this foresight in order to stay competitive. Furthermore, healthcare thrives on the research advances made by the industry. They purchase products and drugs, and use treatment methods developed by the industry.

Additionally, healthcare requires industry resources. In the case of strategic
biobanking, implementation is expensive, and not affordable through public funds alone. Funding strategic biobanking without industry resources would require a reallocation of static funds. Such reallocating of resources is usually not desirable as that could impair other important healthcare functions. However, the co-dependency between the industry and healthcare is more palpable for the industry partner. Healthcare decides who gets access to the patient material, and the industry relies on healthcare to test their hypotheses on real patient material.

5.1.2 Strategic Opportunities

According to informants, healthcare management generally lacks foresight and strategic thinking when compared to the private industry. While this sentiment is not shared by all informants, the industry informants state that pharmaceutical corporations are more experienced with long-term, strategic decisions in order to convert disease knowledge into tangible products. It is intimately connected to their core business strategy, and their future existence depends on their ability to predict the needs of the future. The private actors make better use of multidisciplinary groups, where individuals with different expertise and perspective work together towards a common goal. This is complemented by healthcare’s experience in medical processes, basic research, and identifying current needs.

All informants agree that both perspectives are necessary to accurately predict future needs, and that dialogue and collaboration would result in the best strategic foresight. In essence, industry and healthcare have different competencies, and if they can leverage each other’s strengths, collaboration is a means to better outcomes in research and better treatments.

By integrating the sampling process into routine healthcare, the extant logistical infrastructure can be utilised. In this case, infrastructure is present for patient reception, sample extraction, sample storage and sample extradition.

A strategic biobanking PPP entails a long-term commitment from both the public and private parties to build a shared biobank resource for the benefit of the parties and society. Access to this shared resource provides all stakeholders with more biological material for research.

5.1.3 The Value of a CSV-aligned Strategy and the Issue of Competitiveness

Beyond general synergistic value, a strategic biobanking initiative can provide value in terms of Public Relations (PR). Because strategic biobanking will provide research material for future industry actors and researchers alike, the partnership will indirectly lead to improved patient care in the future. Conveying this in an appropriate way is difficult, however.

The industry is typically perceived as profit driven by the general public, and their genuine, socially conscious efforts are often overlooked. However, it is important that the industry does not communicate in a disingenuous way. They should be clear about the fact that the partnership is financially beneficial to them, and not engage in window dressing activities. Such disingenuous activities could backfire into worsening the relation between the industry stakeholders and the public. For instance, the public could start questioning the industry’s motives and perceive a
Creating Shared Value through Strategic Biobanking - Public-Private Partnerships in Healthcare

Strategic biobanking initiative to be window dressed commercialisation of biological donations. A notion that could be further exacerbated by opportunistic journalists that sensationalise the issue.

On the other hand, a CSV-aligned strategy could prove to be a better choice when engaging in public communication, because it is inherently transparent regarding the industry's incentive. The shared value effects with the public in general—and the healthcare and patients specifically—should be highlighted.

Furthermore, having individual corporate contributors financing specific strategic sampling routines should be avoided. A sole financier for one specific routine would likely have high expectations on prioritisation and guarantees on access to the samples they have helped finance. However, due to the regulatory structure in Sweden, access can never be guaranteed.

Instead, the strategic sampling should be governed by a steering committee consisting of representatives from the public stakeholders and multiple private co-financiers. Consequently, the decision-making underpinning the sampling routines would be grounded in a strategically aligned vision between the public and private, which is congruent with the shared value emphasis of CSV. Additionally, having a steering committee— with multiple stakeholders—to govern the strategic sampling also alleviates the issue of accessibility of samples in the biobank. For instance, by spreading the financial risk of sampling activities on numerous private and public stakeholders.

Furthermore, having multiple financiers in a strategic biobanking partnership helps institute a knowledge sharing culture. Due to the mutual dependencies between stakeholders in the healthcare domain, keeping knowledge to oneself is typically not conducive to generating competitive advantages. Instead, a competitive advantage is generated by making use of knowledge faster, having better hypotheses and by doing better research than the competition. Access to more, and better, biological material doesn’t change the competitive landscape per se. However, it does challenge the R&D departments of corporations, as well as academic researchers, to stay salient and keep up with the competition.

Finally, considering that anyone with an approval from the ethics committee can access the samples in a strategic biobank, the initiative hardly generates an immediately apparent economic competitive advantage for the co-financiers. However, access to a strategic biobank moves the boundary for what is scientifically possible for all stakeholders acting in the healthcare ecosystem, which is a powerful argument.

5.2 Obstacles that Impede Shared Value Creation

This section describes challenges that impede shared value creation and implementation in strategic biobanking PPPs. In subsection 5.2.1, cultural differences on the profit/non-profit boundary—and between physicians and nurses—are described. In subsection 5.2.2, the differences in incentives present on the profit/non-profit boundary are explored. Subsequently, the complexity of biobank logistics is detailed in subsection 5.2.3, while subsection 5.2.4 explains some ethical issues on the profit/non-profit boundary. In subsection 5.2.5, the section concludes by elucidating some issues with predicting future data needs.
5.2.1 Cultural Differences

The main cultural difference is one that is always present in partnerships traversing the profit/non-profit boundary; the private partner is profit driven, and its ultimate goal is therefore to make a profit and please its shareholders. This difference is noted by industry affiliated and healthcare affiliated informants alike. While it is acknowledged by all, it is not seen as an obstacle by any. Referring to the experience of numerous previous successful collaborations, all informants state that this cultural difference is surmountable.

In addition, there are cultural differences between physicians and nurses in public healthcare. These differences affects the process of implementing a strategic biobank. When a new sampling routine is implemented, it is important to decide who, in practice, is going to take the sample. When the sampling process is integrated into regular care, it is logistically and economically favourable to let nurses take these samples, the reason being that the nurses take the blood samples used for regular care. At the time of this sampling, the needle is already inserted and the nurse is present. Taking an extra sample during this phase minimises costs and logistics (see subsection 4.2.3).

This strategy is hindered by a cultural divide. Nurses perceive themselves as part of the healthcare system. They believe that they are there to provide patient care, not spend their time on research-related activities. One interviewed physician at Karolinska states that this sentiment is not shared by physicians, possibly concomitant to the fact that the education for physicians is more academical, theoretical, and research focused.

Another possible reason for the cultural divide is financial. At Karolinska University Hospital, nurse wages are financed with money from the politically contingent governmental healthcare budget. Specific research nurses are typically financed with money from the politically contingent research budget. This could affect how the role of the nurse is perceived in the organisation.

The cultural divide has resulted in nurses reluctantly collecting research-related samples, or shirking altogether. The cultural issue has been circumvented by hiring nurses who are explicitly assigned to only take research-related samples. While the strategy was successful as a work-around solution, it resulted in additional costs and a difficulty in sampling during inconvenient working hours, seeing as it was difficult to have the position staffed at all times (For more in information regarding logistical issues related to research nurses, see subsection 5.2.3). Another attempt at bridging this divide was to finance a portion of the nurse’s wage with the hospital research budget. This was only done with a few select nurses in the hopes that the attitude would spread among a broader group of nurses. The effects of this effort have not yet been evaluated.

5.2.2 Difference in Incentives

Incentives are different in profit and non-profit sectors, and this poses challenges that have to be taken into account when implementing a strategic biobanking initiative (Hofman et al., 2014). While private actors strive to commercialise and profit from project outcomes (intellectual property and patents), the aim of academia is to publish scientific articles with high impact factors (publicly available). Additionally, the aim of the public healthcare sector is to improve patient treatments.
This difference can result in differences in data needs. While the data need tends to converge between healthcare and pharmaceutical companies, samples could differ in their commercial and their value for patient treatment. While healthcare prioritises value for the patient to enable better treatments, pharmaceutical companies prioritise commercial and scientific value to facilitate better research. These differing incentives also complicate the legal negotiations between the public and private sectors. Even though there is a clear congruence in strategic goals between the public and private, settling on a legal agreement underpinning the preconditions for a PPP can take years. This would delay the realisation—and subsequently the desired outcome—of the partnership.

Moreover, when biobank samples are extradited, experts are consulted to ensure that samples can be extradited without jeopardising the quality of the patient’s medical care. Redundancy against failures in the routine healthcare procedures are coveted. As a consequence, based on the recommendation of experts, the biobank may be reluctant to extradite samples. The extradition process is subject to subjective judgement from experts.

Due to the high competitiveness in academia, an expert’s recommendation to not allow the samples to be extradited can be based on medically sound reasoning, or based on adverse self-interest. The effect is greater when the biological material is small, e.g. sampled malignant melanoma (skin cancer). Industry partners experience this as an issue, and suggest that the expert must have integrity and be pragmatic and impartial in order for the industry to perceive the extradition process as fair. It is thus important that the rationale for rejected withdrawal requests is communicated, and well grounded in the patient’s best interest.

5.2.3 Biobank Logistics

In healthcare, logistics are generally complex. New strategic sampling routines must consider logistical challenges. There are logistical challenges related to sample collection, sample availability, sample processing, sample transportation, and sample storage.

First and foremost, storing the samples requires a developed infrastructure, complete with high technology freezers. SMB and Karolinska University Hospital have made significant investments in advanced storage facilities. However, as the strategic biobanking operations develop, new investments have to be made in order for the infrastructure to keep up with the growing amount of samples.

Moreover, the supply chain of biological samples, from the moment of sampling up until storage, must be robust. It must take into account fluctuations in the amount of incoming patients to the hospital. Samples that aren’t handled properly decay, decreasing their quality substantially.

The cultural difference of physicians and nurses brought up in subsection 5.2.1 has logistical implications as well. The issue of different staffing between routine healthcare and research routines creates both additional costs and organisational complexity. Building a new separate infrastructure for strategic sampling is unnecessarily expensive and inefficient as it entails using different nurses for the same procedure but for different ends. Additionally, as mentioned in subsection 5.2.1, there are currently no research nurses available during inconvenient hours which would limit the strategic sampling to daytime hours during weekdays.
Instead, sampling should be integrated with routine healthcare as that enables synergies with the extant in-routine logistic system. Regular nurses are available at all times, and sampling can be done in an in-routine fashion.

5.2.4 Ethical Issues

Sharing samples with the private sector imposes ethical considerations for the public. Sharing must be done in a way that does not compromise the patient’s integrity. It should be noted that industry involvement is not as controversial as it might seem, the private sector is currently able to obtain patient data already if sanctioned by the ethics committee and SMB.

Physicians have traditionally perceived the industry’s incentives as morally questionable, although this notion is less common today. Furthermore, physicians in management positions are more positive toward the private sector than non-managing physicians.

Both industry and healthcare informants recognise that patient health has to be considered in every strategic decision. However, it is primarily healthcare’s responsibility to represent the patient’s interest and health. This has implications in a number of different decisions. For instance, an out-routine sampling routine would be rejected by the ethics committee. The reason is that the benefits of the sampling (future research) are not tangible enough to warrant increased costs and patient risk.

5.2.5 Predicting the Future

The advances in healthcare technology and processes are rapid. The main rationale for sampling strategically without having a specific hypothesis at the time of sampling is to accommodate unknown future needs. An example from radiology that elucidates the potential value of sampling strategically for the future was brought up by one informant. New and more sophisticated analysis methods have been developed in radiology over the years. This has enabled researchers in radiology to revisit old radiology images and analyse these anew. With modern analysis methods, it is possible to extract more clinically accurate information from the images, compared to what was possible when they were taken.

Similar to the advances in radiology, analysis methods for biological samples have also improved. However, a key difference is that biological samples are consumed while radiology images are not. Thus, it makes sense to collect biological samples strategically so that when new research methods and hypotheses become available, the biological material is readily available. The unknown future need has been emphasised across all interviews with both healthcare and industry stakeholders, and thus it serves as a justification for a strategic biobanking initiative.

The unpredictable nature of the future is a double-edged sword however. The fact that the future need is unknown poses difficulties in deciding on the sampling protocol. It is difficult to develop a sampling protocol that will fully satisfy the future, unknown need. All informants state that knowing the technological possibilities in 10 or 20 years is an almost impossible task. The uncertainty is not limited to what type of medication will be developed, but if medication will be developed in the first place. Future research might focus on other areas, such as preventive
medicine through e.g. physician instruction compliance. However, informants also state that not all sampling protocols are equally appropriate, and that sufficient knowledge and competence is necessary to predict future needs to the extent that it is possible.

Another problem that supports the argument that sampling for the future is difficult is the fact that there are biological samples currently unused and slowly decaying in biobanks. This is not only a waste of resources, it also has ethical implications as it can be considered unethical to let donated samples go to waste. The samples are deemed uninteresting because they are not coupled with sufficient clinical data. Nowadays it is desired that the samples are coupled with information on sample quality, and the sample procedure. At the time of sampling, it was not known that this information would be needed years later, and thus it was not included in the sample protocol.

The impact of an unknown future need is not limited to decision regarding what data to collect. When patient data is collected, the patient signs a patient consent form. The consent describes which analyses are admissible for the given sample. To satisfy a future need, this consent has to be broad enough to take future analysis methods into account. The ethics committee is inherently against broad consents in order to ensure patient integrity and prevent abuse. This poses a challenge in crafting a consent that is broad enough to enable future analysis, but narrow enough for it to be approved by the ethics committee. Industry informants believe that the ethics committee will have a more positive and sympathetic presupposition to broad consents if the application is grounded in mutual interest between the public and private.

5.3 Contextual Factors that Shape Shared Value Creation Processes

There are a number of contextual factors that affect the implementation of strategic biobank PPPs. This section begins in subsection 5.3.1 with explaining how regulations impact strategic biobanking PPPs. It then continues to describe the effect of extensive registry keeping in subsection 5.3.2. Finally, the effect of hospital organisational structure is clarified in subsection 5.3.3.

5.3.1 Regulations

Sweden has its own regulatory structure. These regulations affect the implementation of strategic biobanking PPPs in different ways. This subsection details how the Swedish anti-corruption law affects implementation and how the industry value proposition is affected by the Swedish regulatory system.

Anti-corruption Law

In order to prevent corruption and bribery, the use of resources provided by the private industry has to be properly motivated. The resources have to be in proportion to the activity that they are funding, although a certain percentage increase is allowed. The regulation also prevents an industry party from financing any healthcare activities that they do not directly benefit from. This prohibits some strategies
when implementing biobanking PPPs. Had anti-corruption law not been present, the issue of divergent data needs between public and private partners might be circumvented by allowing the private partner to finance both sampling procedures. This is in violation of the law, and as such, it is not an option.

Regulations’ Impact on Industry Value Proposition

Due to Swedish regulations, sample extradition has to be fair and cannot favour any single actor, regardless of who financed the sampling. This has two main implications: (i) There is no guarantee that the ethics committee approves the withdrawal request when a financing industry partner wishes to use the collected samples. (ii) After the samples are collected, other industry actors are allowed to withdraw the samples at the same terms as the financing actor. This makes the investment inherently counterproductive when viewed from a purely financial perspective. Their concern with sample availability is further magnified by the general scarcity of biological material in biobanks.

5.3.2 Diligent Registry-keeping

Sweden is unique in its extensive record keeping of its inhabitants. The Swedish government keeps a number of national registries such as Patientregistret (Patient Registry), Dödsorsaksregistret (Cause of Death Registry), kvalitetsregister (quality registries) and Läkemedelsregistret (Pharmaceutical Registry). The strength of these registries is that they track a large amount of Swedish inhabitants for long periods of time. Other countries, such as the United States, keep registries, but they are kept by insurance providers. When a patient switches insurance providers, they also switch registry. This limits the possibility of long-term longitudinal analyses. Coupling the Swedish registry data to biobank samples increases the value of the data, as it provides researchers with richer information.

The registries differ in what information they contain and to which degree they cover the population. Data from the Cause of Death Registry is available for every (dead) Swedish citizen, while data from a quality registry is only available for a subset of the population. This has an impact on what studies can be done using registries. For instance, if researchers want to monitor the frequency of a diagnosis in the Swedish population, a quality registry should not be used, because it does not represent the whole population. Instead, the more complete Patient Registry would prove more useful. On the other hand, the data in a quality registry is more detailed and allows for other types of research.

5.3.3 Hospital Organisational Structure

Karolinska University Hospital is structured around IPUs. This organisational structure has implications on strategic biobanking PPP implementation. This subsection describes how sampling is affected by the organisational structure, and how differences between diagnosis groups have to be taken into account.
The Alignment of Hospital IPU Structure and Sampling Longitudinally

When implementing sampling routines that aim to sample longitudinally, sampling has to be done in multiple stages during patient treatment. In the traditional format, where hospitals are structured around physician expertise, this requires sampling to be done in multiple different areas of the hospital. In an IPU-structured organisation, the patient remains at the same unit during her treatment. This enables sampling to be done in the same unit during the patient's whole cycle of care, which reduces organisational complexity and logistics.

Sampling within Diagnosis Groups

From the healthcare's perspective, some light was shed on how healthcare's way to organise can affect the internal operations of the hospital. In the VBHC model, the hospital is organised around the patient, and all the competence associated with specific conditions are aggregated in the appropriate diagnosis group. Thus, given a specific interest for strategic sampling of biological material, it is easier to locate the correct patient material pertinent to the scientific interest of the researcher and/or client in the new model. Consequently, the VBHC organisational model is arguably more efficient for healthcare when sampling strategically.

On the other hand, industry informants unanimously agreed that the hospital's organisational model doesn't affect their interest in strategic collaborations. A possible explanation for industry's disinterest in hospital's organisational structure could be that to them, the hospital is a black box where solely the input and output are of interest. When they request access to patients, they are not interested in the internal operations of the hospital as long as they receive access. However, if the hospital can reduce their internal cost by organising in a more efficient way, the overhead costs for strategic partnerships will be lowered as well, and thus have implications on the profitability of such partnerships.

Diagnosis Group Heterogeneity

In order to implement a sampling routine in a specific diagnosis group, the unique properties of the diagnosis group have to be considered. The diagnosis groups are heterogeneous in that they differ in terms of organisational structure, medical needs, patient population size, patient demographics, current practices, and culture.

It is important to consider the difference in size across different diagnosis groups. There are strengths and weaknesses to sampling in a large diagnosis group. While the data quantity is higher, the costs are higher, the logistics are more complex, and the larger amount of managers—inherent to larger organisations—could result in a wider range of opinions and more difficulties in reaching consensus.

Moreover, the diagnosis groups also differ in the typical urgency of the patient's condition. The cardiovascular theme have numerous conditions that requires emergency care, while cancer diagnosis groups often requires less urgent care. This has implications on the logistics. It is easier to schedule less urgent conditions during convenient hours, and thus the extant infrastructure with research nurses can be used to collect research-related samples.

Biobanking maturity differs between diagnosis groups. While systematic biobanking is practised in diagnosis groups in the cardiovascular theme, this is not the case
in the pelvic cancer area. This has to be taken into consideration, because a diagnosis group where biobanking is already practised will have certain routines in place, along with competencies related to systematic biobanking.

As mentioned in subsection 4.2.6, the cancer field is particularly keen on precision medicine, seeing as there is great potential for cutting costs, and because the cancer field is heavily divided into subdiagnoses. When compared to cardiology, oncology diagnoses are more narrow, so they require sampling that is more specific.

Additionally, a deviation was identified between how the two healthcare informants interpreted the potential significance of logistical challenges associated with extended strategic sampling. These differing viewpoints further support the argument that the diagnosis groups at Karolinska University Hospital are heterogeneous.

Despite the differences between diagnosis groups, it is suggested that a generalisable business model is possible. One manager at Karolinska University Hospital suggests that legal, economical and ethical aspects of the business model would be more easily generalisable while other, more context specific, aspects are less so. A generalisable business model would have increased potential and value because it could be applied widely, encompass more patients, and increase data volume. However, constructing a generalised model requires detailed knowledge of diagnosis groups heterogeneity.
Chapter 6

Discussion

In this chapter topics that the authors have deemed interesting to the reader are discussed. Section 6.1 provides some general insights, and recommendations related to strategic biobanking that managers and practitioners may find interesting. In section 6.2, the authors critically review the research methods.

6.1 Insights and Recommendations

This section raises some points for practitioners and managers to have in mind when implementing strategic biobanking PPPs. The section covers both interesting notes and insights as well as practical recommendations for project implementation.

6.1.1 Relevant Medical Fields

The industry informants have expressed an interest in strategic biobanking in order to better understand disease patterns, and how patients respond to treatments. Some specific medical areas were mentioned, namely: Oncology, Cardiovascular diseases, Respiratory diseases, Chronic kidney disease, Diabetes, Metabolic diseases, Alzheimer’s disease, Antibiotic resistance, Neurological diseases and Mental disorders. An interest in oncology was observed across all interviews.

6.1.2 Non-competitive Medical Fields

The informants believe that some of the disease areas mentioned previously—in Relevant Medical Fields—are big public health concerns, where there is a lot of medical progress to be made. By focusing on a medical field that is of big public health concern, politically important and non-competitive, it is possible that the private’s interest may converge with public stakeholders. In a non-competitive field, the private financiers are not driven by increasing their competitive advantage, but by providing public health value. This aligns with the public interest, and also increases CSR potential as the risk of the public doubting industry incentives is decreased. This facilitates involvement of other stakeholders such as government, public innovation incubators (e.g. Vinnova), and NGOs (e.g. STRAMA).

There are instances of industries electing to publish material, thereby making it public, rather than hiding it to secure a competitive advantage. By sharing the knowledge in a non-competitive area, the entire field can develop, and competitors
can compete on core activity efficiency and effectiveness instead. This knowledge sharing culture is also congruent with a CSV-aligned strategy (see subsection 5.1.3).

Non-competitive areas already exist within the pharmaceutical industry, where competitors collaborate and jointly develop a drug, sharing knowledge, experience and costs. Additionally, there are multiple successful EU initiatives to fund research in non-competitive areas e.g. Innovative Medicines Initiative (IMI) and Big Data for Better Outcomes (BD4BO).

6.1.3 Options Regarding Risk Allocation

When implementing a strategic biobanking PPP, the authors identified two main financing strategies: (i) Financing could be done prior to project implementation by private actors. (ii) Initial financing could be done by the public actor, leaving subsequent financing to private actors. They differ in terms of which party bears the financial risk, how attractive the project is to private actors, and what is required of public finance.

If initial financing is done by the public party, the public party bears the financial risk. The risk of project failure or increased costs is high because there is no prior implementation, and a lot of critical factors are unknown. This option also requires that the money is available from the public budget. This is seldom the case. On the contrary, budgetary constraints is one of the most common reasons for PPPs (Blanken and Dewulf, 2010).

If initial financing is done by the private party, this will result in the private actor bearing the financial risk. While this is preferable for the public party, this will decrease the attractiveness for industry actors. This is important to keep in mind, as risk management is an important factor to achieve value for money in PPPs. (Bing et al., 2005).

6.1.4 Implementation

Informants state that implementing strategic biobanking on a smaller scale is a viable strategy. The smaller implementation can serve as a proof of concept, proving the viability of the business model and uncovering previously undiscovered obstacles and challenges. Specifically, a strategic sampling pilot project could be implemented in a smaller patient group at Karolinska University Hospital.

However, it is difficult to formulate an attractive value proposition to the industry since they cannot be guaranteed exclusive rights to extradite the samples in the future. This effect is either magnified or alleviated depending on who bears the financial risk, as reasoned previously in Options Regarding Risk Allocation.

The industry can be incentivised to engage in a strategic biobanking PPP by being granted influence in the sampling activities, e.g. influence on which biological samples, and what clinical data that will be collected. Even though the industry and public healthcare in Sweden mostly agree on the general future trajectory of healthcare, some differences in data needs might emerge. By granting influence, a more attractive value proposition to the private party can be formulated since strategic samples are of great value to them.

The authors suggest that a strategic biobanking PPP should be governed by a steering committee, which is in accordance with suggestions made by Hofman
et al. (2014). The authors also recommend that the steering committee have equal representation and power between the public and private parties. Consequently, all decisions are grounded in a strategically aligned vision.

Moreover, all participating public and private stakeholders in the steering committee should be allowed to suggest new routines through a standardised application format. Final decisions on how the suggested routines will be prioritised—pertinent to the available funds—are done through voting. Votes are equally distributed between the public and the private parties. Among the private co-financers, the votes are contingent on the size of their donation to the mutual fund.

Finally, the authors argue that the incumbent IPU structure at Karolinska University Hospital is highly compatible with the steering committee approach to governing the strategic sampling activities. The steering committee organisation can be put on top of the incumbent organisation, which is illustrated in Figure 6.1.

The authors suggest that the existing strategic managing units are used as intermediaries between the steering committee and the hospital at which the sampling takes place. The strategic managing unit has the capability to verify sampling feasibility and specify which resources are needed for certain sampling routines by consulting with the operational level in the hospital and the biobank.

![Figure 6.1: Illustration that suggests organisational compatibility between strategic biobanking governed by a steering committee, and the IPU organisational structure.](image)

### 6.1.5 Champion

It is important to have interested individuals who are able to initialise and drive cultural and organisational change. In order to overcome obstacles related to project implementation, a wide array of competencies are required from a wide array of perspectives.

This, in turn, requires someone to coordinate the activities and competencies for them to contribute to the initiative. The fact that the initiative does not provide
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direct personal gain causes disinterest in individuals. This is not due to lack of altruism, but by necessity. Resources are scarce within the public sector, and there is neither time nor money to work on projects that do not contribute to core activities.

The authors postulate that the reason for this lack of initiative is because of the incentive system within medical academia. Researchers are valued by how much they publish, and the impact factor of those papers. Had they instead sought to provide the most value to patients, this problem might not have arisen.

6.1.6 Quality vs Quantity

Comparing Sweden to certain, larger countries can be seen as comparing quality to quantity; While researchers in more populous countries have access to larger quantities of patient material, the Swedish registries (see subsection 5.3.2) contribute to higher quality data. By engaging in strategic biobanking, Sweden can position themselves as leaders within strategic biobanking to further increase data quality, providing extensive registries along with biological samples and clinical annotations. This could facilitate faster clinical trials, and incentivise more large pharmaceutical companies to conduct research in Sweden.

Quality and quantity are also dichotomous at the scale of sampling within Sweden. If sampling was to be done in one highly specialised university hospital, sampling can be more sophisticated and of higher quality. However, to obtain larger data volumes, sampling has to be done in multiple hospitals. This limits sampling quality, because the routine has to be simple enough to be implementable in all involved hospitals. This is a balancing act that should be taken into consideration when implementing a strategic sampling initiative.

6.1.7 Selection Bias

Swedes have a positive attitude towards medical research, and their propensity to participate in studies is high. This reduces selection bias. To show this, consider the following: if the likelihood that any given person would participate in a study when asked was 100%, this would result in a selection bias that is equal to the one that the selection process caused. On the contrary, if the likelihood was 1%, this would cause a small subset of the population to participate, causing a larger selection bias. Low participation rates are known to induce selection bias and risk resulting in samples that are not representative of the population (Aigner et al., 2018). This reduced sampling bias is also applicable for strategic sampling. By having reduced sampling bias, the samples represent the population more accurately, and are more valuable to researchers.

The participation rate differs between demographic groups. It is higher in patients with higher socioeconomic status, while illness is more common in areas with lower socioeconomic status. Other factors, like cultural background, may also affect an individual’s propensity to consent. Selection bias is also present in clinical studies. In order to minimise contingency factors like other medications and other sicknesses and to isolate the effects of the drug being tested, the individuals selected for a clinical trial are seldom representative of the population that will use the drug after it is launched. This makes retrospective studies on real world data necessary to explore the effect of the drug on the actual population.
6.2 Critique of Method

Some of the interviews conducted were group interviews. These interviews are susceptible to biases relating to group conformity (Frey and Fontana, 1991), which could affect the findings of the research.

While primary data (see section 2.4) were analysed systematically according to the presented research method, the secondary data (see section 2.4) were not analysed as rigorously. This makes the research process harder to replicate, thus reducing reliability.

The sampling process when selecting which private actors to interview was based on expert advice. While this is useful to reach theoretical representation, the advice were nonetheless subjective, and susceptible to bias. This could result in the sampling group not being representative, thus reducing the external validity of the findings.

The authors mention that interpretive p2p triangulation is used in order to improve construct validity (see section 2.6). The authors have communicated with each other regularly during the research. This could cause their opinions to converge, reducing the effect of the triangulation.

Due to scheduling issues, there were times when data analysis did not take place directly after an interview. This resulted in the subsequent interview not being based on analysed data from the previous one. While the authors did incorporate the data on an ad-hoc basis, it was not systematically incorporated until the next occasion of analysis. The ad-hoc process is not systematic and hard to replicate, and therefore lowers the reliability of the research.
Chapter 7

Conclusions

In this chapter, some implications for managers and researchers are described, limitations are discussed, and suggestions for future research are made. Finally, a summary of the thesis is presented.

7.1 Answering the Research Questions

By answering the sub research questions defined in section 1.4, the important factors that shape the shared value creation process is understood. Consequently, an answer to the main research question can be inferred.

MRQ: How is shared value attained in strategic biobanking PPPs?

RQ1: Firstly, shared value is attained by making the most of the synergistic effects on the profit/non-profit boundary in strategic biobanking PPPs. The pharmaceutical industry and healthcare are dependent on each other, with both possessing resources and capabilities that are crucial for the other’s sustainability. A successful strategic biobanking PPP leverages healthcare’s and industry’s different sets of competencies and resources.

Moreover, in order to attain public interest, a communication strategy that aligns with the CSV framework is powerful. This entails that the private party is transparent about financial incentives and strategic goals. Further public interest can be gained by researching—and co-financing projects—in non-competitive medical fields.

RQ2: Secondly, shared value is attained by having a plan to handle obstacles inherent to strategic biobanking PPPs. While cultural differences exist between the public and private parties in the healthcare sector, the public and private parties are used to collaborating and thus this cultural divide is surmountable. Nonetheless, this is important to be aware of. Additionally, a cultural divide exists between physicians and nurses. Nurses at Karolinska University Hospital are hesitant to aid in research-related activities.

Moreover, the public and private parties have vastly different incentives. These incentives lead to different data needs and to idiosyncrasies that might impede smooth project implementation.

New strategic sampling routines encumber the incumbent logistical system. The logistical system must be robust against fluctuations in the amount of incoming
patients, and it must function during inconvenient hours. Thus, the staffing issue pertaining to the cultural divide between nurses and physicians must be solved also from a logistical perspective. Ideally, strategic sampling routines are integrated into routine healthcare.

Moreover, ethical issues stem from the fact that the private sector is profit driven, and that one can not be certain that patient value is the main priority of a private corporation. This leads to ethical issues of public opinion, and requires that the public party is ethically considerate when extraditing samples.

Finally, when collecting data for the far future, its usefulness is dependent on the ability of present day experts to predict the need for the future. A poor prediction might result in wasted samples. An informed consent that is broad enough to facilitate future research analysis has to be crafted, without jeopardising the integrity of the patient.

**RQ3:** Thirdly, shared value is attained by considering contextual factors that shape the shared value process. In Sweden, the anti-corruption law limits the flexibility of the financing structure of a strategic biobanking PPP. Private stakeholders are not allowed to make targeted donations to finance routines they have no interest in. Thus, in order for a partnership to be fruitful, higher demands on goal congruence is required. Regulations also have impact on the industry value proposition as the financing stakeholders cannot be guaranteed exclusive rights to extradite samples they helped finance.

Furthermore, Sweden is unique in its extensive record keeping of its inhabitants. Sweden keeps a number of different registries, and they differ in population coverage and what data they contain. The extensive record keeping enables longitudinal analysis of registry data that might not be possible in countries with less extensive registry keeping.

Moreover, the hospital organisation structure impacts a strategic biobanking PPP in a number of ways. An IPU-based structure facilitates easier longitudinal sampling. An organisational structure based around diagnosis groups also facilitates identification of patients that are of interest when sampling. Finally, diagnosis groups differ on several points, which impacts decision-making when implementing strategic sampling.

All things considered, shared value is attained by considering the aforementioned synergistic effects, obstacles, and contextual factors. With access to a strategic biobank, the boundary for what is scientifically possible for all stakeholders acting in the healthcare ecosystem can be advanced.

### 7.2 Contribution

This section describes the contribution that the research provides to the theoretical fields that it is based in, and to practitioners and managers implementing strategic biobanking PPPs.
7.2.1 Theoretical Contribution

The scientific value of this thesis stems from the fact that it studies three theoretical fields that are important for future healthcare sector sustainability with empirical evidence to confirm this (Porter and Kramer, 2006; Porter and Teisberg, 2006; Torchia et al., 2015). The thesis studies how these concepts interact, and how they can be utilised to develop better healthcare systems around the world.

Matinheikki et al. (2016) specifically encourages further research to explore the potential of CSV in healthcare. This thesis answers specific questions raised in this thesis such as how power should be distributed among change agents—i.e. public and private—in a CSV collaboration, and what kind of leadership approach best facilitates this change (Matinheikki et al., 2016).

Roehrich et al. (2014) suggest further research to develop their framework for future operationalisation. Their framework consists of three main aspects: PPP Outcomes, The Policy of PPP and The Practice of PPPs, suggesting that their framework could be operationalised further. Similarly, Torchia et al. (2015) suggest that further research needs to be done to understand the effect of regulatory structure on PPPs. This thesis gives further insight into policy and regulatory impact of PPPs and explains these interactions.

Furthermore, Torchia et al. (2015) suggest that the impact of public interest on healthcare PPPs is under-researched. This thesis studies this phenomenon and finds that a CSV-aligned strategy is conducive to attain high public interest. This is in accordance with Smith et al. (2015), who finds that the concept of patient-centered shared value can be used as guidance when developing new strategies in healthcare. The focus on patient-centered value is congruent with the empirical context of this research being a hospital centered on patient value.

7.2.2 Practical Contribution

According to all experts and informants, strategic biobanking is instrumental in order to facilitate future medical research. By undertaking initial exploration of this concept and putting it in context of other, powerful, frameworks, the thesis can serve an interesting and worthwhile read for managers and practitioners interested in strategic biobanking.

The thesis gives valuable insight into current practice, synergies and obstacles when implementing the novel concept of strategic biobanking. This is especially important for managers in the public sector, as this minimises the problematic information asymmetry, which is a common issue in PPPs (Lonsdale, 2005).

This thesis has dedicated section 6.1 to insights and recommendations that are especially useful to managers and practitioners. The section includes recommendations for how to implement a strategic biobanking PPP, alternative options that might be worth considering and insights that could prove useful during decision-making.

7.3 Limitations and Future Research

The strategic biobanking PPP in the case was not implemented during the study. This makes evaluation of the PPP impossible. Further research is encouraged to
study the implementation of strategic biobanking PPPs and how they interact with contextual factors.

The research was conducted through a single, holistic case study. While this is good for documenting unique cases and exploring novel phenomena (Yin, 1994), it is tied to the context of the Swedish regulatory system, and Karolinska University Hospital. This limits the generalisability of the results to the theoretical level. This research does, however, provide a baseline for other researchers to compare different contextual factors against. Researchers are encouraged to study strategic biobanking PPPs in other contexts in order to empirically infer the extent to which the findings of this thesis are generalisable to other contexts.

The cultural difference present between doctors and nurses at Karolinska University Hospital is important to study further. Because many university hospitals integrate their healthcare, education and research, further study in this area would enable a more seamless integration of healthcare-integrated research.

7.4 Summary

The thesis studied concepts that have been deemed important in order to solve the issue of growing health expenditures around the world. Concepts such as VBHC, CSV, PPP and strategic biobanking are all possible parts of a solution. This thesis studied the implications of public interest, regulatory structure and hospital organisational structure when implementing a strategical biobanking PPP. All three of these factors impact the decision making process and have to be taken into consideration when implementing strategic biobanking PPPs.

By adopting a strategy in alignment with CSV, public interest is likely to increase. Regulations impose limitations on what can be done during implementation. This thesis describes the nature of these limitations and proposes strategies to deal with them. Light is shed on the importance of longitudinal sampling and its compatibility with an IPU-structured public party.

Furthermore, the thesis highlights current practice, synergies and obstacles when implementing strategic biobanking PPPs, and draws the conclusion that all these factors are of importance in order to attain shared value in strategic biobanking PPPs.


Friedman, M. (1970). The social responsibility of business is to increase its profits.


Appendix A

Strategic biobanking - further reading

Appendix A provides the reader with more information regarding strategic biobanking that might be interesting for the curious reader. The first section described strength and weaknesses of different blood and tissue samples. The second section breaks down the main cost drivers related to sampling and biobanking.

A.1 Sample Types - extended

The strength of blood samples lie in its simplicity. Blood samples are simple and inexpensive, and the logistics associated with collecting blood samples are less complicated than the ones associated with tissue samples. Additionally, taking blood samples does not generally expose the patient to any additional risk.

Tissue samples, on the other hand, are usually more invasive, and associated with higher costs. There’s always risk involved when physically removing tissue from the body, especially with surgical procedures that involves opening up the body. All sampling must be clinically motivated from a patient’s perspective, and as such, the risk of any procedure must be weighed against the benefits for the patient. Any tissue sampling needs to be clinically motivated for the patient’s benefit.

Tissue samples, however, have other advantages. A large removal of tissue offers a significant mass of biological material. Tissue samples are inherently versatile, as they enable medical analyses that are not available for blood samples. Additionally, more information about the sample can be retrieved through pathological analysis.

In general, tissue samples are scarce, and thus it is difficult to build large biobanks with tissue samples. Some specific tissue samples provide a limited amount of biological material, e.g. certain types of malign melanoma found in an early stage. This could pose a problem if the amount is only sufficient to satisfy the need of one single research. Blood, on the other hand, can be taken in greater volumes and used multiple times.

While tissue samples enable a wider range of analyses, interviewees believe that technological improvements are greatest in the area of blood analyses. This is an argument for using blood-based samples, seeing as their usefulness would increase more with time than their solid counterpart.
A.2 Cost for sampling and biobanking

Implementing strategic sampling is associated with an increased cost. The factors that drive cost include, but are not limited to:

- Cost of obtaining informed patient consent
- Cost of extracting biological material from the patient
- Cost of collecting clinical data from the patient
- Cost of sample processing
- Cost of sample storage
- Cost of keeping registers
- Cost of administration
- Cost of IT related to biobanking services
- Cost of retrieving stored samples

In cancer treatments, there is a trade-off in regard to blood samples and tissue samples. Tumours are generally heterogeneous, resulting in a tissue sample not representing the tumour holistically. At the same time, the analysis methods of blood samples are much more limited, but the holistic character of the tumour is partly captured in the blood.
Appendix B

Biobank-related processes

The storage and extradition of biobanked samples and clinical annotation involve four main processes in the case of the Stockholm Medical Biobank. The first process involves the establishment of a new biobanking storage routine (see Figure B.1), and consists of three main steps:

1. An application is sent from the principal, stating what samples are to be biobanked, if the consent is standardised or customised, and more.

2. The ethics committee approves or denies the application.

3. If the application is approved, the principal enters into a sample gathering agreement with the biobank, that specifies which samples will be sent and stored in the biobank.

![Figure B.1: Establishment of new biobanking routine](image)

The second step is to gather the data from the patient and to store it in the biobank. These processes are different depending on if the consent form is standardised (see Figure B.2a) or customised (see Figure B.2b). If the consent is standardised,
the sample can be used for patient treatment, research, and medical development. The samples will be prioritised for patient treatment, and if the biological mass is deemed too scarce, researchers might be denied access to samples that are gathered with this consent. Custom consents are specified in the ethics application (see Figure B.1) and enables other usages, depending on what the ethics committee allows.

The standardised consent form is opt-in, meaning that the patient consents to sample usage per default, and has to explicitly redact his/her consent. Custom consents are opt-out, and the patient has to explicitly give his/her consent in order for the samples to be used.

(a) Sample storage process in the case of standardised consent forms

(b) Sample storage process in the case of customised consent forms

Figure B.2: Storage processes for different consent forms.
The third step is for the biobank to extradite the collected samples to researchers or private actors who wish to use the stored data for analyses and studies. This is done in a number of steps (see Figure B.3):

1. The researcher sends an ethics application to the ethics committee, specifying which samples he/she wishes to study and for what purpose.
2. The ethics committee approves or denies the application.
3. If the ethics application is approved, the researcher and the biobank enter into a sample gathering agreement, specifying the samples and data to be extradited.
4. The biobank samples are extradited to the researcher.
5. The data is used for analysis and is subsequently sent back to the biobank or destroyed.

Figure B.3: Sample extradition process