Faculty of Social Sciences
University of Helsinki
Finland

Reorganizing Biomedical Research

Biobanks as Conditions of Possibility for Personalized Medicine

Heta Tarkkala

DOCTORAL DISSERTATION
to be presented for public discussion with the permission
of the Faculty of Social Sciences of the University of Helsinki,
in lecture room 5, University Main Building,
on the 27th of April, 2019 at 10 o'clock.

Publications of the Faculty of Social Sciences, no: 114 (2019)

Distribution and sales: Unigrafia, Helsinki
https://shop.unigrafia.fi

Figures 1-3 reproduced with permission of Sitra
Figure 4 reproduced with permission of Nature

Cover picture: Heta Tarkkala
Layout: Timo Päivärinta, PSWFolders Oy/LTD

ISSN 2343-273X (printed)
ISSN 2343-2748 (online)
ISBN 978-951-51-3383-0 (pbk.)
ISBN 978-951-51-3384-7 (PDF)

Unigrafia
Helsinki 2019
The Faculty of Social Sciences uses the Urkund system (plagiarism recognition) to examine all doctoral dissertations.

Abstract

In recent decades biomedical samples and data have been organized into large depositories such as biobanks. These biobanks have also been founded in Finland to allow for increasingly large-scale, international, and data-intensive biomedical research. Simultaneously expectations of personalized medicine have increased – in the future individuals instead of averages will be treated, and genomic data may be utilized in the clinics or in disease prevention.

This study – rooted in science and technology studies, and linking to discussions of the role of expectations and imaginaries – examines biobanks as conditions of possibility for personalized medicine to become reality: that is, how biobanks are expected to make personalized medicine possible. The rearranging of biomedical research through biobanks is investigated against the backdrop of personalized medicine as a sociotechnical imaginary: a vision of a desirable future, which is both built on, and continuously requires, science and technology, and therefore societal efforts, for its fulfillment (Jasanoff and Kim, 2015).

Consequently, this study asks: *What do the expectations related to biobanks as conditions of possibility for personalized medicine tell us about the knowledge production in which biobanks are supposed to participate, and the role biobanks play in it?* To answer this question, biobanking is studied through three different lenses. The analytical sections unpack, first, the claims of high quality samples they store; second, the ideas related to research population(s) seen to be stored in biobanks; and third, their link to the expectations of translational medicine. Thus, it is explored how biobanks are expected and said to contribute to contemporary biomedical knowledge production that takes place in highly regulated settings.

The main argument of the study is that the very idea of biobanks is being reshaped as operations, conventions, regulatory frameworks, and new expectations are linked to the imaginary of personalized medicine and require that action be taken. The different layers of stakeholders, regulations, developments, and projects that condition and constrain biobanking and hence knowledge production, have, and continue to have, an effect on what biobanks are considered and understood to be, and the kind of knowledge and scientific practices they could foster. The analytical chapters illustrate the multiplicity of tendencies and linkages attendant on biobanks as they begin to reorganize biomedical research.

Acknowledgements

When I started to plan my PhD studies, I had a discussion with Ilpo Helén who convened the master's seminar in which I had participated. He said that my doing a PhD should be no problem as, "You already have a supervisor". "Do I? Who is that?" I asked. "Me," he said. So Ilpo, thank you for supervising my work and securing the funds for research to continue – for example in the "Good(s) for Health" project, funded by the Academy of Finland at the University of Eastern Finland – and, Ilpo, keep enjoying the cakes in the years to come! My second supervisor, Karoliina Snell, has accompanied and guided me since my master's thesis. The support and encouragement I have received from her is something to which every PhD Student should be entitled, and I have valued it highly. Whether for help with academic abstracts and questions, or with aqua jogging, I have always been able to count on you. You have also convened the projects with which I have been involved at the University of Helsinki. Thank you, thank you, thank you!

For the opportunity to start PhD research with three years of secured funding, I thank Juha Tuunainen, who accepted my topic as part of the research project he convened, "University-Society Relationship and Institutions of Research Collaboration", funded by the University of Helsinki. This secured a good start for my work at what used to be the Network for Higher Education and Innovation Research (HEINE) at the University of Helsinki, whose members warmly welcomed me into their community. My academic home since 2015 has been the Totemi PhD seminar under Petri Ylikoski, Karoliina Snell and also Mianna Meskus who, when I was preparing my bachelor's thesis, said something about my "working like a real researcher": a small comment, but one which meant a great deal to me. Petri has provided me with input regarding scientific research and its process, as well as always supporting my project. A special mention goes to fellow graduate students in the Totemi seminar (of whom some are no longer students): Elina Helosvuori, Kamilla Karhunmaa, Tomi Lehtimäki, Jose Cañada, Jaakko Taipale, Lotta Hautamäki and Sampsa Saikkonen, as well as those, such as Vera Raivola and Annerose Böhrer, who took part in the graduate seminar and our writing camps in Tvärminne and Lammi and all the other seminar participants who patiently read and commented on the lengthy drafts of this dissertation – my thanks go out to you all. Moreover, in the final stretch towards the finalization of this dissertation, the pre-examiners – Professors Ayo Wahlberg and Paul Martin – have also provided encouraging comments on the manuscript for which I am very grateful.

Aaro Tupasela has not only traded Pokémons, but also helped in academic life. In 2013, he laid the groundwork for my visit to the LSG at the University of Vienna. There, Paul Just, Johannes Starkbaum, Ingrid Metzler, Jürgen Portschy, Katharina Paul, Christian Haddad and all the others made my stay pleasant. Collaboration with Aaro turned into an article draft during my short visit at the University of Copenhagen in spring 2017. My thanks also go to the people in health services research there; it was nice to dive straight into everyday life in Copenhagen – lunching, enjoying coffee and doing *pausegymnastik* together! During

the summer of 2018, I spent about ten days working with this manuscript at the Institute für Europäische Ethnologie at the Humboldt University in Berlin. Thank you Jörg Niewöhner, Milena Bister, Anja Klein and others for making me feel so welcome. There are also friends outside the academy who have provided me, and my family, a place to stay during research and conference visits. *Danke* Anouk Jacobs and Christoph Müller for the friendship and your *gastfreundlichkeit* in Vienna! I have also enjoyed the company of Annastina Lanne and Lau Reinholdt Kjeldsen in Copenhagen, *tusind tak*!

This study could not have been conducted without the help of those who agreed to participate in the interviews; I thank everyone who has given up their time to discuss biobanking and increasingly data intensive biomedicine with me. My immediate environment has also added a special ingredient to this research and the discussions connected with it. Mervi Kuronen and Saara Ollila were the stand-by bioscientists ready to clarify things, Riikka Perälä commented on my research plans and Henni Alava's feedback on the final drafts of this Phd was indispensable. Salla Sariola then gave me some important advice one day when heading home from our allotments with our boots caked with soil: "Unless you end it, research is never over!" So now, two years later, having been both supported and challenged in all these relations and connections with friends, scholars and thinkers, this is it, here the research ends. With this thesis, which became more sophisticated after Marie-Louise Karttunen did the work of proofreading and language editing, and Timo Päivärinta finalized the layout. Thank you all!

This is also the place to thank both my mother and my mother-in-law whose support, especially in the form of childcare, has not gone unnoticed. Another key person has been Johanna Laukkanen, who has taken care of our dog Into when necessary. My friends near and far have listened to my mutters and excitement, standing by my side. There are also my nearest and dearest to be mentioned: thank you Alvar and Edvin Tarkkala for being the most fabulous and lovable persons just the way you are. And finally, Otso Linnalaakso, my companion in the metamorphosis of life, thank you. For you it has never been a priority whether I finalized the dissertation or not – it has just been something which can be left behind if it does not feel right in my life. With you, I have the space and foundations to do my things, whatever they are.

Helsinki, March, 2019

Heta Tarkkala

Contents

Abbreviations

AML	Acute Myeloid Leukemia
BBRMI	Biobanking and BioMolecular resources Research Infrastructure. Also BBMRI ERIC (European Research Infrastructure Consortium).
CML	Chronic Myeloid Leukemia
CRO	Clinical Research Organization
FDH	Finnish disease heritage
GWAS	Genome-Wide-Association-Studies
HGP	Human Genome Project
ICD	International Statistical Classification of Diseases and Related Health Problems or a shorter form used as well: International Classification of Diseases
MEE	Ministry of the Economy and Employment
MSH	Ministry of Social Affairs and Health
R&D	Research and development
R&D&I	Research and development and innovation
SOP	Standard operating procedure. Used in clinical laboratories.
THL	National Institute for Health and Welfare. Terveyden ja hyvinvoinnin laitos (THL) in Finnish.
VALVIRA	National Supervisory Authority for Welfare and Health. Sosiaali- ja terveysalan lupa- ja valvontavirasto in Finnish.

A subtle mixture of belief, knowledge, and imagination builds before us an ever changing picture of the possible. It is on this image that we mold our desires and fears. It is to this possible that we adjust our behavior and actions. In a way, such human activities as politics, art, and science can be viewed as particular ways of conducting this dialogue between the possible and the actual, each one with its own rules.
(Jacob, 1982: viii).

Why would we expect economies to grow and sciences to advance?
(Tsing, 2015: 21)

1. Introduction

This study discusses the early stages of Finnish biobanks, and presents an analysis that studies biobanks as a precondition for the development of personalized medicine. It addresses the rearranging of human biological samples in biobanks for contemporary biomedical research that is increasingly large-scale, international, data-intensive, collaborative between public and private, and intermingled with care. In the case of Finnish biobanks, practices and expectations are in constant interplay: they are intertwined, malleable, and molding. In particular, I explore how biobanks are expected and said to contribute to contemporary biomedical knowledge production. To do so, this study unpacks central notions in relation to Finnish biobanks: high quality samples, population(s), and translational medicine.

Biobanks are "precariously situated at the intersection of science, genetics, genomics, society, ethics, the law and politics" (Moodley and Singh, 2016: 1). They organize the standardized production, storage, and distribution of samples and related data for biomedical settings, and serve as an infrastructure for research, development, and innovation. Biobanks are also seen as an answer to the problems of health care systems dealing with aging populations and rising costs. Additionally, they articulate the commitment of university-based research to benefitting society, not only in Finland but also internationally. In light of this, there has been an ongoing national and international drive to establish research infrastructures and networks such as biobanks, and to advance personalized medicine. These are initiatives conducted in the name of health benefits for citizens and the economic success that would follow from an increase in innovation activities and investments (e.g., Eskola, 2005; European Union, 2009, 2011, 2016, 2017a, 2017b; Ministry of Social Affairs and Health, 2015; OECD, 2007, 2009; Sosiaali- ja terveysministeriö, 2007; Zika et al., 2010).

This study is rooted in the field of Science and Technology Studies (STS), with sociology as my disciplinary background. A central understanding in STS is that scientific facts and scientific knowledge are not pure, isolated entities waiting to be found (e.g., Latour and Woolgar, 1979; Rheinberger, 1997); rather, they are deeply rooted in the practices of specific contexts and, thus, part of society. Indeed, scientific results are gained in orchestrated settings where the conditions of possibility for their emergence are built through the careful crafting and setting up of methods, objects, apparatuses, regulations, technologies, materialities, shared conventions, and so on (see, e.g., Cambrosio et al., 2009; Knorr-Cetina, 1999; Latour and Woolgar, 1979; Rheinberger, 1997; Subramaniam, 2014). Therefore, this study builds on work that has addressed scientific practices in relation to the research materials used such as drosophila flies or cultured cells (see e.g., Fujimura, 1996; Kohler, 1994; Landecker, 2009); in the course of this, it has exposed the intriguing ways that the making of biomedical knowledge based on biobanks' offerings "can be at the same time realist and constructivist, immediate and intermediary, reliable and fragile, near and far" to use the words of Bruno Latour (1999: 30). I also draw on discussions of the co-production

of science and society, especially through the imaginaries involved, and the roles played by the regulations and collective actions in the making of new knowledge in biomedical science (Cambrosio et al., 2006; Cambrosio et al., 2009; Jasanoff, 2004; Jasanoff and Kim, 2015; Keating and Cambrosio, 2003).

Biobanks exemplify loci where the careful crafting of research materials for future-oriented biomedical research is actually being carried out, something reflected in the subtitle of this study "biobanks as conditions of possibility for personalized medicine". Indeed, they have been seen as vital to the development of personalized medicine, that is, medical practice that can treat individuals (instead of averages) based on validated knowledge and the utilization of different types of genomic and phenotype data (see, e.g., Nimmesgern et al., 2017). This has led to my interest in how biobanks would, and could, matter for care, research, and innovation. Also linking to my interest in contemporary biomedical knowledge production and its requirements, conditions, and constraints is, firstly, the effort to increase the validity and reproducibility of research results (see, e.g., Begley and Ioannidis, 2015; Bustin, 2014; Ioannidis, 2005). Secondly, the unique Finnishness that is framed as a competitive edge and of interest for investors seems to be crucial in innovation policy, although there are also those who regard the potential multiplicity of populations as an advantage. Thirdly, not only are biobank samples often collected as part of patient care, biobanks have also been envisioned as informing such care, meaning that they could function as translational biobanks. The analytical sections of this study unpack these elements on their own terms and thus can be read as individual chapters that are drawn together by research interest rather than an axiomatic storyline.

Thus, the study brings together a focus on biobanks and promissory biomedicine, and one related to biomedical knowledge production and its prerequisites. The main argument is that the very idea of biobanks is being reshaped, as actual operations, conventions, regulatory frameworks, and new expectations are linked to the personalized medicine imaginary and require that action be taken. The different layers of stakeholders, regulations, developments, and projects that condition and constrain biobanking and hence knowledge production, have, and continue to have, an effect on what biobanks are considered and understood to be, and what kind of knowledge and scientific practices they could foster. The analytical chapters illustrate the multiplicity of tendencies and linkages attendant on biobanks as they begin to reorganize biomedical research. The chapters can be read as empirical examples of this kind of promissory environment constantly in the search of the new, investigating societal visions that seem to promise a future better than the present. However, the researcher herself is not necessarily committed to these visions nor always convinced about their realization in the near future.

This study departs from biobank research that addresses, for example, matters of informed consent, or the relationships between publics and biobanks. I acknowledge the plethora

of social science literature and work being done in this field,[1] although I turn to those discussions only insofar they share an interest in knowledge production, expectations, and infrastructures (e.g., Aarden, 2017; Fortun, 2008; Kohli-Laven et al., 2011; Morrison, 2017; Pálsson, 2007; Timmons and Vezyridis, 2017; Williams, 2017). In what follows in the rest of this introduction, I contextualize biobanks in Finland and discuss them as collections. Then I outline the structure of the study as a whole, before moving on to the next chapter where the theoretical orientations of this research are presented, followed by a chapter on data and methods.

What are biobanks?

Biobanks are sample collections that serve as a resource for biomedical research. The samples themselves are combinations of, for example, tissue, blood, or saliva, and donors' related health data; these comprise an elementary part of what is being stored in biobanks. These biorepositories are often collected prospectively for the purposes of future research, development, and innovation; typically, the specific uses to which the sample will be put is unknown at the time of its collection. Different kinds of biobanks may be, for example, clinical, disease-specific, or population based (Gottweis et al., 2012: 13). It is often assumed that gene banks and biobanks are same thing, but they differ in that biobanks are usually based on samples of human origin (see, e.g., Hewitt and Watson, 2013) while gene banks

1 For example, on the attitudes and perceptions towards biobanks, biobank participation and biomedical research see e.g., Halverson and Ross (2012a), Hemminki et al. (2009, 2009), Johnsson et al. (2008, 2010), Kettis-Lindblad et al. (2006), Lipworth et al. (2011), McCormack et al. (2016), Nobile et al. (2013, 2017), Snell (2012) and Tutton et al. (2004); for trust and biobanking see e.g., Dabrock et al. (2012), Hansson (2005), Petersen (2005) and Thornton (2009); privacy e.g., Snell et al. (2012); for the significance of informed consent see e.g., Caulfield and Murdoch (2017), Hoeyer (2003), Hoeyer et al. (2004), Hoeyer and Hogle (2014) and Tupasela (2008); for the potential incidental or secondary findings and returning of research results from biobanks e.g., Halverson and Ross (2012a, 2012b), Hoeyer, (2010), Knoppers and Kharaboyan (2009), Meulenkamp et al. (2012), Murphy et al. (2008) and Solberg and Steinsbekk (2012); for the publics and populations of biobanks e.g., Busby and Martin (2006), Gaskell et al.. (2013), Gottweis et al. (2011), Hinterberger (2012c), Prainsack (2007), Rose (2003), Tupasela et al. (2015), Tutton (2009) and Winickoff (2006); for the commercial use of tissue and data e.g., Critchley et al. (2015), Martin et al. (2008), Steinsbekk et al. (2013) and Tupasela and Snell (2012); for policy developments and governance see e.g., Boeckhout and Douglas (2015), Gottweis (2008), Gottweis and Petersen (2008), Lauss et al. (2011), Palsson (2007), Palsson and Prainsack (2011), Tupasela (2011) and Tutton (2007). This literature overlaps, intersects, and links with the plethora of social science and STS studies that address genomics, postgenomics, and different aspects of biomedical research and its making e.g., Cooper (2008), Cooper and Waldby (2014), Fox Keller (2009), Franklin (2007), Fujimura (1996), Helen (2016), Keating and Cambrosio (2003), Landecker (2009), Leonelli (2016), Lindee et al. (2003), Lock and Nguyen (2011), M'charek (2005), Montoya (2011), Parry, (2004), Rabinow (2002), Reardon (2009), Richardson and Stevens (2015), Rose (2009), Sunder Rajan (2006, 2012), Tamminen et al. (2013), Thacker (2006), Thompson (2013), Wade (2017), Wade et al. (2014) and Waldby and Mitchell (2006).

may store plant and animal materials. There have been biobanks[2] (collections of samples of human origin) for decades, but significant changes in the field of life sciences have led to a growing interest in founding biobanks that meet contemporary requirements (Gottweis, 2008: 22–23).

Internationally, there is not a clear definition of biobanks as they come in different forms, for different purposes, are administered differently, and work according to different governance requirements (Hewitt and Watson, 2013). Hewitt and Watson (2013: 314) reach the conclusion that a biobank could be defined as a "facility for the collection, preservation, storage and supply of biological samples and associated data, which follows standardized operating procedures and provides material for scientific and clinical use". However, in Finland, and also in this study, what is understood as a biobank is guided by the Biobank Act (2012), according to which a biobank is "a unit maintained by an operator engaging in biobanking activities for the purposes of collecting and storing samples and information associated with the samples for future biobank research". The Biobank Act defines biobank research as "research utilising the samples contained in a biobank or information associated with them for the purposes of promoting health, understanding the mechanisms of disease or developing the products and treatment practices used in health care and medical care". Moreover, in Finland, all biobanks must be registered and approved by the National Supervisory Authority for Welfare and Health (Valvira). Before a biobank can be registered, or even file a register application, ethical approval from the National Medical Research Ethics Committee (TUKIJA) must be obtained. A biobank's register application includes

> documents showing legal status; the statement of TUKIJA; nomination of "custodian of the biobank" and his or her training and experience; accounts for risk management and quality control; organization chart; personnel; capacities and responsibilities; personal register notifications; and list of standard operating procedures (Soini, 2016: 28).

Moreover, biobanks need to be "registered with the data protection ombudsman", while Valvira[3] guides the activities of registered biobanks "and has competence to intervene, order and make inspections or injunctions if necessary" (Soini, 2016: 28).

2 For example, in a report by Zika et al. (2010), cohorts of the National Institute for Health and Welfare (THL) are identified as Finnish *biobanks* along with The Finnish Twin Cohort, Helsinki Sudden Death Study, Tampere Coronary Study and Tampere Acute Coronary Syndrome Study. Additionally, according to the report, "there are many small research biobanks established by various researchers and research groups at the universities" (Zika et al., 2010: 42–43). Nowadays many of the collections listed in the report are part of the collections of Finnish biobanks, but not considered individual biobanks as such.

3 At the latest from 31.12.2019 onwards FIMEA will be responsible for these activities (http://www.fimea.fi/-/terveysteknologian-valvonta-siirtyy-valvirasta-fimeaan).

A biobank in this dissertation refers to collections of samples and data that in Finland are biobanks in the sense of the legislation. Generally Finnish biobanks differ slightly from each other in terms of whose data are included and what kind of samples are collected. There are six clinical biobanks storing patient samples, the biobank of the National Institute for Health and Welfare (THL) which stores population-based and disease-specific sample collections, the Biobank of the Finnish Red Cross Blood Service storing samples from a population of blood donors, and, currently, one disease-specific biobank, the Finnish Hematology Registry and Biobank (FHRB), that stores samples from patients with hematological diseases; since 2017 the private health care provider Terveystalo has also had its own biobank. The disease-specific Helsinki Urological Biobank (HUB), once independent, has now merged with the clinical Helsinki Biobank. The two disease-specific biobanks started as pilot biobanking projects, which meant that they initially operated as individual research projects; however, I refer to them as biobanks instead of differentiating between pilot projects and biobanking, since they were formed with the idea of eventually meeting the requirements of the Biobank Act. What made them different from previous sample collections for research was the goal of collecting samples prospectively for research purposes, and the aim of creating a collection of samples of human origin with attached clinical data to be used for various research settings by a range of researchers and private partners: in brief, a collection of biological material and attached data accessible to many, whether private or public, unlike previous collections of research materials.

Biobanks collect samples for their prospective collections with the consent of patients. Often the sample is blood, but there are also broader collecting efforts: for example, the FHRB and the HUB have collected disease specific samples from different stages of cancer and the FHRB stores living, viably frozen cells (see http://www.hematology.fi/en/shy/fhrb/fhrb-sample-status). Despite the effort to collect samples prospectively, most of the samples stored in the epidemiological and clinical biobanks are based on older sample collections, such as research cohorts and pathology archives. The Finnish legislation has allowed this "special procedure" (Soini, 2016: 30) of translating old samples into biobanks if they were collected before 1.9.2013, that is, prior to the Biobank Act's coming into force. The transfer was possible on condition that "the person from whom the sample has been taken does not object", the "use for clinical purposes (patient care) is not jeopardized", and a "regional ethics committee approves the transfer" (Soini, 2016: 26). Even though consent was not asked before storing these old samples in biobanks, a "specific notification procedure" and the possibility to opt out were required (Soini, 2016: 30). It was argued to be too costly to reach everyone whom the transfer concerned individually, and a notification in newspapers, institutional webpages, "or an official journal" was considered sufficient (Soini, 2016: 30).

With these old samples, related donor data have, of course, also been translated, since they are an important part of the samples and their usability. Sample-related data include,

according to a directional letter[4] from Valvira and Tietosuojavaltuutetun toimisto (2015), general donor information, such as the sex, date of birth, and time and cause of death of the subject. Sample-related data can also comprise technical details related to the sample type, processing, diagnoses, sample history, or already generated analyses based on the sample, and further material relating to the sample, such as diagnostics, medical operations or procedures, laboratory results, time spent in hospital, and so on. Finally, the analyzed results of biobank-based research projects can also be regarded as sample-related data (Valvira and Tietosuojavaltuutetun toimisto, 2015).

A brief background history

Since the late 1990s and early 2000s, there has been a growing emphasis both internationally and nationally on establishing biobanks (Eskola, 2005; Palotie and Peltonen-Palotie, 2004; Sosiaali- ja terveysministeriö, 2007; Tupasela, 2006a, 2007; Yuille et al., 2008; Zika et al., 2010). The first collections, clearly preceding contemporary biobanks, were already in place in the 1990s: for example, in Iceland and Estonia. According to Hewitt and Watson (2013: 309), the term biobank first appeared in 1996 in the titles and abstracts of scientific literature. At that time, at the end of the '90s and at the turn of the millennia, examples of biobanks included, for instance, the Danish neonatal serum bank and the biobanks of the United Kingdom and Japan (Hewitt and Watson, 2013: 309). However, probably the most famous biobank project has been that in Iceland. The Icelandic biobank, DeCode Genetics, accompanied by the Health Sector Database, has served internationally as an example and reference for later projects (Winickoff, 2006), accelerating the development of these kinds of databanks elsewhere. Indeed, numerous countries now have their own biobank projects: Japan, Taiwan, Canada, China, Iceland, United Kingdom, Sweden, Singapore, and Estonia to name a few (Aarden, 2017; Fan et al., 2008; Gottweis, 2008; Nordforsk, 2017; Ong, 2016; Pálsson, 2007; Sunder Rajan, 2006; Tsai, 2010). However, the Icelandic case also exemplifies the hurdles and challenges to such projects; DeCode genetics has suffered bankruptcies and also created tensions in Iceland with regard, for example, to the private ownership of the collection, which has had several owners over the years (e.g., Fortun, 2008; Pálsson, 2008; Reardon, 2017; Rose, 2006). Similarly, the Generation Scotland biobank has faced problems of sustainability and must actively search for ways to make its collection attractive (Reardon, 2017: 107–111).

Biobanks in Finland are very much part of the international enterprise to establish biobanks and organize the collection, storage, and distribution of samples and data, encouraged by organizations such as the OECD (2007, 2009) and European Union (2009). In many ways, the intensified creation of biobanks during the first two decades of the 21st century has

4 This letter by Valvira – the National Supervisory Authority for Welfare and Health and the Office of the Data Protection Ombudsman can be found (only in Finnish) at: http://www.tietosuoja.fi/material/attachments/tietosuojavaltuutettu/tietosuojavaltuutetuntoimisto/tiedotteet/puAfi7h0p/Valvira__TSV_ohjaus.pdf (Valvira and Tietosuojavaltuutetun toimisto, 2015).

also resulted from developments in the life sciences, bioinformatics, and technologies. For example, the Human Genome Project (HGP) and the first reading of the complete human genome in 2003 generated considerable enthusiasm and optimism; as a result, genomics were expected to provide new cures and knowledge of health and disease very rapidly (e.g., Reardon, 2017). Meanwhile, a new need for samples has emerged, since methods in molecular biology and proteomics (and other –omics such as metabolomics), as well as the growing capacity to handle data, have led to new possibilities in the pursuit of both health and economic growth (Gottweis, 2008: 23).

To research the complex mechanisms behind diseases, large populations need to be studied, a requirement which has led to considerations and claims about which populations are the most suitable for this endeavor (Hinterberger and Porter, 2015; Tupasela, 2016; Winickoff, 2006). One result of this is that many countries have claimed that their own collections are drawn from populations offering especially high potential for biomedical research (Tarkkala and Tupasela, 2018). The isolated Finnish gene pool, for example, is being framed as particularly valuable in terms of innovation materials and strategies fostering the health care sector and its growth (e.g. Ministry of Social Affairs and Health, 2015).

Simultaneously, the data that biomedical research enterprises require must be harmonized in order to be as widely usable as possible. Therefore, current biobank projects are often accompanied by a plethora of complementary projects and organizations aiming to foster and harmonize practices relating to the standardization of sample quality and data:[5] in Europe, for example, BBRMI-ERIC is playing a key role in developing common practices and guidelines for European biobanks and biomolecular resources (www.bbmri-eric.eu). As the handling of 'big data' and data masses is now considered possible, and research concentrates on very detailed and specific aspects of phenomena, vast quantities of harmonized data are needed. Indeed, standards and standardization are said to be one of the cornerstones of the wider field of biomedical research (see, e.g., Keating and Cambrosio, 2003); they align practices in different places as they "make things work together over a distance" (Timmermans, 2015: 79).

Gottweis (2008: 23) has noted that "what biobanks are 'doing' goes far beyond contributing to basic research in biology". They are "connected to a variety of scientific, economic and political objectives" (Gottweis, 2008: 24). In recent years they have become an important policy matter, with large genomics initiatives being introduced in different countries in order to be forerunners in the research, development, and utilization of the field. These include the 100,000 Genomes Project in the UK and the All of Us Program in the USA, the latter accompanied by a renewed call for war on cancer (Cancer Moonshot), as well

5 E.g. ISBER, BIOMEDBRIDGES, ISBER, BBRB (by NCI), P3G, ESSB, P3G, BBMRI-ERIC, ELIXIR, ICPerMed. See Chapter 4.

as the German Personalized Medicine Initiative; in Finland, biobanks are currently being utilized as part of the FinnGen study, which aims to genotype 500,000 Finns. In recent years Finland has also introduced a series of initiatives all aiming to foster personalized medicine in the country.[6]

When it comes to the development of biobanks over time, Simeon-Dubach and Watson (2014) have argued that, in the first phase, biobanks concentrated on collecting "large numbers of biospecimens"; quantity was believed to be required for methods such as Genome Wide Association Studies (GWAS), which led to the conclusion that biobank networks were needed (Simeon-Dubach and Watson, 2014: 302). In the next phase biobanking focused more intensively on quality, as it became evident that inconsistency in this area is a problem for the credibility and validity of research and, for example, the development of biomarkers (Simeon-Dubach and Watson, 2014: 303). From the focus on quality, the writers suggest that biobanks then moved on to emphasize "enhancing the value and impact for the three major sets of external stakeholders (people/patients, funders, and research customers)" (Simeon-Dubach and Watson, 2014: 306). This means that instead of setting up basic operations, the focus would increasingly lie on how to operate sustainably and effectively over time. This enhancing of value for society is what is also expected from biobanks in Finland, which link health efforts with the innovations and policies of knowledge-based societies.

Building biobanks in Finland – infrastructure with unique opportunities

In Finland the first biobanks which were prepared to meet the requirements of biobank legislation – the Finnish Hematology Registry and Clinical Biobank (FHRB) and the Helsinki Urological Biobank (HUB) which began as independent pilot projects – started to operate in 2012-2014. Eventually, the Biobank Act came into force in 2013, after which new biobanks were founded. Currently, there are ten that meet the requirements of the legislation and are officially registered in the biobank register held by Valvira (see Table 1, p. 10).

The legislation made it possible to register biobanks in Finland officially and has simultaneously guided understandings of what is meant by the term. Finnish proponents had argued for a decade, both in international and national arenas, for the need to establish biobanks before the legislation finally came into force (Eskola, 2005; Käpyaho et al., 2004; Palotie and Peltonen-Palotie, 2004; Yuille et al., 2008). Since the initiative to establish biobanks in Finland began, the basic storyline has remained the same: Finnish tissue samples which have already been collected offer potential value for scientific research

6 Not only are there now biobanks, but the Finnish Comprehensive Cancer Center was also founded, and a Genome Centre and Neurocenter are on their way; meanwhile legislation concerning the secondary uses of health and social data has just been accepted (see https://stm.fi/yksilollistetty-laaketiede).

and the economy, and their use for research purposes should not be restricted – therefore biobank legislation is needed (Tupasela, 2006: 105). In 2006 The Ministry of Social Affairs and Health appointed a group to prepare the relevant legislation. This resulted in a report entitled, "Biobanks - in our common interest. Final Report of the Working Group examining how to use collections of samples of human origin" (Sosiaali- ja terveysministeriö, 2007). The path to the finished Biobank Act still took time; a new government was formed before the Act was eventually approved in 2012, and the legislation adopted in 2013. Throughout the process, and still today, Finland has been advertised and regarded as an excellent environment in which to found biobanks,[7] exemplified by the following quote from Auria Biobank's homepage: "Finnish biobanks are supported by a uniform public health system, precise registration of medical history, a population register and citizens who have a positive attitude towards research work" (www.auriabiopankki.fi).

Less than five years after the first biobanks were established, a process with the aim of merging the clinical biobanks into a single Biobank Finland commenced. An expert group was appointed to consider this possibility, which resulted in the Finnish Biobank Cooperative, FINBB (Ministry of Social Affairs and Health, 2016), seen to serve as a one-stop shop if a collaborator is interested in utilizing samples and data from the clinical biobanks in Finland. A process to review the biobank legislation was also initiated at the same time and it is expected that renewed legislation will come into force in 2019. It is apparent that biobanks in Finland operate in a changing and developing landscape.

Biobanks as collections

In many ways biobanks represent a continuation of the history of medical collections, particularly when we consider the earlier clinical samples and population cohorts on which many Finnish biobank collections are based. These specimen collections with their related data, now translated into biobank collections, have thus existed for decades. Bruno Strasser (2012a: 303-304) has put the collecting and collections into historical context from the viewpoint of the present, observing that contemporary reasoning often assumes that it is only recently that we have been confronted with data masses beyond our imagination. Yet biobanks are built on a history of medical collections and only the new samples are collected using the standardized protocols of today. Thus, these collections, both old and new, are part of a longer history of *collecting as scientific practice* (see, e.g., Heesen and Spary, 2001; Strasser, 2012a).

Aaro Tupasela (2008) has connected tissue collections such as those in biobanks with the concept of epistemic cultures (Knorr-Cetina, 1999). By epistemic cultures, Knorr Cetina

7 This rhetoric is strikingly similar to how Iceland was, and still is, framed as an environment for genomics (Fortun, 2008; Pálsson, 2007; Rose, 2003; Winickoff, 2006), see Chapter 5. Furthermore, the biobanks and registers in Nordic welfare states have been identified as "goldmines" for biomedical research (Nordforsk, 2014, 2017), an issue to attend to in further research on the topic.

Table 1. Biobanks with biobank projects that started before 2013

Pre-act projects or collections (prior to 1.9.2013)	Registered in 2014-2015	Registered in 2016-2018	Member of Biobank cooperative, FINBB 2017
FHRB 2011-2014	FHRB 15.7.2014		
HUB 2012-2014	HUB 10.11.2014		
	Auria 10.3.2014		x
	THL 10.3.2014		
	Helsinki Biobank 21.4.2015	HUB integrated to Helsinki biobank in 1.3.2016	x
	Borealis 10.7.2015		x
	Tampere biobank 8.9.2015		x
	Itä-Suomen biopankki 29.10.2015		x
	Keski-Suomen biopankki 29.10.2015		x
		Red Cross Blood Service biobank 30.5.2017	
		Terveystalo biobank 11.10.2017	

(1999: 1, emphasis original) refers to the "arrangements and mechanisms" that "in a given field, make up *how we know what we know*". Her goal is to amplify "the knowledge machineries of contemporary sciences" to display the practices that are at play in the ways knowledge is being built (Knorr Cetina, 1999: 3, 10). Based on seeing collections as part of a particular epistemic culture, Tupasela (2008: 44) underlines the exchange value and productive potential of the collections in a commercial sense. Moreover, there have been other kinds of circles of exchange on the side of more institutionalized medical or research collections; in the history of natural collections the establishment of the circulation of samples was crucial (see, e.g., Müller-Wille, 2001; Müller-Wille and Charmantier, 2012; Star and Griesemer, 1989), while in medical research the circulation of certain samples has taken place between collaborators and researchers[8] as routine practice. Nowadays exchange is institutionalized and stabilized, some say even democratized, in biobanks compared to past, socially organized practices between researchers.

What we can see in biobanks and in the organization of their samples for molecular biology, is, following Bruno Strasser (2012a), the merging of two traditions in the natural

8 See Kohler for how geneticists established an exchange system of standardized drosophila flies, creating a distinctive way of using the fly as a tool while simultaneously aligning the laboratories' work (Kohler, 1994); for traffic in samples as well as sample exchange between various stakeholders involved in the many contexts of medical research, see Warwick Anderson's *Collectors of the Lost Souls* (2008).

sciences: scientific experiments and collecting as it took place in natural history collections. Therefore, the DNA sequence database, GenBank, for example, which serves as an important tool for researchers, does not only represent the "cutting edge of biology", but is also part of a "tradition of natural history" characterized by "collecting, naming, comparing, and organizing natural objects" (Strasser, 2008: 537). Thus, databases such as GenBank exemplify a hybrid culture based on natural history and the experimental sciences (Strasser, 2008, 2011). In this sense biobanks are also part of the kind of knowledge production that is crucially about "collection, comparison, and computation of biological data", and thus not only about the triumph of experimentation (Strasser, 2012a: 305).

In line with this I argue that the merging of experimentation and collecting is demonstrated by the biobank samples and the reasoning about their purpose. The possibility for experiments needs to be maintained; only in this way can biobanks contribute to the identification and development of new tools such as biomarkers. In the same manner, Strasser (2012a: 335) emphasizes the required connection to experimenting; one can spot connections between different outcomes from the databases, but these connections need to be verified by experiments (Strasser, 2012a: 335). Thus, the samples in biobanks, as data and as wet samples, as virtual and as material to be worked on, seem to allow both the finding of connections and their experimental verification. Indeed, the biobank materials are not only for comparison but also for the experimental production of new knowledge; they both enable and are built on experimentation. Strasser highlights the "hybrid character" of producing "knowledge through both experimentation and collection" in "current biomedical research" (Strasser, 2012a: 336) that combines "the data-driven and hypothesis-driven, the comparative and the exemplary, the experimental and natural historical" (Strasser, 2012b: 87). With this hybrid way of doing biomedical research the "boundaries between specimen collections and molecular data collections are becoming increasingly blurred" (Strasser, 2009: 1672), which is also evident in the case of high quality samples, as I demonstrate in my analysis in Chapter 4.

Structure of the study

The structure of the study continues as follows. In the next two chapters (2 & 3) I present and discuss the main concepts and theoretical frameworks of the volume as well as the data, methods, and the analytical process on which it is based.

The following three chapters (4, 5, and 6) present my empirical analysis. In Chapter 4 the making of personalized medicine is discussed in the context of the "high quality samples" biobanks are now said to offer to the field of biomedical research and development (R&D). The goal of the chapter is to explore and present what is woven into the concept of "high quality samples" and the key role they play in the knowledge production that takes place through these building blocks of distinguished quality.

Chapter 5 turns the focus to research populations in biomedicine and what Finnish biobanks offer biomedical R&D in this field: first, an innovation policy effort aims to build a competitive edge based on the genetic homogeneity of Finns; second, and in contrast to the first point, the multiple and malleable populations that can be stratified and pooled in Finnish biobanks were expected to be of interest for biomedical R&D. I analyze and discuss these twofold approaches in relation to populations stored in biobanks in the making of personalized medicine. Moreover, I show how these reasonings, and the populations, are bound up with ideas of Finnish society more widely and echo the case of Iceland.

Chapter 6 addresses how it is expected that personalized medicine will develop in the clinics with the help of biobanks, especially under translational medicine concentrating on individualized cancer care and the utilization of clinical data that have served as examples of what biobanks could foster. In the analysis I show how biobanking and the expectations of closer connections between clinical care and research are conditioned and constrained by the many layers of regulations that are not just top-down restrictions. Furthermore, the distinction between clinical care and research is seen in the analysis as ambiguous.

The last chapter of the study (7) offers a review of the empirical sections and concludes with discussion of the main themes of the study: sociotechnical imaginaries and biobanks as the conditions of possibility for personalized medicine. I point out how the constant change and iteration of the personalized medicine landscape not only forces biobanks to adapt, but also restricts and defines what they can be, which might turn out to be counter to the ideas on which they were built.

2. The sociotechnical imaginary of personalized medicine and biobanks as conditions of possibility

Expectations and prospects play a crucial role in the development of biobanking, largely because the establishment of biobanks is seen as elementary in enabling large-scale biological research and thus, eventually, personalized medicine (see, e.g., Gaisser et al., 2008; Gottweis, 2008: 23; Hewitt, 2011). This study utilizes the concepts of sociotechnical imaginaries and conditions of possibility to analyze biobanks, setting out from the premise that imaginaries and expectations related to infrastructure such as biobanks are what make things happen. They coordinate actions and label them, provide motivation, and bring people and things together in pursuit of how things ought to be, even if goal fulfilment is uncertain (e.g., Borup et al., 2006; Brown and Michael, 2003; Tarkkala et al., 2018).

In this chapter, I operationalize the key concepts that contextualize my analysis. I first discuss expectations and sociotechnical imaginaries, followed by the concept and phenomenon of personalized medicine and why I see it as a sociotechnical imaginary. I then connect biobanks – as conditions of possibility for personalized medicine – to a specific understanding of regulatory objectivity as a characteristic of knowledge production in biomedicine. The concepts that frame the overall context and research questions share an emphasis on dynamics related to science, technology, society, policy, regulations, scientific practices, and futures in the making[9]. Lastly, I present the research question(s) and the contribution made by this study to discussions related to expectations and sociotechnical imaginaries.

Expectations and sociotechnical imaginaries

Medicine, biomedicine, and genomics have been analyzed in the context of hopes, promises, potential, and future imaginaries and orientations (e.g., DelVecchio Good, 2003; Helén, 2004; Novas, 2006; Petersen, 2015). Many social science and STS studies variously address the role played by future orientations, or the creation or maintenance of certain futures, in contemporary societies (see, e.g., Adam and Groves, 2007; Adams et al., 2009; Appadurai, 2013; Beckert, 2016; Borup et al., 2006; Brown, 2003; Brown and Michael, 2003; Fortun, 2008; Franklin, 2001; Fujimura, 2003; Hedgecoe, 2004; Jasanoff and Kim, 2015; Rabinow and Dan-Cohen, 2005; Selin, 2008; Taussig et al., 2013).

STS studies of emerging technologies have shown that expectations are not just hype; rather, they legitimate certain projects or initiatives, attract investment, and indicate certain directions and paths to the future, thereby reducing uncertainty. Expectations also have

9 This also relates to the concepts utilized in the analytical sections: for instance, Hans-Jörg Rheinberger's (1997) dynamic loop between technical objects and epistemic things stresses the interplay in science between the standardized and already-known and its orchestration in order to allow the emergence of something previously unknown.

a coordinating effect: they bring actors, institutions, and networks together and organize practices and communities (Borup et al., 2006: 285–286; Fujimura, 2003: 192; van Lente, 2012: 773–774); they also reconfigure and reorganize resources to highlight particular futures and shape practices, thus mobilizing futures today (Brown, 2003: 5). Indeed, expectations are "*situated* or *located* in real-time current conditions and settings" and they "reflect our present" (Brown and Webster, 2004: 181 emphasis original). Biobanks, and the role they are seen to play in pursuing genomics and personalized or data-driven medicine, mobilize those futures in the present despite whether the expectations placed in them are eventually met (see also Helén, 2016: 248-251).

The role of imaginaries in social life has also been investigated (e.g., Anderson, 1991; Beckert, 2016; Taylor, 2004), while biomedicine and its ability to produce hope[10] has been discussed in terms of specifically medical imaginaries (DelVecchio Good, 2003). Similarly, expectations related to science and technology in society, and their particular contexts, have been conceptually addressed in STS through the notion of *sociotechnical imaginaries* by Jasanoff and Kim (2009, 2013, 2015). The aim with this concept is to fill a gap in the literature when it comes to understanding future-oriented "interconnections between technoscientific and political practice", especially in regard to innovations (Jasanoff, 2015a: 10). According to Jasanoff (2015a) sociotechnical imaginaries are

> collectively held, institutionally stabilized, and publicly performed visions of desirable futures, animated by shared understanding of forms of social life and social order attainable through, and supporting of advances in science and technology. (Jasanoff, 2015a: 4)[11]

This view addresses the constitutive role of science and technology in the building and realization of the imaginary. Science and technology are likely to play key roles in our understandings of what should be achieved in our societies and by which means; thus, sociotechnical imaginaries also highlight the co-production of science and society (Jasanoff, 2004). As Francois Jacob writes:

> In some respects at least, myths and science fulfill a similar function: they both provide human beings with a representation of the world and of the forces that are supposed to govern it. They both fix the limits of what is considered as possible. (Jacob, 1982: 9)

10 On hope in promissory biomedicine see Brown (2003), Franklin (1997), Helén (2004), Kitzinger (2008), Martin et al. (2008), Moreira and Palladino (2005), Novas (2006) and Petersen (2015).

11 Originally sociotechnical imaginaries were defined as "collectively imagined forms of social life and social order reflected in the design and fulfilment of nation specific scientific and/or technological projects" (Jasanoff and Kim, 2009: 120). The new formulation is less committed to national level.

As encapsulated by the concept of sociotechnical imaginaries, the tools and means provided by science and technology play an important role in imagining our futures. Simultaneously, built as they are on the past, visions of desired futures are by no means neutral (Jasanoff, 2015a: 22). Moreover, imaginaries such as personalized medicine often come with specific local characteristics (e.g., Faulkner, 2017; Felt, 2015; Jasanoff and Kim, 2009, 2013, 2015). For example, in Finland, success in personalized medicine is configured based on the national registers, regulatory environment, and the population as a homogeneous isolate, among other things (e.g., Ministry of Social Affairs and Health, 2015). However, the genomics in Latin-America, for example in Brazil and Mexico, are very much built on racial heterogeneity (e.g., Benjamin, 2009; Wade et al., 2014), while in Singapore the goal is to stay competitive, and put the heterogeneous "Asian" populations onto the map of biomedical research, thereby ensuring that the needs of these groups are met (Ong, 2016).

The concept of the sociotechnical imaginary (Jasanoff and Kim, 2015) resembles earlier, future-oriented conceptualizations and discussions in STS. Other STS scholars have also seen the role of science and technology as important in constructing the future (see, e.g., Brown et al., 2000); while Hedgecoe (2004), for example, has demonstrated the politics inherent in pharmacogenomic expectations. However, I have chosen to frame my research with the notion of sociotechnical imaginaries, since the concept guides work towards specific imaginaries, such as personalized medicine, enabling analysis of developments and changes in imaginaries over time in their specific and particular contexts, and in relation to different policies (Jasanoff, 2015a, 2015b). Consequently, the concept also demarcates, since there always are specific imaginaries under study.

Personalized medicine as a sociotechnical imaginary

Personalized medicine, as a term, currently refers to a more individualized way of treating patients. Offering the same standard treatment to everyone is no longer considered an option; instead, every patient and every disease is regarded as potentially one of a kind (National Research Council, 2011). According to Tutton (2014: 3), personalized medicine rearticulates "long-standing debates in medicine about how to make sense of individual differences and what they mean for disease prediction, treatment and care". While there is no official definition, in the European Union Council conclusions on personalized medicine for patients (2015) it is defined as follows:

> [P]ersonalised medicine refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention. (European Union, 2015)

Simultaneously, the term overlaps notions of stratified medicine and precision medicine in many ways and may be regarded as virtually synonymous (e.g., Day et al., 2017); all share

an idea of accuracy and efficacy that goes far beyond treating the average with standard treatments offered for many diseases today.

For example, Hood and Friend (2011) have envisioned medicine becoming "predictive, personalized, preventive and participatory", otherwise referred to as P4 medicine (Hood and Friend, 2011). These four Ps are usually part of what is understood by the scope of personalized medicine in which patients are expected to take increasing responsibility and more active roles when it comes to their health and disease prevention, and to receive more individually tailored treatments (Prainsack, 2017; Tutton, 2014). Indeed, for personalized medicine to become reality, it is argued that patients need to be active: new alliances and partnerships are expected and needed (Hood and Friend, 2011; Prainsack, 2017). This is something Prainsack (2017) has identified as the novelty[12] of personalized medicine. In practice, it means that patients are, according to Prainsack, becoming "prosumers", as they participate both in the production and the consumption of the goods, contents, products, and services in the field of health (Prainsack, 2017: xv). What is considered relevant information when personalizing treatment has changed from "family and social relationships" and "mental state" into a data package of "genetic predispositions", "lifestyle information", and "clinical data" (Prainsack, 2017: 4). Thus, nowadays, the idea of personalization is increasingly data intensive (Prainsack, 2017: 4). Prainsack (2017: 9-10) also notes that personalized medicine, and genomics more broadly, comes with the risk of creating inequality: if a population is understudied, and therefore underrepresented, they do not receive the benefits accruing to other, more studied populations (Bentley et al., 2017; Cornel and Bonham, 2017; Prainsack, 2017: 9–10).

Alongside more general personalized health and personalized medicine developments, there are also more specific and concrete developments. In clinical practice there is already a growing number of examples of personalized medicine, although, in general, knowledge in genomics has not translated into health benefits as was expected in the wake of Human Genome Project (Burke et al., 2010; Guttmacher and Collins, 2005; Lander, 2011). This first reading of the human genome, at the beginning of the millennium, raised hopes of a new kind of medicine, based on better knowledge about diseases and human bodies, and better serving public health. It was expected that "human traits would be linked to common genomic differences" (Stevens and Richardson, 2015: 1). However, biology turned out to be more complex than had been believed (Stevens and Richardson, 2015: 2). Currently, perhaps the best-known examples of individually tailored treatments are the targeted medical substances used in cancer care. For example, one called imatinib (Gleevec) specifically targets the cancer pathway in chronic myeloid leukemia (CML), which has revolutionized the care and life expectancy of people living with CML (Druker et al., 2001; Keating and Cambrosio, 2012; Maughan, 2017); another example of such targeting

12 On the historically changing understanding of what is meant by "personalized medicine", including prior to genomics, see Tutton (2012, 2014).

is the treatment of HER2-positive breast cancer with monoclonal antibody trastuzumab (Herceptin) (Ely, 2009: 305; Keating and Cambrosio, 2012: 315–316).

As noted earlier, personalized medicine comes with expectations of better treatment, more accurate diagnostics, and the prevention of diseases (e.g., Hamburg and Collins, 2010; Hood and Friend, 2011; Swan, 2012), assumptions which appear in the numerous articles, books, reports, and strategy papers written on personalized medicine and in its name (e.g., Collins, 2010; Collins and Varmus, 2015; Hood and Friend, 2011; Ministry of Health and Danish Regions, 2016; Prainsack, 2017; Tutton, 2014). Simultaneously, personalized medicine conferences are filled with "stories of extraordinary outcomes" – successes, that is, even when the field as a whole is perhaps more accurately characterized by its complexity and uncertainty (Maughan, 2017: 17). As Hedgecoe pointed out over ten years ago in the context of pharmacogenomics, it "exists more in the speculations and promises of its supporters than in terms of scientific results and marketable products" (Hedgecoe, 2004: 17), which still seems to hold true. Personalized medicine has also been described as "hype" and portrayed in popular press "as a positive health-care trend associated with few concerns" (Marcon et al., 2018: 6).

The promises of biobanks gain credibility and power from the general visions and actual efforts connected with personalized medicine, which legitimizes biobanking and its re-purposing and reorganization of samples and health data. Simultaneously, both health and monetary values are linked to these efforts (Tutton, 2014: 3). It is no surprise, then, that Tutton has asked whether personalized medicine is "a powerful vision of the future to be likened to a national infrastructure project, merely a marketing strategy, or an approach to patient care that emphasized the 'whole patient'?" (Tutton, 2014: 2). He describes the imaginary of personalized medicine as "the speculative, propositional fabric of scientific thought concerned with the application of genomic knowledge and technologies to the biomedical enterprise" (Tutton, 2014: 10). Following Waldby (2000), Tutton (2014: 8) suggests that imaginaries rely on culturally intelligible fantasies which, for personalized medicine, is individuality. However, in this dissertation, I examine personalized medicine in relation to biobanks through the theoretical lens of the sociotechnical imaginary (Jasanoff and Kim, 2013, 2015) and, thus, my gaze is not directed towards, for example, the growing role of patients (see Prainsack, 2017) or individuality (Tutton, 2014).

Discussions and visions concerning personalized medicine provide prime examples of sociotechnical imaginaries. Personalized medicine is in many ways about economical, societal, and ethical reorganization, with its proponents pushing to create an environment where the imaginary can be actualized; the emphasis lies on potential (Tarkkala et al., 2018). For this reason, I understand personalized medicine as a sociotechnical imaginary that is collective, both locally and internationally, shaping both national and multi-national policies and scientific endeavors. In Finland, biobanks, among other institutions, activate and put into practice the personalized medicine imaginary. Biobanks are established to

serve as infrastructure for research; they organize the collection, storage, and distribution of what is needed for research and development in the field of biomedicine. Understanding personalized medicine as a sociotechnical imaginary (Jasanoff and Kim, 2015) underlines how personalized medicine is not merely about medicine or health (see e.g. Ong, 2016; Sturdy, 2017; Tutton, 2014), but very much about rearrangements being made and actions being taken that arguably are necessary for it to be realized (Tarkkala et al., 2018).

Consequently, the European Alliance for Personalized Medicine, for example, claims that the "European Commission, the European Parliament and EU member states" should "improve the regulatory environment so that Europe's patients and citizens can have early access to personalized healthcare" (www.eapm.eu). Similarly, the International Consortium for Personalized Medicine, founded under the EU, states in its action plan that personalized medicine hinges not only on widespread use of health data and "improved understanding of the biological mechanisms and environmental interactions that govern disease progression", but also on a supportive "policy and regulatory environment" (International Consortium for Personalized Medicine, 2017: 5). Indeed, regulation and policy are not without significance. In recent years, Finland has tried to create "enabling legislation" in order to become a forerunner in this field (e.g., Ministry of Social Affairs and Health, 2015). Meanwhile in the US, Peter W. Huber (2013) regards the regulatory traditions of medicine as an obstacle to what could otherwise be achieved with the new medical technologies and analyses. This crucial role of regulation in scientific practice is also well known through the case of stem cell research in the US from the early 2000s (e.g., Thompson, 2013).

Based on these examples, it is easy to see personalized medicine as a societal phenomenon with links to interests, policy, and regulations. Hilgartner et al. (2015: 7) underline this when they write that "the sociotechnical imaginaries one can distill from policy documents and the public sphere reflect the attempts of governments to integrate expected developments in conceptions of the future world and how we should relate to it and engage with it". Furthermore, personalized medicine as an imaginary that shapes biomedicine comes with intense expectations of economic value, growth, and profits (Aarden, 2017; Sturdy, 2017; Tarkkala et al., 2018). To me too, this aspect also comes under the rubric of the sociotechnical imaginary of personalized medicine. Analytically, the concept of sociotechnical imaginaries allows to see how expectations of social and common good "inform science and technology policies and strategies for their implementation" (Aarden, 2017: 754).

Biobanks as a condition of possibility in a field characterized by regulatory objectivity

This study analyses the role of biobanks in building a future of personalized medicine in which research and clinical care are developing links with increased public and private collaboration. The research infrastructure is seen as a vital element in the creation of the

prerequisites for knowledge production and, therefore, new knowledge as well. This is because biobanks are set up to organize and store much-needed research materials that provide, arguably, both the quantity and quality that biomedical R&D requires. Therefore, biobanks are seen as a condition of possibility for personalized medicine.

My choice to call biobanks a condition of possibility stems from literature[13] which posits practical and regulatory arrangements as crucial constituents of biomedical research and knowledge (e.g., Cambrosio et al., 2017; Keating and Cambrosio, 2003). When biomedical knowledge production is seen from this point of view, it also becomes evident how biobanks and their multiple connections and traces of practices from various stakeholders are involved. Kohli-Laven et al. (2011: 497–498) have described a biobank as a "condition of possibility" in the context of a clinical trial, since the biobank was able to provide tissues and related data that were needed for the research. Their analysis links biobanks to biomedical knowledge-building characterized by regulatory objectivity (e.g., Cambrosio et al., 2006; Keating and Cambrosio, 2003). Regulatory objectivity in the biomedical domain is about "collective production of evidence" meaning that shared conventions are initial elements in paving the way to scientific results and their clinical appropriations (Cambrosio et al., 2017: 164). In this kind of constellation, then,

> standardized dyes and reagents, for instance, account not only for the possibility of seeing something in the first place, but also for the crucial task of establishing equivalences between observations of similar specimens in different locations. Equally as important, they allow researchers to decide whether those specimens and the conditions under which they were analyzed are the same or different. (Cambrosio et al., 2009: 659)

That is, for new knowledge to qualify, the objectivity of these findings hinges on shared conventions and shared "protocols, instruments and substances" that are used in the generation of these findings (Keating and Cambrosio, 2003: 3). These shared reagents, methods, and SOPs are elementary in reaching consensus about the relevance of given results, what they mean, and whether they are valid. It is crucial that the alignment of practices and the interconnectedness of various actors are such that the same actions, tests, and methods can be practiced and utilized in exactly same way in different places (Keating and Cambrosio, 2003). Biobanks are said to contribute to this as they play their part in building and strengthening certain conventions that can serve as references in the

13 "Conditions of possibility" is wording used productively in different contexts, with a key role, for example, in Immanuel Kant's (2004 [1787]) transcendental philosophy. Moreover, in Michel Foucault's (2005) *Order of Things* it is used in reference to an episteme: what makes certain knowledge possible at all in theory or in practice and, therefore, what the necessary prerequisites of knowledge are (Foucault, 2005: xxiii, 185). I do not wish to connect this study with these lines of thinking, as for me the notion, "conditions of possibility", stems from an approach, discussed in this chapter, that underlines the crucial role of conventions and collective actions in the context of biomedicine (see Keating and Cambrosio, 2003).

evaluation of biomedical research (Keating and Cambrosio, 2003: 327). The important point is that "regulatory activities conducted at all levels of research are constitutive" of new applications, new tools, and new knowledge in this field[14] (Keating and Cambrosio, 2003: 3).

In this study regulatory objectivity also characterizes biobanking, as the many layers of regulations are elementary in biobanking activities and their future potential. There must be standards – which conceptually draw together both regulation and objectivity (Thévenot, 2009) – protocols, records, and access policies in order for biobanks to be able to be part of biomedical research. Cambrosio et al. (2006: 194) write that regulatory objectivity foregrounds "collective forms of expertise combining people (clinicians, researchers, administrators, patients, etc.) and objects (entities, instruments, tools, techniques, etc.) connected by specific coordination regimens". When institutional arrangements such as biobanks draw together standardized objects, entities, and tools, with researchers, private companies, and forms of public-private collaboration, as well as various data sources, they are part of the "evidential regime" of biomedical research and knowledge production (Cambrosio et al., 2009: 659). In this regime, according to Thévenot (2009: 796), the "qualification of new scientific entities … is closely linked to the production of standards that are relevant for guiding practice". In other words, the regulation and constitution of novelties in this domain are inseparable (Cambrosio et al., 2017: 161). Conceptually, then, regulatory objectivity is one of the reasons why biobanks can be seen as conditions of possibility (see also Kohli-Laven et al., 2011). It leads to a focus "on the interlaboratory level of scientific and medical research" (Keating and Cambrosio, 2003: 3) – the field in which biobanks operate.

Imagining and co-constituting science, technology, and society

Sociotechnical imaginaries as a concept also connect to the wider landscape of co-constituted and co-produced science and society (Jasanoff, 2004, 2015a). For example, biobanks as research infrastructure allow certain uses while simultaneously producing new questions, and are thus part of the mutual constitution of the research infrastructure itself as well as knowledge production (see also Aarden 2017: 754). As Jasanoff has put it:

14 This might also eventually lead into the founding or emergence of new biomedical platforms. With the concept Keating and Cambrosio (2003) have drawn attention to functioning and prerequisites of specific biomedical platforms, such as immunophenotyping for cancer diagnostics, which connects specific technologies and bodies through a biomarker in a coordinated way. Thus the concept of biomedical platforms draws attention to interdependencies between specific and simultaneously "various components of a platform and the related actors, as well as between platforms" (Keating and Cambrosio, 2003; 332). Biobanks in this study, then, cannot be considered biomedical platforms as such, but they can be expected to contribute to new biomedical platforms. For example, the drug screening project presented in Chapter 6 demonstrates the potential of a biomedical platform, if it develops into standard clinical practice in the treatment of acute leukemias (see also Beaudevin et al., forthcoming).

"scientific and technological ideas, in short, are produced together with ideas about science and technology" (Jasanoff, 2015b: 333). When we also understand science and society as co-produced and co-constituted more widely, it becomes evident how the conditions of possibility need to be built for the production of scientific knowledge, and how this happens in interaction with society.

Lindee et al. (2003: 3) remind us that samples and databases "can never be the product of a 'clean birth'", but are part of "cultural-historical contexts" wherein power relations, politics, and production of knowledge become linked. It should be kept in mind that biobanks and their collections represent ideas about what is perceived as necessary for medicine to advance, and also the kind of world we are pursuing. The goal of building a good society using scientific and technological means becomes apparent when certain research topics are rendered important and seen as meeting the needs of society (see Jasanoff and Kim, 2015). "Science", as so many social science scholars have argued, is always embedded in specific contexts, values, and policies (e.g., Haraway, 2004; Jasanoff, 2004; Reardon, 2017; Subramaniam, 2014).

Research questions and contributions of the study

In this study, biobanks are investigated as conditions of possibility for personalized medicine, as "machines to make a future" (Gottweis, 2008: 24; Jacob, 1982; Rabinow and Dan-Cohen, 2005). Within a sociotechnical imaginary of personalized medicine, rearrangements of scientific practices and the organization of samples of human origin are legitimized and reasoned. The samples are also assigned different characteristics: for example, they seem to be able to serve both the health and the economy, both nationally and internationally, both now and in the future. Moreover, regulatory, societal, and ethical issues are continuously of practical concern in how knowledge production is organized and takes place. Erik Aarden (2017: 754, emphasis original) has argued that biobanks mirror "how *imaginaries* of desirable futures that inform science policies are reflected, negotiated and contested in the configurations of material *infrastructures* for knowledge production".

The object of this study is the rearranging of biomedical research, which is investigated by paying attention to personalized medicine as a sociotechnical imaginary and biobanks as a prerequisite for personalized medicine. In this way, the entanglements between research and clinics, and commercial, industrial, regulatory, and policy developments, goals, and interests come to the fore. Consequently, this study asks: *What do the expectations related to biobanks as conditions of possibility for personalized medicine tell us about the knowledge production in which biobanks are supposed to participate, and the role biobanks play in it?* To answer this question, biobanking is studied through three different lenses, each offering specific nuances to the answer of this question. In the analytical sections I trace *how biobanks as conditions of possibility for personalized medicine can be understood through unpacking, first, claims about the high quality of the samples they store; second, ideas related*

to research population(s) seen to be stored in biobanks; and third, their link to the perceived need for hybridity in knowledge production articulated through the goal of translational medicine. Following Franklin (2001, 337) my interest lies in "how and why things mean what they do, how knowledge is constructed and how understandings are produced". I attend to this by building the analytical sections around key notions: high quality samples, research populations, and translational medicine. My aim is to unpack certain claims related to biobanking made by informants in the interviews, presenters at the events I have attended, and in the popular media and published materials. Theoretically, this study brings a new perspective to discussions of *sociotechnical imaginaries* by addressing biobanks as conditions of possibility in the fulfillment of such an imaginary.

This research thus contributes to the literature concerning expectations and futures by offering an empirically rich analysis that shows the shifts and multiplicities involved in making and maintaining biobanks as valuable tools for personalized medicine, itself also an evolving imaginary still being molded. These processes are not only dictated from the top down; rather, biobanks and what is considered valuable in, and possible through, them are flexible and might even work against the ultimate goals of personalized medicine (health and wealth). However, as the case of the early years of Finnish biobanks shows, personalized medicine as an imaginary is not static, rather requiring constant maintenance (see also Tarkkala et al., 2018). This, I argue in this study, places biobanks in an environment characterized by uncertainty that continuously requires flexibility in regard to the very idea of what biobanks are, what they offer as infrastructure, and what can be achieved through them.

3. Understanding biobanking: on data and methods

To understand what biobanking is and what biobanks are, I needed to become familiar with many contexts: not only combining different data sets to gain a more nuanced picture, but also acknowledging that there is no single clearly defined activity or practice called "biobanking". In terms of the structure of this thesis, the analytical chapters variously illustrate the multiple sites of biobanking, discussing questions such as: Just what is a "high quality sample"? Is it really the homogeneous genetic Finnishness of the samples that makes them interesting for research? What about the translational research projects that serve as examples of biobanking? The different themes that caught my attention during data collection have been used to shape my approach to writing up my findings, as I have structured the thesis around them (Hennink et al., 2010: 279). A similar strategy has been deployed by Sara Shostak in her book, *Exposed Science: Genes, The Environment, and the Politics of Population Health*, in which she made "the concepts, objects, and assumptions of scientists' worldview explicit foci" of the study (Shostak, 2013: 219–220). This, she argues, enabled her "to maintain critical distance" while simultaneously building her understanding of the field of science and epistemologies under study (Shostak, 2013: 220). Likewise, the questions that have been important for this study, are linked to the reassembling of biomedical collections and associated data for knowledge production in contemporary biomedicine, building on previous studies in STS that have shown how science is not an isolate; rather, scientific knowledge is made and co-produced in specific contexts, and therefore reflects the social, political, and cultural (e.g., Fujimura, 1996; Jasanoff, 2004; Knorr-Cetina, 1999; Kohler, 1994; Latour and Woolgar, 1979; Rheinberger, 1997).

It is often said that a method is what you did and the methodology why you chose to do it that way (Madden, 2010: 25; Silverman, 2001: 4); however, in practice the research process does not unfold so neatly. One makes methodological choices informed by prior theoretical and empirical knowledge even before data collection begins. Then the knowledge and information gained during the course of collecting data feeds into refining of the conceptual and methodological choices, while the research questions feed into analysis. Again, through choice of categories and coding in analysis, empirical results are brought into connection with already existing theories and concepts. In the end, then, some of the concepts and theories utilized might have been carried along (unless changed during the process) all the way from the moment when data collection was still a plan. This is in a sense the nature of qualitative analysis and qualitative research more widely. The research design and implementation are "interlinked" (Della Porta and Keating, 2008: 29), and the inductive and deductive, as well as empirical and theoretical reasonings are best described as cycles (Alasuutari, 1995: 175; Hennink et al., 2010: 24–25).

In this dissertation, interpretative analysis of the research material is the result of the kind of process and interplay described above. Therefore, it is inevitable that there are

methodological remarks inside sections that concentrate on "data", and that some details of the research data are mentioned in relation to the "methodology". In the following, I present my data, the informants, and my methodological choices, although these categories leak into each other. I then describe methodological concerns, data collection, and the analytical process whereby this study has fulfilled its research tasks.

Following "biobanking": multi-sited data collection

If it is not easy to define what a biobank is and what it does, how do you study them? As is often the case with complex issues, this study utilizes different types of qualitative data to understand the rearrangement of storage and distribution of samples and data for biomedical R&D&I through biobanks. In terms of data collection, I was inspired by the specific idea of multi-sitedness first articulated by Marcus (1995) in the context of ethnography. He argues that there are phenomena under study that are not to be found in a single site (Marcus, 1995: 95–96); rather, they require being "there… and there… and there!"[15] (Hannerz, 2003). A similar point made in the field of STS is presented by John Law in his book, *After Method* (Law, 2004). He argues that the social sciences need methods that grasp the messiness of the world, its fluidity and elusiveness (Law, 2004). I, too, started from the premise that biobanking is a phenomenon of a complex kind, the result of my prior experience of biobanking while conducting research for my master's degree. Thus, a cycle of empirical experiences and theoretical reasonings had produced this premise in the first place. Furthermore, in the search for answers to my research questions I expected I should "follow people, connections, associations, and relationships across space" (Falzon 2009, 1-2). Similarly, in an STS study about life sciences in Singapore, Aihwa Ong traces "relationships among many things – researchers, governments, capital, populations, mutations, maladies, and emotions" in order to "crystallize an emerging biomedical frontier" (Ong, 2013: 69). Methodologically, in STS studies, laboratory ethnographies as well as multi-sited ethnographies are often conducted (on the method of multi-sited ethnography and for examples of research utilizing ethnography, see, e.g., Coleman and Hellermann, 2011; Falzon, 2009b; Fujimura, 1996; Hannerz, 2003; Hautamäki, 2016; Knorr-Cetina, 1999; Latour and Woolgar, 1979; Marcus, 1995, 2011; Nadai and Maeder, 2005; Ong, 2013).

In practice, studying biobanking in its different contexts meant that during the data collection I visited biobanks and saw corridors, meeting rooms, offices, and sometimes freezers, too. I visited laboratories where the samples were processed for storage. I learned, for example, that the moment when a sample's status changes to become "frozen" is not

15 That an object of study *is* there and there and there is visible in Annemarie Mol's (2002) study of atherosclerosis. In *Body Multiple* she brings practices to the foreground, arguing that a disease is enacted in practices. Therefore, goes the argument of multiple ontology, atherosclerosis is one thing in the context of patients' everyday lives, another in medical examinations, and yet another in medical operations – while all the time being "atherosclerosis" (Mol, 2002).

the moment when it is put in the freezer. Rather, it is when the barcode is read, minutes before actually being placed in the freezer (Fieldnotes, 2013). Thus, to illustrate the multi-sited approach, a "frozen" biobank sample seems to be different things at its different time-points. Furthermore, I went to events where biobanks were presented and discussed. I listened to lectures. I collected newspaper articles, journal articles, editorials, policy papers, and leaflets. I listened to radio interviews. I went through webpages of the biobanks and watched videos uploaded on channels such as Youtube or Vimeo. I came across visions, representations, and the material samples themselves travelling from hospital to laboratory accompanied by their own taxi credit card. In sum, wherever biobanks were mentioned, I wanted to be there too. Of course, and most importantly, I met people of whom some became my informants.

During the study, data collection evolved and took new routes in comparison to the original research plan. When I started research in 2012, the initial focus was the establishing and institutionalization of two biobanks: the Finnish Hematology Registry and Biobank (FHRB founded in 2011) and the Helsinki Urological Biobank (HUB founded in 2012). However, I soon started to collect data from the wider field of emerging biobanking in Finland. In fact, by going to biobank-related events I had already started to familiarize myself with the whole field. For example, my interest in the quality of samples was something that was a shared emphasis throughout the Finnish biobanking scene, as well as a topic to which attention was paid internationally (see Begley and Ioannidis, 2015; Ioannidis, 2005, 2014; Munafò et al., 2017; Paltiel et al., 2012). Eventually I started to interview people I had met or heard about at these events – people who were involved in other biobank projects in other hospital districts or who had some link to biobanks more widely. However, the initial interest in two cancer biobanks is still particularly visible in the analysis in Chapter 6, although it would lack its character without knowledge of the whole field.

Moreover, I have tried to collect bits and pieces on the topic as they came along: screenshots and copies of webpages, strategy papers, and newspaper articles. I did this without always being sure whether these data would eventually be utilized in analysis; rather, I collected them as potential "specimens of the same phenomenon" (Alasuutari, 1995: 13). This approach created a data set from which I could draw supplementary, complementary, and at times contradictory data to discuss and highlight themes and content from the interviews and to use as background information. The other side of the coin is that I ended up with an excess of data. Qualitative studies, just like genomic medicine, produce vast amounts of under-analyzed data (see Alasuutari, 1995: 44). Indeed, at the events in which I participated, I often heard that there are considerable stores of genomic data, but less understanding about what they all mean. The take-home message was to understand that each scientific endeavor focuses on a specific research question and thus only utilizes the data from that point of view, which means that a lot of data is excluded in the process.

The whole data set consists of (see also Appendix 1):

- Interviews (n=47)
- Observations in laboratories (n=4) and events (n=38)
- Written documents

The 47 interviews with 42 stakeholders and experts from biobanks, biomedicine, and biomedical research were semi-structured and partly open. The observations, and fieldnotes based on the observations, document laboratories and an operating room (n=4), where I familiarized myself with key moments of sample processing and preparation of samples for freezing: part of the standardizing work for the sample quality in practice. Observations also concern events and seminars in which I participated, where biobanks, biomedicine, cancer care, and health data as Finnish assets were discussed and presented (n=38). The written documents include materials such as records, protocols, policy documents, strategy papers, websites, information leaflets, presentations, newspaper and journal articles, and so on, published by the biobanks or about the biobanks, biomedicine, translational medicine, or personalized medicine. For example, in Chapter 4 I have utilized scientific journal articles relating to sample quality and standardization in biobanking (e.g., Hewitt, 2011; Malm et al., 2013; Paltiel et al., 2012), and, in Chapter 5, journal articles on Finnish genetic homogeneity and its potential significance for biomedical science as it has been presented over the years (e.g., Chheda et al., 2017; Jakkula et al., 2008; Kääriäinen et al., 2017; Kallio et al., 2009; Lim et al., 2014; Norio, 2003a; Peltonen, 1997; Peltonen et al., 1999; Peltonen, 2000; Peltonen et al., 2000; Varilo et al., 2000).

At the time I started data collection, it was expected that biobank practices, including sample collection and distribution for research purposes, would commence sooner than was the case in practice. Since I collected the main unit of interview data in 2012 and 2013, it reflects the expectations and perceptions that people involved had about what they were building and establishing. Furthermore, I believe that employing various types of materials has resulted in analysis that demonstrates how biobanks are expected to participate in the biomedical enterprise and what they are expected to deliver, both scientifically and societally. Finally, as already noted, throughout the research process I drew on the idea of multi-sitedness – the biobanking that interested me could have not been understood by standing by the freezers.

Interviews and informants

I conducted 47 interviews with 42 informants initially selected by contacting people who were clearly related to biobank projects and whom I had seen or heard speaking about biobanks and biomedicine in public presentations and events. Most of my informants had some sort of institutional connection to biobanking, as biobanks – or even the mere idea of a biobank and the collection of samples and data – have links to research institutes, clinics, companies, policymakers, developers, and so on; additionally, some people whom

I interviewed were found through recommendations from other informants. Once the research questions became more refined I started to identify, usually from the events in which I participated, people who had knowledge of the specific themes and notions that interested me: high quality samples, genetic homogeneity, or translational medicine in biobanking.

Most interviews were conducted with a single informant, occasionally with two, while six key informants were interviewed twice or three times as I wanted to follow up on issues raised. The interviews lasted approximately 1-1.5 hours and, although I had a prepared list of questions, they were not necessarily asked in a predetermined order. Instead, during the interview I merely made sure we covered the topics that I had planned beforehand. Additionally, as the interviews were partly open, there was always space for other themes to emerge if the informant felt they were related to the topic in an important way. I also had the space to ask questions, if something new came up. The prepared questions covered the following themes:

- How the informant was connected to biobanking
- Establishing and founding of a biobank
- Samples, data, and sample quality in a biobank
- Utilization of biobank samples
- Benefits and obstacles related to biobank activities
- Biobanks and the clinical environment
- Commercial partnerships and access policies of biobanks

As noted, I collected research materials related to biobanks that were already operating (at least in some sense – if only in terms of a coordinator's preparing the initiative). Since some biobanks were established, founded, and started to operate later than others, I have not interviewed representatives of all the different biobanks operating in Finland today because, as noted, most interview data were collected in 2012 and 2013 with informants involved in the first biobank projects. The saturation indicator came when interviewees began repeating each other and new data replicated in many ways what had already been said – which does not mean that all the interviews contain the same information (Alasuutari, 1995: 59; Hennink et al., 2010: 88–90; Strathern, 2014). Some interviews concentrated more on efforts to allow health data to be utilized; some on patients' expectations and how biobank sampling becomes part of everyday life at the clinic; some on the viewpoints of the industry in relation to Finnish developments; and some on privacy concerns and regulative issues. The main body, however, consists of interviews with people who had close connections to biobanks, whether clinical, disease-specific, or population-based. Some of these people were both clinicians and researchers, some were involved in coordinating the establishment of biobanks, and some worked in a biobank themselves. They represent various views on the topic: researchers who had an interest in using biobank collections; biobank employees in different roles in policy, governance, legislation, research, or sample processing, among

other things; clinicians; and those with overlapping or multiple roles during the years, or even simultaneously.

In relation to the topics of sample quality, cancer care, and the development of personalized medicine, I also conducted a few interviews in Austria in 2013 with a handful of informants. These interviews serve as complementary data that I have utilized, for example, in regard to high quality samples, as the issue touches on the whole field of biomedical research. There is nothing specifically Finnish in the quest for high quality samples. The interviews in Austria have also informed analysis in Chapter 6, where translational medicine and individualized cancer care as an example of personalized medicine is discussed.

I refer to my informants with numbers ranging from 1-42, adding their roles as descriptive tags. If an additional number is provided in parentheses – for example, (i1(2)) – it indicates the second interview with informant i1. I have provided a list of the different roles of the informants in Appendix 2. To avoid precise identification, I have chosen not to list interviewees specifically indicating all roles and positions in the text or appendices, merely the different roles, and since people may hold more than one, the number is greater than 42.

However, I needed to provide additional information about the informants in the analysis, such as their position as "clinician" or "researcher" or their relationship to a specific biobank, in order to show the context in which some remarks have been made. Without this information, analysis would have suffered. Indeed, as a result of the way research was conducted for this dissertation, there was a need to be context-sensitive about what it was about "biobanking" that was being discussed. This was also something to consider in relation to the different types of data utilized. Every excerpt has a context inside the interview or presentation, but also a context that varies between these different data-sets utilized – all these needed to be kept in mind during the course of thematic analysis in order to provide legitimate interpretations (see Cronin et al., 2017).

Observations

As already noted, the multi-sitedness of the ethnography has had its effect on data collection and the final research questions. The fieldnotes of the events and situations I documented and observed reflect thematical interest in what is being said about biobanks, translational medicine, samples, health data, or expectations. Recorded observations gave depth to the analytical process, as well as showing which topics needed more attention or cross-checking and follow-up interviews. Fieldnotes also contain occasional comments about how bioscientists circulate the same power point slides among themselves, or how the same picture of "crossing the valley of death" is used over and over again in presentations (see Chapter 6). This reflects the fact that I was present in these situations to understand how science is organized and reorganized in society, and how the human materials that scientific practice is said to require are being reassembled.

I participated in these seminars and events between 2011 and 2018, which means that I started to familiarize myself with the topic and field even before my PhD research officially started in 2012. However, the three events (see Appendix 3) which I attended in 2011 and early 2012 were important for the formulation of the initial research questions and development of my multi-sited approach to data-collection and biobanking; later, these events were also important in indicating changes in ideas of what biobanks in Finland could be. While I no longer conducted interviews in 2017 or 2018, I continued to attend public events on themes relating to the realization of personalized medicine, whether about biobanks or not. The level of my participation in these events ranged from passive to active depending on the event and situation (on different types of observation, see Hennink et al., 2010: 178–188). I participated fully in some events, with my own presentation or poster, or had coffee with my informants during breaks. Sometimes I also travelled or dined with informants without taking fieldnotes or regarding the occasions as opportunities for observation; nonetheless, they were part of building relationships with the community under study and, as such, worth mentioning. Then again, at other events, I merely observed without engaging very much, although on every occasion there were at least some of my informants or people I had met during the research process present (or presenting), whether I knew it beforehand or not.

Written documents

The written documents include policy and strategy papers, public documents, and newspaper articles that date from earlier or later than the time span for the interview data collection period between 2012 and 2016. These materials cover a wider time span than the other materials as I also familiarized myself with background reports of biobank projects and the state of biomedical research in Finland. Thus, these materials provided important insights for my analysis, allowed informed questions to be asked, and offered direction for the analytical gaze. In Chapter 5, where previous framings of the Finnish genetic heritage and its importance for biomedical research in Finland are discussed, the different published materials have a key role. Likewise, when juxtaposed with data from past years, current documented changes, such as legislation, provide perspective and help to thematize topics like the possibility for medical translations.

I collected articles published in newspapers and journals and made searches with keywords such as "biobank", "population isolate" and "translational medicine". I also took screenshots from the webpages of biobanks at different time-points that contained, for example, information on their standardized operating procedures and access policies. The leaflets and materials available at events and fairs were also collected. Reading these materials was part of the analytical process, highlighting and contradicting issues present in the interview data and fieldnotes. For example, there were mismatches between what was said by some informants in newspapers and presentations, and what was said in the interviews, leading me to perform cross-checks and sensitizing me to ask more about certain topics, interests,

or processes, even if just few more questions. These kinds of follow-up took place either over a cup of coffee at an event, or in an interview or e-mail. Guiding me in my selection of materials has been either their relevance to certain themes in the study, such as the populations in biomedical research or translational medicine, or the background they provide that helped me to situate biobanks in the field of biomedicine and to understand biobanking.

Analytical process

Before I could start writing the first drafts of this dissertation, I coded the transcribed interview materials using the ATLAS.ti program. A code, in the words of Susan Leigh Star, carries something with it from the world on which it is based on, but takes an abstract form of it: it simultaneously separates and attaches (Star, 2016: 129, 131). A code connects the analytical process with the research data and is part of asking the sociological question: "Of what is this an example?" (Star, 2016: 126). The whole dataset was surveyed twice, as coding evolved during the process and became more nuanced. For example, the category "high quality sample" became too wide to be usable and I had to narrow it down by cutting it into subcategories underlining different related aspects, such as usability or whether the sample was old or new. ATLAS.ti was only utilized to organize the data and coding in the sense of locating certain topics from the data (Hennink et al., 2010: 217). After I had organized the interview material thoroughly, I once again worked through the specific materials that were relevant to analysis; I then arranged, sorted, and organized the data yet again during the writing process – which itself is part of analysis (Alasuutari, 1995: 178; Cronin et al., 2017; Hennink et al., 2010: 269).

I conducted thematic analysis and organized the relevant materials under key concepts. This thematic analysis in the manuscript is based on different types of materials collected, a strategy which also reflects the research process. For example, there was a moment when I noticed that the Finnish genetic heritage seems to matter in the publications and presentations linking biobanks with innovation efforts in the field of personalized medicine. However, the same unique heritage had no role in the interview data, which was all about what makes the biobank samples usable and valuable for clinics, innovations, and research. Consequently, I started to pay attention to notions related to populations that appeared in the different materials I had collected and searched for more concerning Finnish genetic heritage.

The analysis and the research process could also be described using the concept of multi-sited ethnography; there is a thin line here. Much like this study, there is typically no aim to produce thick description and a thorough and in-depth interpretation of a certain culture in multi-sited ethnographies (Falzon, 2009a: 7). Moreover, Nadai and Maeder have pointed out that a characteristic of more sociologically oriented, multi-sited ethnographies is that "the object of study is not a particular field and all its culture, but some theoretical concept,

which supposedly can be best studied in a certain context or field" (Nadai and Maeder, 2009: 245). In terms of writing, multi-sited ethnography is said, firstly, to accommodate "differences of perspective" from different positions, and, secondly, potentially to allow "for new knowledge by shifting one's frame of reference" (Fortun, 2009: 82–83), both of which are points that resonate with my research efforts.

The analytical process with the data set I have collected led me to problems with scales and (dis-)proportions, something which is considered to be part of the multi-sited research process more generally (e.g., Falzon, 2009a; Fortun, 2009; Nadai and Maeder, 2009). At times, I felt that the analysis was not going anywhere, since even though my premise had been that there is no single form of "biobanking", I still needed to know just which pieces belonged together analytically. When was the case about the "same" and if so, in which ways? What piece of biobanking are we talking about? In the data, there are references to old and new samples, targeted and large-scale studies, biobanks for research and then suddenly examples where it seemed to be the biobank doing the research; then there were the unexpected shifts between these. There are complex multi-variant common diseases, and then there are rare diseases, and even the claim that every disease is a rare disease.

With these thoughts in my mind, I found a lot of comfort in reading Marilyn Strathern's (2004) *Partial Connections*, where she writes about scales and about the way we tend to write, work, and theorize in the (social) sciences. The crucial point in partial connections, or partial views and partial theories, concerns the complexity regarding parts and wholes, and how this complexity behaves when scales shift. Ultimately, there are always complexities, as well as losses and gains in detail, no matter the scale, something produced by the way we collect our data and do our research (Strathern, 2004: xiv–xvi). The world is not about clear-cut and neat wholes from which we can cut nice, clearly defined slices to observe and investigate. Analytically, there is the challenge of how and on what grounds one will build similarities and differences in the analysis, and how the concepts and empirics are connected by each making the other work (Strathern, 2004: 39-40, 51-53). Thus, our knowledge even at best is always partial; it is localized practically, theoretically, and also through the researcher: "no one perspective offers the totalizing vista it presupposes" (Strathern, 2004: xvi, 40). What remains is to acknowledge and work with the understanding of the partiality and situatedness of our knowledge, without compromising the commitment "to truthful, faithful accounts of the world" (Strathern, 2004: 31; see also Haraway, 1988).

Therefore, in terms of biobanking and its potential in my data, both informants and presentations are situated in certain contexts, and I needed to be sensitive about that and about how it produced movements in scales inside the research data. Often I felt like I was reproducing in my own study the issues discussed by my informants that related to high quality samples (Chapter 4): eventually it is I as a researcher who must understand what kinds of research settings are meaningful with regard to this particular material. What kind of questions can it answer? What kinds of claims can I make about it? I had to use the data

responsibly, keeping in mind the provenance of a certain view; for example, some people were researchers themselves while others were clinicians with different kinds of links to the emerging and slowly operating field of biobanks.

I noticed that the scientific method and scientific work of natural laboratories and sociologists doing qualitative studies can meet when it comes to methodological concerns. The problems with gaining high quality data that produce high quality results is an issue for all scientific studies. You have to use data that are fit for purpose; no data are qualified to answer all questions so you have to know what you will use to answer the research questions you have in mind. Accordingly, in my study, I have tried to collect materials that are fit for purpose, resulting in a process whereby I have adjusted and re-adjusted my data collecting according to the knowledge gained during the research process. In my analysis, I have tried to remain sensitive to the inevitable situatedness, while simultaneously making the most of it.

Research ethics and data management

Of key ethical[16] concern in this study are choices regarding when referencing / accrediting and anonymization are required. Ethics in these cases is not always simple and protection is not always solely ethical (for more on research in which the real names of all informants are supplied, see Keating and Cambrosio, 2003), and I have had to consider decisions in these fields carefully. For example, should the informants be accredited or anonymized when the information they provided was publicly presented?

My choice in the latter case was to refer to people by their real names if I have used other published and publicly available materials containing them, since the materials are openly available to anyone; in this way I can publicly accredit people who have made this research possible, rather than anonymizing them. On the other hand, the importance of my informants' insights is visible, even when anonymized, in the number of quotes I use in the text: the data provided in the interviews are important building blocks of the arguments in this study that I do not want to hide. Moreover, as the field is not very big in Finland, full anonymization has been impossible to guarantee; clues are inevitable, although probably merely narrowing the options rather than providing full recognition. As the informants were interviewed in their positions as experts and were neither placed in a vulnerable position nor interviewed about personal matters, I consider this sufficient, given the topic and the goals of this study.

16 In Finland ethics approval is needed only in specific cases, such as when research interferes in the physical integrity of the research subjects or if the study may cause long-term mental harm (see https://www.helsinki.fi/sites/default/files/atoms/files/when_are_ethical_reviews_required.pdf). My research does not meet any of the criteria listed.

The fact that the data excerpts have been translated into English offers another layer of anonymization; the style of speech and ways of saying things in the mother tongue have inevitably been lost. In the text I have slightly modified the interview excerpts when necessary, being careful not to change the meaning. I have, for example, reduced repetition or removed filler words in order to make the excerpts more readable. This is also a way of keeping my informants and myself in the same register of discussion; as my voice in this dissertation is academic and more formal, light editing has balanced their voices with mine.

I have also anonymized the fieldnotes taken during public presentations in the same way as the interview excerpts, as the presentations on which my fieldnotes are based are usually not publicly available. I considered this was polite since, when participating in the different events, I have not informed everyone present that I am there to observe; that would have been impossible. Thus, some people have inevitably been unaware they have contributed to my research: for example, by making insightful comments to the presenters which have helped me to see things from different perspectives or identify themes that I have decided to explore further. At the same time, it is important to remember that I was not there to observe people in their personal dimension. What was of interest to me was the topic under discussion: biobanks and personalized medicine.

Another important theme in research ethics is the notion of informed consent. In terms of the interviews, I contacted all the informants myself, usually with an e-mail briefly introducing my project and asking if they would agree to be interviewed. In general, I also outlined topics which we would be discussing: for example, translational medicine and sample quality. A positive response to my e-mail was taken as consent to participate and no further written consent was requested. When conducting interviews, I ensured that people were not opposed to my recording them. I also asked whether there was any part of my study about which they would like to know more. Furthermore, the informants received no payment for their participation. I often tried to buy their coffee if we met in a public café, but I seldom succeeded in what I considered merely a polite gesture of gratitude for their participation.

I have stored the transcribed interviews so that I am the only one accessing and using the data. This means that most of the material (interviews, photos, screenshots of webpages etc.) is stored behind a password on my computer, backed up by the university. The other materials, such as leaflets and newspaper articles, have been stored in the office where I have been working. After concluding the dissertation, the data will be stored for at least five years for use in research articles based on the study; if used again for other purposes, the informants will be re-contacted.

4. Standardized and flexible: high quality samples in biobanks

Biobanks organize the samples of human origin needed in medical research; they also collate and store data concerning the sample or the sample donor. In comparison to historical medical collections, some of the most distinctive features of biobanks are, first, that the collections are prospective and, second, these collections are not for a single purpose or a single researcher or research group. Instead, they are open to all researchers, research organizations, and companies that meet the access criteria of biobanks (see, e.g., https://www.terveyskyla.fi/helsinginbiopankki/en/for-researchers).

Biobanks are considered research infrastructure because they provide materials for biomedical R&D (e.g., Meijer et al., 2012; Reichel et al., 2014) and are part of other already established practices and infrastructure, such as science and health care systems. They are accessible to a wide range of interested users, with the possibility of transforming themselves if R&D so requires, or of transforming the way research is conducted (Aarden, 2017: 754; Bowker and Star, 2000b: 35; Star, 1999: 381–382). Biobanks utilize standardized operating procedures, but also standardized data-collecting criteria such as the International Classification of Diseases (ICD), which provides infrastructure for clinical work and diagnostics globally (Bowker and Star, 2000b: 35; Star, 1999: 381–382). The biobank samples themselves, the topic of this chapter, are expected to be of consistently high quality, which is a key characteristic of biobank samples in order for them to be usable in the production of meaningful and valid results once they are circulated and utilized outside the biobank freezers (on the key role of circulation, see Ong, 2016). The following extracts exemplify the usage of the notion "high quality samples" in biobank rhetoric:

> A sample and data register that combines millions of samples offers the opportunity to search for high quality samples that support the research goals. (www.auriabiopankki.fi/en)

> Helsinki Urological Biobank has collected tens of thousands of high quality samples. (https://www.fimm.fi/en/)

What, however, is a high quality sample? How is this quality established and why is it required? What does the continuous talk of it in the different contexts of biobanking reveal about the knowledge production that biobanks are here to foster? How does talk of quality relate to the dynamics of science? Asking these kinds of questions about high quality samples sheds light on how biobanks claim they draw together various needs and developments in the field of biomedicine: the shortage of specimens, the problem with replicating results, the quest for biomarkers, the need to build a bridge from bench to bedside, as well as innovation policy. Thus, biobanks are founded to produce data (or the prerequisites for data production), to provide adequate and sufficient samples for research

purposes now and in the future, to create interest, and to advance the biomedical research environment and ecosystem in Finland (Sosiaali- ja terveysministeriö, 2007).

This analysis, concerned with sample quality in biobanks, is based on how high quality is framed in presentations, webpages, and interviews, and how it is created in laboratories. In the analysis, the general (and native) concept of "high quality sample" embodies different characteristics of what is considered quality in relation to biomedical research, its outcomes, and the materials it is claimed that research requires. Samples known to be of high quality become material prerequisites for personalized medicine, but simultaneously need to remain flexible in order to be actually usable for the future and in the future.

The call for professionally collected standardized samples

In Finland the establishment of biobanks during the 2010s has been about the professionalized production of collections of "high quality samples" (see also Morrison, 2017). It is no longer considered efficient for researchers to collect samples only on their own behalf, their preferred mode (see also Stephens et al., 2011). In fact, it is argued that researchers cannot even create the kinds of huge collections of samples that meet research needs. They would not have enough funding, nor would they meet the demand for both quantity and quality. For example, Majewski and Bernards (2011: 310) write in *Nature Medicine* that improvement of sample quality is needed in the development of cancer biomarkers as "the availability of high-quality specimens might turn out to be one of the biggest bottlenecks". Therefore, a professionalized system, such as that produced by biobanks and their networks, is expected to secure the availability of materials that meet the requirements for evidence in biomedical research, both in the development of biomarkers and more widely. An expert who was involved in planning a biobank describes:

> There is an understanding that research needs to be based on really high quality samples. It cannot be just anything ... like melted serum found at the bottom of the freezer. (i5, 2012)

Since the beginning, new biobanks have often been part of international initiatives to standardize and harmonize resources for biomedical research, expected to benefit not only research, but also trade and the economy (Timmermans and Berg, 2003: 11–12). As the scale of trade has increased, standardization has become a necessity and even a priority for international actors such as the European Union, which has been playing a key role in establishing research infrastructures in Europe (http://ec.europa.eu/research/infrastructures/index.cfm?pg=esfri). Indeed, it is easy to see that standardization is widely expected to work as "a key instrument" in "shaping Europe as a unified economic area across which innovations can be rolled out" (Hauskeller et al., 2017: 4).

Exemplifying this, the BBMRI-ERIC[17] (and its preparatory phase BBMRI 2008-2011), a joint European effort to coordinate and facilitate access to biological resources, aims to bring common standards, procedures, and harmonization to the field of biomedical research (www.bbmri.eu, bbmri-eric.au). These kinds of efforts have thus been politically encouraged, in terms of both biological samples and data, resulting not only in the BBRMI-ERIC, but also Biobank Standardization and Harmonization for Research Excellence in the European Union (BIOSHARE), a program that took place during 2012-2015 (www.bioshare.eu). In a similar vein, the International Society for Biological and Environmental Repositories (ISBER) works to promote best practices in terms of quality in biobanking (www.isber.org) and the Global Alliance for Genomics and Health "aims to accelerate progress in genomic research and human health by cultivating a common framework of standards and harmonized approaches for effective and responsible genomic and health-related data sharing" (https://www.ga4gh.org/aboutus/)[18]. According to my informants it is a good thing that Finnish biobanks are involved in these projects and programs; as one observed:

> It is exactly one of the major goals and benefits of these European biobanking activities that we can compare people living in different countries and living conditions and the variation in sample quality does not bring more variation – so it is clearly an advantage. (i34, 2013)

Thus, biobanks come with a simple claim: the samples stored should be what they are said to be. This might seem trivial, but as STS scholars have previously shown, it is often fruitful to pay attention to matters that might seem mundane or even boring (e.g., Bowker and Star, 2000b; Star, 1999; Star and Lampland, 2009; Woolgar and Lezaun, 2013). This is particularly pertinent given that it was common for my informants to mention that the samples used in research prior to biobanks were not always what they were supposed to be:

17 For more on BBMRI, now a part of European Research Infrastructures Consortium (ERIC), see, for example, Asslaber and Zatloukal (2007), Calzolari et al (2014), Ommen et al. (2015) and Reichel et al (2014), and also European Strategy Forum on Research Infrastructures (ESFRI) roadmaps (http://ec.europa.eu/research/infrastructures/index.cfm?pg=esfri).

18 Other initiatives and organizations in terms of data harmonization and sample quality include, for example, biomedbridges (http://www.biomedbridges.eu/, ended in 2015 but continued as Corbel http://www.corbel-project.eu/home.html) funded by European Union, Elixir (https://www.elixir-europe.org/), P3G public population project in genomics and society (http://www.p3g.org). See also a comprehensive list of these efforts in Harris et al. (2012). Standards for biobanking are being developed under International Organization for Standardization ISO too (https://www.iso.org/committee/4514241.html). Recently, in relation to the Million European Genomes Alliance project, a list of "National personalized and genomic medicine initiatives and strategies" was published along with a table showing "alignment with other European initiatives" (Horgan et al., 2017: 175–177), essentially showing the interconnectedness of the many efforts taken in this field.

> [I]f we look at some southern European so-called biobanks before the European BBMRI, then breast cancer samples from there, for example, might have been something other than breast cancer up to 60% of the time! (i31, 2013).

Moreover, biobanks are expected to bring with them increased co-operation between research groups, research institutions, academia, and companies. This co-operation is needed to achieve improved diagnosis and treatments (e.g., Yuille et al., 2008). A prerequisite for meeting the expectations of personalized or translational medicine is said to be the "efficient organization of the resources that are the objects of study" (Yuille et al., 2008: 14). Through biobank infrastructure that can provide "both high quality samples and associated data" (Paltiel et al., 2012: 225), this efficiency is said to become reality. The ability to produce standardized, consistent sample quality is a key element of biobanking (see also Leonelli, 2016; Morrison, 2017: 76; Williams, 2017).

It is standardization that is said to play a crucial role in samples' being seen as high quality (see Bowker and Star 2000). Standardization of biobank samples refers, first, to "set of agreed-upon rules for the production of (textual and material) objects", and, second, a way of organizing industrial-type production of samples for the research field (Bowker and Star, 2000a: 150). Standardization is about "rendering things uniform" (Timmermans and Berg, 2003: 24). Furthermore, standards set a certain point of reference, which allows for comparison (Timmermans and Berg, 2003: 24). Potentially, biobank samples from multiple collections can be considered similar, exchangeable, comparable, and measurable because the same standards are applied in collecting, processing, and storage (Nowotny and Testa, 2010: 90). This also connects standardization to promises about the future. As Timmermans and Almeling (2009: 25) have pointed out, the belief that "predictability, accountability, and objectivity will follow standardisation" is one of "enlightenment master narratives promising progress through increased rationality."

The need for comparable and exchangeable biobank collections is linked to the need for extensive sample collections suitable for international collaboration and large-scale research (Kere, 2007). This relates to the requirements journals have for studies they accept for publication, and also to the understanding that biology is more complex than was thought at the time when Human Genome Project (HGP) was declared finalized in 2003. The latter understanding, combined with the multiple factors effecting morbidity and the development of a disease are, according to many of my informants, behind the need for biobanks. Simultaneously, technological progress has been rapid:

> We have new technology and it is possible to analyze large numbers of samples at fractional cost. In order to answer questions related to many biochemical or biological phenomena that have to do with nature or life, we need large sets of samples as the individual variations and single effects are so small. (i40, 2015)

Only large numbers of standardized samples allow statistically relevant conclusions and sufficient of the same kind for specific analyses and settings. As mentioned previously, standards and protocols play a key role in making "things work together over a distance" (Timmermans, 2015: 79). In relation to cancer research, Fujimura (1996: 210–211) has pointed out that standardization has the effect of aligning different places and localized and contingent practices that are embedded in the messiness and uncertainty of the everyday. This view of practices and uncertainties is somewhat different to that of Annemarie Mol when she discusses the actual practices that are all called "atherosclerosis" in a localized setting (Mol, 2002). Where Fujimura stresses that standards reduce messiness, Mol points out that reality might be multiple even when we think we are speaking of something that is the "same" (Fujimura, 1996; Mol, 2002). Interestingly, both scholars seem to ask the same kind of a question: How is it that something (e.g., research on cancer or atherosclerosis) that is in practice uncertain and different, may at the same time seem so stable?

It is expected that the standardization and continuous record-keeping of biobank samples allows them to be usable for research in which the capacity to establish "equivalences between observations of similar specimens in different locations" is of importance, allowing "researchers to decide whether those specimens and the conditions under which they were analyzed are the same or different" (Cambrosio et al., 2009: 659). This is especially important in the case of rare diseases. In the following a professor who is involved with a biobank describes a situation where the samples needed are very strictly defined, noting that collaboration between biobanks is required in order to have access to a sufficient number of samples:

> If you're dealing with, "I wanna have a tumour sample" … I could say, I think we have about two million. But, I wanna have a tumour sample from this specific tumour, from male or female, from this age period. From the paraffin or a cryosample and, and, and. All of a sudden you go from two million down to five. Right? I think this is the major issue. This is why we have to join forces in terms of biobanking. (i37, 2013)

Bad quality samples and the crisis of reproducibility

The unmet promises of genomics of the previous decade (e.g., Burke et al., 2010; Guttmacher and Collins, 2005; Lander, 2011) hinge now on big collections, standardized operating procedures, and especially data harmonization. One of my informants described the situation by saying that the "low hanging fruits have already been picked" in terms of competition in the research world, adding that, in order to produce a remarkable new finding that goes beyond easily found associations such as the connection between lung cancer and smoking, "you cannot just toss your samples together half-heartedly" (i24(1), 2013). Instead, "high quality science" relies on the high quality of the whole research process, from samples and data to the people doing the analysis (i24(1), 2013). Claims that increased standardization and harmonization are needed also gain ground and urgency through the so-called reproducibility crisis (e.g., Begley and Ioannidis, 2015; Bustin, 2014;

Ioannidis, 2005, 2014; Munafò et al., 2017; *Nature Methods*, 2013). There has been criticism that too many research results cannot be replicated and therefore are not valid; that is, many of the results gained in biomedical research are in fact results reflecting the sampling process, meaning the results are flawed (Grizzle et al., 2015; Huppertz and Holzinger, 2014; Kousta et al., 2016; *Nature Methods*, 2013). An expert who was involved in the process of building Standard Operating Procedures (SOPs) for a Finnish biobank stresses that as a result of the development in methods and analyses, the quality of the sample makes a bigger difference today than in the past; these methods now "find variations, which do not reflect the sample but, for example, the storage" (i5, 2012).

There is a growth in the scientific literature concentrating specifically on sample quality, for example, in the field of biospecimen research (e.g., Blow, 2009; Carter and Betsou, 2011; Elliott and Peakman, 2008; Grizzle et al., 2015; Hewitt, 2011; Paltiel et al., 2012; Peakman and Elliott, 2008; Scott et al., 2012; Shabihkhani et al., 2014; Simeon-Dubach et al., 2016). This field of studies is expected to boost knowledge about the importance of sample quality, as well as having an impact both on funding decisions and on journals' publishing requirements (Hewitt, 2011: 112–113). Early in 2016, *PLOS Biology* introduced a meta-research section to encourage, promote, and contribute to "research on research" and "to improve research standards in the biological sciences and beyond" (Kousta et al., 2016); other journals, such as *Nature Medicine* and *Nature Genetics*, have also addressed the issue of irreproducibility in science (Bustin, 2014: 39).

It is no wonder, therefore, that throughout recent years the topics of reproducibility and improving quality have been constantly addressed in the meetings, conferences (Fieldnotes), and articles on biobanks. Indeed, at the HandsOn: Biobanks Conference in Helsinki in 2014, a presenter estimated that "50% of research is flawed by sample quality issues!" (Fieldnotes, 2014). Similarly, Paltiel et al. (2012: 225) observe that the "biological material collected, processed and stored in biobanks are important research tools and it is important to minimize preanalytical variations to provide researchers with high quality biological material that will give reproducible results". An expert involved in founding and operating biobanks in Finland, describes the situation prior to biobanks and the fact that there was no knowledge on the importance of quality as follows:

> Several published results are based on samples that have been processed in an inappropriate manner, or stored in an inappropriate manner, and still these results… No one has understood or had the knowledge to attend to the fact that the results might become distorted because our freezer… yeah, it melted a year ago but no one remembered it and we just put the melted samples into another freezer. And then we just kept on using them. This is what the world is full of, these kinds of publications and the results… (i1(2), 2012)

One researcher (i37), involved in biobanking himself, describes this as a disaster. First, the situation is an economic disaster since it is about wasting money and resources, but, secondly, it is a disaster in terms of medical impact. For instance, in terms of clinical practice, the amount of contradictory data regarding some biomarkers mean that these markers are not making their way to the clinics where they would be most needed. This researcher (i37) stresses that this is why it is important to elide results that merely reflect the quality of the sample. A new kind of accuracy is expected to emerge, according to one professor (i24(1), 2013), who suggested that there will be more replicable results and therefore "more of our results will be true". However, this professor qualified this by adding that "nothing can be true in science or biological science" (i24(1), 2013), since if replication of research findings is indicative of objective knowledge, truths in this sense may abound in the field of medicine (Cambrosio et al., 2006: 192). Indeed, there is a vast body of published results based on different kinds of data sets, which has its consequences:

> If you go into PubMed there would be thousands and thousands of papers, based on bad quality samples. But the results are out there; people read them and think, "Okay that's true". And they base their own research on these kind of data and they're pointing in a totally wrong direction, because they start to base their hypothesis on these data derived from samples that are not properly stored or taken care of. This is dangerous. (i37, 2013)

Biobanks are thus playing their part in building and strengthening certain conventions that serve as reference points for the evaluation of biomedical research, particularly in the creation of objectivity and universality in biomedicine through shared conventions (see, e.g., Cambrosio et al. 2009, 653; Keating and Cambrosio 2003: 3). Cambrosio et al. (2006: 194) have argued that this convention-based objectivity of the field is regulatory objectivity, thereby referencing the collectives and collective actions needed in the generation of new knowledge and its applications. As Moreira et al. (2009: 666) write, "the establishment of conventional standards and systems of regulation" are, from the viewpoint of regulatory objectivity, "requirements for ongoing knowledge production, innovation and clinical work rather than forms of external control." That is, regulatory objectivity

> turns the focus away from objects towards collective forms of expertise combining people (clinicians, researchers, administrators, patients etc.) and objects (entities, instruments, tools, techniques etc.) connected by specific coordination regimes (Cambrosio et al. 2006, 194).

Furthermore, Keating and Cambrosio (2003) point out that the field, while generating new knowledge, approaches, and technologies, simultaneously forms collectively "a consensus about what counts as a technology of the present" (Keating and Cambrosio, 2003: 328). In this case, the technology of the present is clearly standardized and professionalized sample processing, so it is hardly surprising that the research culture prior to biobanks is

in many ways a source of legends and stories of sloppy handling of samples. There seems to have been a careless past. Ignorance was often seen as a characteristic of academic life and a working culture where people, especially "students", are more interested in research elements other than pre-analytical issues and practices. In the words of a professor and proponent of biobanks and translational medicine:

> There might have been a sample … like if a student went to get it from the clinic, and went to eat lunch in between, and just kept it somewhere, and then froze it somewhere else, and first it was in at -20, and then someone said to transfer it to -80, and in the worst case the samples have melted at some point and this… this is an impossible situation in which to accomplish good quality research. (i22, 2013)

Interviewees described melted and re-frozen samples, of samples standing on someone's desk for a few days before freezing, and of course there were also incidents when freezers simply broke down. It is expected that the latter kind of problem will now be avoided through the use of liquid nitrogen freezers that work for days even in the case of power outages. Again, standardized operating procedures are of course part of this (Scott et al., 2012: 143).

In contrast to the situation where everyone collects samples in their own way, biobanks are now the professional option for collecting, storing, and management of research materials, so there is no longer any need for a researcher to be involved in this. There are now professionals whose career it is to take care of samples (on sample care, see Meskus, 2018), which also reflects a new type of professional in the co-operative building of biomedical knowledge (Ankeny and Leonelli, 2015: 127). An interviewee with long experience in working with large cohorts describes this professionalization:

> When there is a person for whom this is a career, taking care of samples and their high quality, and the researchers get high quality stuff, then it just works better. (i24(1), 2013)

Bruno Strasser has also pointed out that, traditionally, academic life has not rewarded collectors and therefore the collecting of data was earlier considered "mundane, clerical, or even trivial" (Strasser, 2012a: 329). Simultaneously, as collections were meant to be "tools for the production of knowledge" it was perceived necessary to organize "the data in ways that would be most productive epistemically" (Strasser, 2012a: 329). This also applies biobanks, increasingly data-depositories themselves, as they are meant to be used and usable for knowledge production. How this is achieved, however, is a task of its own. The samples are collected, processed, and stored for a future that is unknown, but in practice the decisions about how this is done are based on the knowledge of today: what is said in the research literature and what is known due to experience. I asked an expert involved in the Finnish BBMRI and the founding of a biobank whether the basis on which they

evaluate what is considered important in terms of sample quality will also be important in the future. The answer was: "There is no basis, it's like.... off the cuff, a good guess" (i35, 2013).

Other informants confirmed that you just have to deal with uncertainty and the impossibility of knowing for sure. As in the case of umbilical cord blood banking there is a "complex and ongoing negotiation" in relation to "the demands of a scientific community whose expectations are ever in flux" (Williams, 2017: 481). An informant acknowledges this temporal uncertainty by saying:

> I don't know which kind of technologies will be there in ten years' time. And again the technologies may be completely different and may lead to completely different types of samples we need to store and a different setting, we're not aware of today. But we cannot have any idea of what will be necessary in 15 years. No way. (i37, 2013)

Of course, there could have been, and have been, high quality samples in the past; nonetheless, the professionalism in todays' biobanks is said to be distinctive, bringing clinical and research practices closer together, because now the clinical quality of the samples is often also that of research samples. This is so because, in Finland, most new, prospective samples are collected as part of the everyday practices of an accredited clinical laboratory or even as part of care when it comes to tissue samples taken simultaneously for the purposes of diagnostics; that is, care and research. As a result, sample collection is business as usual for the clinics. When I asked why these samples are so much better, I got interesting answers, like the following from a clinician involved in biobanking:

> In a way, it is not that these are remarkably better quality than any other sample before. That is not a claim we want to make here. But [it's] just that they've been through the same process and they are all collected in a same, standardized way. (i29, 2013)

Thus, professionalized sample processing and storage is in many cases not significantly special even technically – in comparison, that is, to normal protocols and work done in an accredited laboratory. An employee at a site where samples are processed for a Finnish biobank confirmed this when saying that it makes no difference whether the sample is being processed for a biobank or for other purposes: "It's like basic… if you purify bone marrow or the cells it's just, there is no difference" (i19, 2013).

If, as described in the following example, there is perhaps nothing spectacular in collecting these samples, the novelty indeed is in claiming how collection is now conducted *professionally,* which simultaneously indicates standardization:

> It is by no means groundbreaking. They [samples] have been collected as long as we have had medicine or surgeries, [therefore] as long as we have collected samples and done things with them. But the revolutionary part is that now we aim to do it professionally. (i2(1), 2012)

The best quality could be guaranteed by using robots in "fully automated" sample processing (i.e., i37, 2013), since the machine is believed to do everything in exactly the same manner every time: once again, in a standardized manner which ensures "confidence that the work is valid and reliable" (Timmermans, 2015: 80). This explains the goal of automatizing the sample flow to keep the quality constant and minimize variation (Hewitt, 2011: 115). However, Meskus (2018) has pointed out that in the field of stem cell research the care for the samples,[19] and sample processing as a craft, are, along with industrialization and automatization, still important for scientific practice and scientific knowledge production. The skills related to taking care of the samples are vital elements in how science is actually being done and how the field is developing (Meskus, 2018).

Sample, data, and sample as data

For a sample to be of high quality something elementary is still needed: the donor-related data (Timmons and Vezyridis, 2017; Tupasela, 2008: 42–43) and those of the sample. In the interviews it emerged that the biomedical research enterprise does not only lack biological samples, but, "above all, data … linked to the samples" (i40, 2015). A researcher described this lacuna as "one of the biggest bottlenecks at the moment" (i40, 2015). Another interviewee, a clinician and researcher, described the close connection between the sample and the donor data, foregrounding the importance of data:

> Both the information and the sample are so closely linked that the sample is nothing without the data attached. … It is a very simple thing; the samples are quite easy to collect, but if you don't have any metadata attached to them their usability is extremely poor. (i3, 2012)

Additionally, when a biobank sample is used for research purposes it is simultaneously cumulating and expanding a package of data with potential multiple links to other data sets. This is so, first, because the information and data on a person increase with follow-up data from health care and hospital visits, and as public registries and other data depositories accumulate over the years. Indeed, "when data on the same person accrue, that is what creates the value", said a seminar presenter involved in a biobank (Fieldnotes, 2015). Second, as Finnish biobanks early on adopted the custom that data should always be returned to the biobanks, the data in a biobank grow when the collection is being used and analyzed in biobank-based research projects. During the early years this data return became the operating model for biobanks in Finland, also partly the result of the underlying idea of

19 On researchers' and technicians' care for the cells, see also Suzuki (2015).

not wasting the samples: it should suffice to do a certain analysis once. Thus, there is always a layer of new results being added to the old ones. In banking rhetoric both these ways of accruing data augment how samples "gain interest".

> I would love to think that the sample… as a matter of fact, the biological sample is not necessarily always crucial at all, but the data … on top of it. That is valuable. And then additional data pile up along with research. That would be just great. And then research could utilize that. (i6, 2012)

This was accepted practice throughout the country, often supported by the argument that the Biobank Act requires data return. Later, however, two storylines emerged: one that saw data return as a requirement based on legislation; and another interpretation that there was no such requirement in law, even though it had become the practice of all biobanks in the country (Fieldnotes, 2018).

In fact, Finnish biobank legislation was from the start criticized for being too sample-centric, one of the central reasons why processes to revise the regulations started shortly after the Act came into force. In terms of the emphasis on data, the regulations' "sample-centeredness" is very telling (see, e.g., Sosiaali- ja terveysministeriö, 2015; Tupasela et al., 2015b). For example, pharmaceutical companies have shown interest in the clinical data only. However, the legislation does not allow the use of these data if a person has already consented but there is no sample in storage yet. Thus, very early on biobanks noticed that there was interest in their data collections, or "lakes" as they call them nowadays, but that work on the level of data was only possible when there was a sample stored in a freezer. However, this problem concerns only the new, prospective samples collected with formal consent. When the old clinical collections were transferred across to biobanks, access to a huge data depository was created: for example, the Helsinki Biobank's website claims that their "largest retrospective sample collection contains diagnostic FFPE samples from 1.4 million individuals collected during the years 1982-2013" whereas in June 2017 they had "over 12,700 EDTA plasma and buffy coat samples" collected as part of their ongoing prospective blood sample collecting (https://www.terveyskyla.fi/helsinginbiopankki/en/sample-collections). In one presentation it was estimated that the Helsinki Biobank's retrospective collection has over 4 million samples in total (Fieldnotes, 2018). Similarly, on the webpage of Borealis Biobank it is stated that in their collection the old pathological collection of the Oulu University Hospital alone "includes 1,800,000 pathology tissue and cell samples beginning from 1978". However, they have also stored the pathology archives of another four central hospitals since the early 90s, as well as the Finnish Maternity Cohort with 2 million serum samples and, of course, the new prospective collection (http://www.oulu.fi/university/node/38474). What remains an open question in these listings on the webpages of biobanks is the question of whether these samples are truly high quality samples in terms of standardized and professionalized collection and sampling processes.

Aarden (2017: 759) has argued in relation to the Singaporean Tissue Network that the "usefulness of the repository depends not exclusively on the quantity or quality of the tissue, but its connection to other forms of knowledge". This potential connecting of different kinds of data sets to become the data actually utilized in research settings is indeed crucial (on the importance of the circulation of data, see Ong 2016). Therefore, additional data in Finland are expected to be both continuously generated and returned to a biobank. However, it was not clear for biobanks *what the data are that should be returned*. Do the biobanks have the means for data management and storage? It has been suggested that what is returned to a biobank should be agreed on a case to case basis. Questions are also posed about whether the data should be raw or confined to results. In the interviews it came up that "some pretty radical decisions on the data masses" are needed "if we are to sequence the whole genome of a person" as that would mean huge amounts of raw data (i35, 2013). Some have suggested that DNA is actually an efficient way to "store data" (Fieldnotes, 2016). Furthermore, there is again the question of harmonization and interoperability:

> So, who, after several years, is going to be the one connecting these different data sets from different labs, collected with different techniques and so on. … In fact, for you to make a good, enormously big study and to find something, then you have to have a single lab doing something using a certain technique from an enormous set of samples. And this is what biobanks might now bring. (i10, 2012)

Again, technologies have their impact on results and therefore the circulation of data is a challenge. Genetic and genome information is said to be basically fairly easy to combine, but the more complex elements, such as proteins, glycanes, and lipids, are more difficult (i10, 2012). These results from different laboratories are, according to some, hardly comparable. Yet, simultaneously, there is an imperative to collaborate and combine samples, with some of the informants stressing that it is not possible to rely just on Finnish samples; that is, what is on offer nationally is not enough (see, e.g., Kere 2007).

The life-span of the sample as a "high quality sample" is about combination. The first part of the combination is the biological sample; the second, the health care data of the donor; and the third, the results that come back to the biobank and can potentially be added to the sample as a data package that will be utilized in specific contexts. All these three continue to create questions of quality even after the material sample has gone. For example, when researchers merely utilize data in their work, they should be able to trust the consistent quality of the sample, as argued throughout this chapter: not only as the sample was when originally placed in the freezer, but also throughout its different journeys and the multiple connections between data sets that become part of what is actually utilized and enacted in a given study (on data journeys, see Leonelli, 2016). An expert (i34, 2013) observed in an interview that researchers are usually easily able to see whether the RNA has been breaking or whether it is intact and of "prima quality". Yet if it has started to break, it does not mean that the whole sample is useless, since it might still contain intact molecules. Therefore,

the sample could still qualify for some analyses, even though it is suboptimal for others. However, this kind of tacit knowledge does not travel readily as data:

> The problem arises when the RNA analysis of the sample becomes numerical data. Now it does not say in the data that the RNA was a bit poor. The data get so easily disconnected from the sample history. And then you make comparisons between that data and 10,000 other data sets, and how can you or anyone then say that it would make sense to pay less attention to this one? (i34, 2013)

Secondly, there is the attached health care and clinical data. For example, Finnish health care registers are often said to be of high quality because they are standardized and based on ICD codes. Simultaneously, on the other hand, "The way they are collected is not of such a high quality", said one informant. "Often the clinician, as the final task of the day, when already feeling tired, just types in any code whatsoever" (i40, 2015). Nonetheless, according to the same interviewee, it is generally well known which ICD codes work and are usable, and which ones are not. For instance, endometriosis is considered "vague" because it might be typed in the registries as a pain diagnosis. Thus, a good understanding of clinical practices might play an important role in assessing the usability of attached health care data. Thus here, too, there is contingency in terms of the accuracy of data and what they entail.

Thirdly, the quality of the returned results is a concern of its own. A pathologist in a seminar on biobanking presented a question from the audience, summarizing the problem as follows:

> This biobanking requires the fulfilment of certain quality criteria. And then these materials will be given to researchers, and data from them will be returned to the bank, so what means should be used to ensure that this returning data also fulfills the quality criteria? (Fieldnotes, 2013)

Whose analyses would one trust (see also Aarden, 2017)? Are the others doing quality work? Should you replicate the setting yourself as well? Here social factors such as reputation and trust come to matter, with familiarity and tacit knowledge also playing their part:

> To put it crudely, it is easy to assume that a Finnish researcher will trust results produced by researchers in certain countries more than those in others. In Nordic countries, for example, we are methodologically compatible so it feels pretty clear that when you know the people who produced the data, they always seem more reliable. (i34, 2013)

Biobanks are part of the life sciences that are dependent on the travels of data (Nowotny and Testa, 2010: 101); meanwhile the line between data and material sample is becoming less clear in increasingly data-driven medicine. Indeed, whether it is meaningful to

separate donor-related data and the sample is not obvious, even though it seems that one is material and the other is not. Leonelli argues that we should understand data as material too, because data always come in some physical medium, be it sequence, specimen, label, or photograph. The medium will "affect the ways in which data can be disseminated, and thus their usability as evidence. In other words, when data change medium, their scientific significance may also shift" (Leonelli, 2016: 81). She further argues that the dissemination of data resembles packages travelling as mail, since among other things, their "ability to travel depends on infrastructure designed for this purpose, as well as interventions by people other than their senders and receivers" (Leonelli, 2016: 25). In terms of materiality, Thacker similarly argues in relation to biology more widely that it "is *information, and that information is both material and immaterial*" (Thacker, 2006: 21, emphasis original), and, currently, biomedical research is often conducted based on already generated data. In one information leaflet issued by the FIMM in 2012, biobanks are described as "turning into biodata banks", because, increasingly, the "tissue sample is analyzed and broken down into bits, after which data alone are processed". Indeed, an interviewee who was involved in setting up a biobank and continues to work for one, said that "you can do research based on knowledge of the sample. There will be no wet lab work; instead you can just handle the data, combine it differently and so on" (i4, 2012). Thus, in today's research world a researcher does not necessarily even see the biological sample, be it blood, hair, bone marrow, tissue, or something else, while even if a researcher actually uses the samples, they "come bar coded, readable to a computer, and automatically separated" (i24(1), 2013). Consequently, the material sample is expected to transform into data altogether, as the following quote states: "Samples are not... as we know they are only a starting point. We need to convert that into data" (Fieldnotes, 2015).

In the end, ideally, it is expected that there will no longer be a material sample in the freezer, merely data that keeps circulating. A sample has been transformed into reliable data that can be used repeatedly in new kinds of research settings with multiple data links, with the result that the data in the biobank accumulate. A clinician and researcher sums up the message: "When material decreases the information increases" (i29, 2013). The measure of high quality lies in the absence of issues that challenge the credibility of the data. As a biotechnology expert related in an interview:

> And then there is this one sample-related issue whereby you think that the biological is the most important thing in the world. Actually, when knowledge piles up, the meaning of the sample decreases and eventually vanishes. You do not have to mourn the sample; think about the data and information! That is what is important, in my opinion. (i6, 2012)

Moreover, the attached health care data contain traces of other material samples already analyzed and converted into data, while if a person has consented to participate in biobanking, there are growing layers of sample-based data regardless of the number of

samples specifically stored in a biobank. This is so since many of the diagnoses in clinical practice are based on laboratory results, which then become part of the added health care data on the donor. I argue that in biobanking a "sample" should be understood as an evolving data package and, in temporal terms, ever present, because it potentially gains follow-up data as well as analysis data every time the participant receives health care, or data from research are returned to the biobank. Even when the biobank sample and data, or biobank sample as data, are what is being enacted in a specific setting (see also Leonelli, 2016: 83), it is potentially different every time. A biobank participant should understand, therefore, that biobank participation involves a lot more than a single sample's being stored on a certain day.

The old is the new "new"

The aim of biobanks is to collect and provide usable, credible, comparable, suitable, and exchangeable samples and data for the use of biomedical research, but as mentioned above, Finnish biobanks are not based solely on the new, prospective samples collected professionally since biobanks were established. Old sample collections are also transferred to biobanks and translated into quality-assessed objects for research. Thus, old samples need to be re-established as qualifying for the research methods and technologies of today and the future. With quality assessment a workaround is created to deal with unknown histories, the possibility that freezers have melted, or the amateur manner in which the samples have been collected, but, first, agreement on the criteria for quality assessments must be reached.[20] Different biobanks have launched projects to assess and evaluate the quality of old collections that would then allow researchers to trust the usability of the samples:

> Then we can say that if you isolate DNA in this and this way then it will be suitable for this and this part of this method, so that we will have at least some kind of reference as to what these samples qualify for. (i31, 2013)

The old collections of hospital districts and the National Institute of Health and Welfare form the main unit of samples in biobanks in Finland. In 2007, Professor Juha Kere was already writing about the need to establish biobanks and expressing his concern about the

20 The quest for collections that meet research needs also finds social science resonance in discussions on auditing and technologies of assurance (see, e.g., Strathern, 2003; Wahlberg, 2015, 2018). The analysis presented in the chapter shares with those discussions the interest in how some samples can be differentiated from others on the basis of their high quality through appealing to their standardization and registered history, thus, how their quality is framed as assured: for example though the involvement of accredited clinical laboratories (Wahlberg, 2015). This topic, however, is something that requires further investigation to provide detailed analysis of how auditing in this context plays out today as biobanks' quality control protocols, quality goals, and quality management systems, for example, are still being implemented (see the homepage of biobank Auria on their quality management).

quality of older collections. He wrote that it could be challenging and difficult to utilize samples from the old pathological tissue archives in a systematic way because the sample quality varies. He added that it is not "evident that you could isolate good enough DNA from the old collections for the new, sensitive analysis methods" (Kere, 2007: 865). Does it make sense, therefore, to transfer old collections to biobanks if the old samples are part of what biobanks are designed to overcome in terms of dubious quality?

Kere also points out in his text that biological samples are only a part of these collections, since the data are of greater importance and "therefore the advantage of old archived samples is slight" (Kere, 2007: 866). Yet now, a decade later, the growing emphasis on data means that these old collections have something the new prospective ones cannot have: follow-up data already in place. Therefore, these collections are sometimes considered even more valuable than the new ones. Additionally, the value of old samples is growing not only because of the attached data, but also as a result of developments in techniques that increase the possibility of using them for meaningful analyses. In this sense, these old samples have been re-set for the future, while upcoming developments might once again change the usability and significance of the samples of today as well as those of yesterday; thus, there is flexibility in the temporal value of the sample.

Another reason why these old samples might prove to be valuable for some analyses lies in the fact that, in the case of cancer, for example, the treatments have developed and differentiated so that certain cases rarely occur anymore. This means that new samples possibly say more about the choices made in treatment and therapy than about the development of the disease. This efficacy of different treatments might be in the interest for some researchers; however, there are others who would like to examine what is called "the disease itself" – that is, its natural cause and development – and arguably it is precisely that which is to be found in the old collections:

> Today patients always get different treatments, so it's not easy to understand the original biology of the disease and the effect of different therapies. Then there are also disease stages. Today we see some tumors only in very early stages, no longer advanced stages, whereas in Africa, for instance, we have a situation with many tumors like we had in Europe maybe 20, 30 years ago; they have this situation now. And advanced disease stages require different treatments than the early stages. (i36, 2013)

The point about the different stages of disease is very important in the development of biomarkers and disease monitoring (in all populations). Furthermore, as some diseases no longer develop to such an extent, thanks to the effectiveness of newer treatments and therapies, there are certain questions that would be simply impossible to answer with the new materials (i36, 2013).

Matters of width and depth

In Finland, biobank samples are collected mainly as part of clinical care since most of the biobanks are of the clinical variety. This means that for prospective collections it is usually a blood sample that is collected in an accreted clinical laboratory, and thus the clinical quality is the outcome of the process. However, specialized collection and processing is also possible and the first two disease-specific biobanks have had the opportunity to start with more extensive sample collections in terms of kinds of samples and time points at which they are collected. For example, the Finnish Hematology Register and Biobank (FHRB) aims to collect samples based on different stages of disease; diagnostics, remission, relapse, remission, and so on. The first sample is especially important as once the treatments have started the "situation changes and you do not necessarily get the same information as you would get in the beginning from the samples taken afterwards", a clinician reported in an interview (i13, 2012). Indeed, the samples from different stages of disease and collected over time are considered especially valuable.

The Helsinki Urological Biobank Sample Collection[21] is in a somewhat different situation nowadays than it was when the collection was formed under the HUB biobank project. For example, the samples collected after they merged with the Helsinki Biobank are different from those they were able to collect as an independent initiative. When the HUB was still an independent project, part of its goal was to create best practices for sample collecting, processing, transportation, and storage. It simultaneously had the opportunity for more extensive sample collection and different types of samples from the same patient in different stages of disease were gathered in order to see how certain markers behave in different stages of treatment. Since the collection of the HUB biobank project is now just one sample collection in the Helsinki Biobank, this collection is currently being enriched with only one blood sample and, as "more extensive sample collecting" compared to the usual prospective samples, one follow-up sample is also collected (i2(3), 2016). This makes visible one important question, namely, whether it makes sense to collect samples in terms of width (big n) or depth (extensively from a smaller n).

Another important question regarding the usability of the samples – as a combination of data based on registries, and data based on biological sample – has been the following:

21 The collection of the Helsinki Urological Biobank project (now part of the Helsinki Biobank) is referred to as the "Helsinki Urological Biobank (HUB) Sample Collection" (http://www.hus.fi/en/about-hus/helsinkibiobank/Sample_Collections/Pages/default.aspx) and described as follows: "During the years 2012-2015, 1976 urological patients were recruited to donate their blood, urine and tissue samples into HUB Biobank. Most of the samples have been collected from prostate cancer patients but other urological cancers are also represented. There are 27 628 single samples that have been collected at the time of diagnosis and on follow-up visits. Number of prostate cancer patients with blood and urine sample taken before and after surgery as well as tissue sample collected in the surgery: 390." (http://www.hus.fi/en/about-hus/helsinkibiobank/Sample_Collections/Pages/default.aspx)

when are the samples valuable for their users? The answer to this has shifted during my data collection. Earlier, the idea was that the HUB model, for example, could be considered successful biobanking if the samples were rapidly utilized in the development of individualized treatments (i2(2), 2013); in other words, if, during its first few years, it moved things forward and accelerated translation, both in research and the clinics. Now that the Helsinki Urological Biobank Sample Collection is part of Biobank Helsinki the samples in this collection are suddenly *not yet* useful. Instead, the HUB samples are now stored for the future:

> This type of cancer progresses typically very slowly and now when we have been collecting these samples, they will be the most valuable in about 10 years' time. (i2(3), 2016)

This refers specifically to follow-up data. Thus, what is regarded as carrying the potential is changing and flexible in the samples themselves. Additionally, techniques are developing along with changes in methods and usability of the samples. For instance, there are growing expectations connected to liquid biopsies, which would allow the detection and analysis of cancer from a blood sample (i2(3), 2016). Thus, what is possible in research due to biobanks' collections changes according to new ideas as they come along.

Aligning the industry, the academy, and the clinic

Biobanks in Finland started with the goal of fostering translational medicine,[22] something strongly underlined by the cancer biobanks, the FHRB and the HUB; the aim is, and has been, to bring clinical care and research closer together and develop more individual treatments (see Chapter 6). Moreover, co-operation between academia and public and private institutions is expected to increase, bringing the results gained in laboratories more quickly to the clinical environment for the benefit of the people. However, again, sample quality matters for the commercial utilization of biobank collections and health registries through biobank infrastructures in the making of personalized medicine (see Timmons and Vezyridis, 2017).

Translational medicine, in order to align research, clinics, and the industry, connects to the call for standardized samples that ideally meet the needs in all these different areas. According to my informants, there has been a general understanding that samples used in academic medical research have differed significantly in terms of quality from the samples in the clinics or industry (see also Kere, 2007). It was considered impossible for industry and clinics to use the same materials as academic research, which has had an impact on

22 To illustrate this, the title of the Biobank Borealis web page is: "Biobank Borealis of Northern Finland – from bench to bedside" (http://www.oulu.fi/university/node/38474) and the Helsinki Biobank is described as one that "supports the translational research done in the region, and network with national and international biobanks", on the web page of BBMRI Finland (http://www.bbmri.fi/bbmri-network/finnish-biobanks/).

the pace of translation and clinical validation of new medical products and substances. Indeed, traditionally the understanding has been that universities perform basic research and commercial actors produce the medicines – thus business and science have often been separated (Lee, 2015: 208). Now, however, institutional structures are portrayed as changing and public-private partnerships are increasingly encouraged (e.g., Sunder Rajan and Leonelli, 2013).

The industry has been considered "the exact opposite" of the academy in terms of standards in sample processing and storage (Fieldnotes, 2016). The story goes that previously, because of the unknown quality of samples used in academia, pharmaceutical companies had to replicate research with their own samples, since they work in the highly regulated field of drug development. According to an expert I interviewed: "It is a million-dollar issue for pharma only to do research on samples that are as reliable as possible" (i34, 2013). Knowing the costs of developing new medicines, this does not surprise. It seemed to be self-evident to my informants that the pharmaceutical industry requires, not only the right to use the samples (i.e., informed consent must be in place), but also the most controlled, well-documented, and standardized quality.

Similarly, in clinical work, sample quality cannot be compromised, as the samples are used for diagnostics and care. It would be unacceptable to risk making inaccurate diagnostics with messy samples. The accredited laboratories are doing their job according to standardized operating procedures, so if biobank sampling and sample processing is conducted as part of their routines the result is, therefore, "quality" (Fieldnotes, 2015). Samples from accredited clinical laboratories bring quality to research, thereby opening the possibility of collaboration, although clinical quality can also be a compromise. In practice one often has to plan sample collecting so that it fits into the everyday practices and schedules of the clinic, meaning that it is as much about what is possible in economic and practical terms as about quality:

> The money talks here and we have to think about the solutions all the time, like what is possible, what is desired, and what is rational, as the samples are sort of part of normal clinical practice, so we have to settle for the standards that have been established in clinical sampling. (i30, 2013)

The clinical standards in sample processing in Finland should mean that the samples are suitable both for research and care. It is expected that biobank samples could likewise be actually meaningful in the care of patients (see Chapter 6). In a translational biobank, the samples, and data fulfilling clinical standards and often collected at the clinics, are expected to move back to the clinic in the form of results; thus it is not so much about returning incidental findings as using results to tailor treatments. This is where disease-specific cancer biobanks in Finland could have, or could have had, an impact on clinical care. As

mentioned earlier, the older divide between what qualifies in the clinic and what qualifies in research is being reconceptualized (see Cambrosio et al., 2018).

> Traditionally the understanding is that if something is done in academic research it is only risk and a problem if you return that knowledge back to the clinic, since academic research does not work according to same quality principles as a clinical laboratory. There has been a firewall. And that is still the case, but the quality demands of academic laboratories are changing quite a lot in terms of core facility services with which we serve researchers widely, according to very strict principles and with new tools such as genome sequencing. We have here a genome sequencer, and a clinical lab has a genome sequencer and our quality does not differ from theirs. (i22, 2013)

Still, some people consider that despite this advantage of biobanks – that research samples often meet clinical standards – the findings would always have to be verified and validated again, and that one cannot think of applying the results directly back to patient care. Again, there might be a "student" messing everything up:

> In our place many research laboratories are accredited, but not all, so in some labs let's say a summer student does something and finds something. We cannot tell that kind of thing to a patient. At most we can say that we found this kind of thing but that it may very well be incorrect, because of this complete screw-up who does this research at our place… It does not matter much when we have 10,000 samples if one pair of samples was mixed or whatever, messing up what might have taken place, but it matters extremely to the individual. … How could we give that information to the people as required by legislation? (i16, 2013)

Thus, the idea of movement back from research to clinic is deemed problematic, and again, the question arises of whose results are considered trustworthy in practice. The loop back to the clinic is a step that calls for further validation for something that was framed as clinical quality (in terms of new samples). However, there were some who said that the quality of genome sequencing is often not very consistent either, and certainly not something to be utilized in clinics without further analyses:

> The basic laboratory results come from accredited laboratories, but if we go to the whole genome sequencing or other results or data sets that seldom come from accredited labs, then it is never so that you would just use it directly for clinical decision making. You would have to run extra tests… (i31, 2013)

In sum, appealing to clinical standards in research is linked both to improving the clinical utility of research findings and making it easier to collaborate with the industry. It seems that, ideally, common usability between industry, academia, and clinics could be established when standardized samples also become part of routine practice in academia. However, as

Fujimura (1996: 5) has put it: "One lesson we have learned from ethnographic studies of science is that scientific practice is much more diverse and locally contingent than it was once assumed to be." This reminds us that the clinical practice of validating everything one more time makes sense, even when it is so clearly stated that finally these samples are of high quality – and aligned to suit clinic, research, and pharma.

Quality is recorded history

The talk about the high quality of the samples has encouraged me to ask, during my own research process, questions about "things embodying concepts", as Rheinberger (1997: 8) has put it. How can you try to define a "high quality sample"? One way of defining quality is that it comes with standards and protocols and that all steps are written down. That is, high quality samples in practice gain their name through their *known* quality (also Leonelli, 2016). As a clinician / researcher involved in establishing a biobank said:

> Quality means that it is documented. It does not mean that if you do research you are doing it wrong if you do not act according to principles of quality; rather, it means that you do not keep track that *this* is when I took the sample and *this* is when I put it in the freezer – and if you don't have that written down, then you don't have quality. (i35, 2013)

A whole workflow needs to be organized in order to achieve a well-documented and registered history for a sample. For example, in the case of two cancer biobanks in Finland, the HUB and the FHRB, there have been significant efforts to organize the sampling process – to decide on the tubes and reagents, where the sample processing will be done, who will transport them, when consent is asked and by whom – before the sample is even taken and transferred into liquid nitrogen freezers. In other words, what is gained through the now professionalized process is information: documentation about the history of the sample, where it has been, when, how long, and in which temperatures it has travelled. It is also deemed important what happens during storage, not only that the sample was frozen quickly or prepared for storage in a certain manner. The history must also be registered and recorded *during* storage and, afterwards, all these previous steps and their careful documentation are the precise things that make the sample one of high quality. Practice in clinics and laboratories has adopted this requirement to record every step, which means that the effort to record and document both guarantees the quality and participates in its creation.

Researchers must be able to access the whole history of the sample until the moment it is analyzed by them. Of course, there are also differences between sample types in regard to how sensitive they are to these different steps and timepoints. Mostly DNA is described as stable and RNA as more challenging in terms of achieving and keeping high quality, and DNA is more stable than serums and plasmas. Yet, concerning the sampling:

> As soon as you take the sample it starts to change, it starts to be modified, it starts to be degraded. The longer you wait, the more it becomes less similar to the original. Even during storage you need to check which kind of storage temperatures, which kind of storage infrastructure you need to use. (i37, 2013)

One of the goals in some collections is to maintain the sample "as it was", as if it were the same as it was in the biological environment of the body. The idea is for the sample to be as close to the original situation as possible in terms of content and structure, and able to represent the in vivo situation (i37, 2013). This is the case with the hematological biobank's freezing of living cells, but it is not a simple goal. Indeed, it is one of the drivers for the well-planned processes of new prospective biobank collections and even extra effort from the laboratories.

There are certain contradictions that relate to the quality and usability of these samples. The flexibility, the qualities of being valuable as old or new, as simultaneously academic, clinical, and commercial, recalls what Mike Fortun (2008, 8) pointed out in relation to Icelandic deCodeGenetics and the Health Care Sector Database as "difficult doublings". In Iceland, according to Fortun, there were simultaneous contradictory notions in the promise of genomics, such as "public / private", "little value / great value" and "owned / not-owned" (Fortun, 2008: 8). These doublings are both active and blurred in relation to high quality samples, depending eventually on how they are enacted in research and in what kind of research (as we remember, the lines are often blurred in the making of biomedical knowledge [Cambrosio et al., 2017]). Moreover, Mackenzie et al. (2013: 703) point out that in the field of biomedicine, standardization and stabilization are almost impossible as the "unchanging attribute" a standard needs is "what biology essentially lacks". This is why one can only standardize the quality assessment procedure or the operating procedures in the quest for high quality samples, not the content of a sample as "biology". However, as a sample turns into data it connects to multiple different kinds of standards such as those attendant on ICT systems, taxonomies, codes, and so on. A lot of the difficulty in being explicit about what matters and what is valuable relates to the analyses and methods one wishes to use. For, ultimately, the high quality of a sample fulfils its promise in research only through the right use of it. What is sought is the appropriate use of a defined sample, for analysis that is doable, with precisely those kinds of data. This is also considered to be an efficient use of a specimen. When high quality is about when the right analysis is done based on the right sample(s), the quality is repeatedly determined in specific research settings:

> The problem is the quality of a sample is not an intrinsic property of a sample itself. There is not a – let's say – a common quality standard: this is an outstanding, this is a good, this is a poor quality of a sample. That's not true; it does not exist. Because the quality of a sample is always defined in the context of the research question you want to answer, and the technology you want to apply. So a sample, which is excellently

> suited for a histologic investigation with a microscope, might be absolutely inappropriate for doing a metabolomic analysis. (i36, 2013)

This pathologist described the ambiguity of the high quality sample very clearly. At the end he concluded: "And therefore, in principle any sample is of appropriate quality if you use it right" (i36, 2013). Thus, in order to know what is of appropriate quality for which analyses, what samples are usable for what purposes, there is a need for further research and knowledge for the purposes of quality control. Perhaps it is for this reason that the pathologist also indicated that a better expression to describe the quality of a sample would be one of "defined quality" (i36). Similarly, Sabina Leonelli argues that the "successful reuse" of biological data is eventually as much a matter of how data is used as it is about how it is produced (Leonelli, 2016: 26).

Many of my informants stressed the importance of the scientists' expertise – another kind of professionalism at play in relation to the samples. Researchers are eventually the people responsible for using the samples in an appropriate manner. They should be able to understand what is possible and what is not, which analyses make sense and which do not. In a sense the issue of quality is organized through a biobank only up to a certain point, after which it lies in the hands of researchers and their expertise. In this the same is true for old and new samples: you have to use the "right material for the right questions" (i36). The goal of being able to provide high quality samples for every possible setting is simply not considered realistic:

> We would have to go to very expensive and practically inoperable lengths if we wanted to have samples with which one could do anything that we can imagine could be done in the world. The important thing is that we document how the samples are processed, how they are stored and so on. (i30, 2013)

Flexibility, standardization, and the dynamics of science in knowledge production

The sample is in a sense a depository in itself. It embodies standardized operating procedures, medical history, and information. It is a small "machine to make a future", for it could allow something new to emerge in the field of biomedicine; but this new emerges only from control, from the conventions and registered history of the sample (Morrison, 2017; Rheinberger, 1997). The way biobank samples represent the dynamics of knowledge production in science can be captured with Hans-Jörg Rheinberger's (1997) terms "technical object" and "epistemic thing", with which he illuminates the conditions of possibility for new scientific knowledge in an experimental setting. Technical objects refer to arrangements that meet and can be characterized by the "given standards of purity and precision" (Rheinberger 1997: 29): that is, defined and known characteristics so that the object can serve as a tool. Then the biobank samples as technical objects can contribute to "determining the realm of possible representations of an epistemic thing" (Rheinberger,

1997: 29), which, as a concept, refers to the previously unknown that possibly emerges in scientific experiments, enabled by the standardized and flexible character of a sample. However, if the epistemic thing is then eventually "sufficiently stabilized", it might become a vital part of "the technical repertoire" of further studies (Rheinberger 1997: 29). That is, in experimental settings one can first produce something that was previously unknown, which is also the goal in the making of knowledge, but then it is possible that the production of "replicas" may start and, for example, "standardised kits" emerge (Rheinberger 1997: 80). In biobanking, this could mean finding biomarkers to help in diagnostics, which can result in a validated medical product that will eventually be used in the clinics and, furthermore, might be crucial in future knowledge production.

Consequently, in biobanking, professional and standardized sampling is about the production of technical objects to be used to contribute to epistemic things. The samples as technical objects are based on routines that narrow down what is meaningful and possible to do in order to answer research questions (Rheinberger 1997: 30). There is a thin line between an "epistemic or technical entity" (Rheinberger 1997: 30) since it is case-dependent and becomes clear "in scientific practice"; nonetheless, the difference helps to elucidate "the occurrence of unprecedented events" in the first place (Rheinberger, 1997: 31). These two concepts also point to a certain epistemic loop that acknowledges the materials scientists use and need in order to "make a future" (Rheinberger 1997: 28), and captures the simultaneous standardization and flexibility of the high quality samples. Thus, the concepts "technical objects" and "epistemic objects" address the interplay in what high quality samples are built to be.

In fact, the duality of flexibility and standardization has to inhere in the samples for them to be part of the future-making machinery of biobanking.[23] According to Rheinberger (1997: 2-3) "experimenters shape and reshape their epistemic things" in experimental systems where "the scientific objects and the technical conditions of their production are inextricably interconnected". One of the key features of these systems is their ability to "behave as devices for producing scientific novelties that are beyond our present knowledge" (Rheinberger 1997: 3). The notion of "machines to make a future", adopted from Francois Jacob (1982), is thus already present in the previous example (see also Rheinberger 1997: 28). Simultaneously, postgenomics is "perpetually under construction" (Rabinow and Dan-Cohen, 2005: 2). This making of futures, standards, and flexible objects carries the potential for multiple ends: scientific breakthroughs, collaborations, economic growth, and clinical care to name a few. As Rheinberger (1997: 134) points out, even unprecedented events do not just happen, "they are made to happen through the inner workings of the experimental

23 The link between future-making in biobanks and postgenomics based on Rheinberger's thinking has also been made in the previous literature (see Gottweis, 2008: 24; Rabinow and Dan-Cohen, 2005). According to Rabinow and Dan-Cohen (2013, 2), however, the genomics company they were following was not interested in scientific discovery, and it is here where they delineate their postgenomic case from Rheinberger's, although there are similarities as well.

machinery for making the future". Scientific phenomena are made to take place and are at the same time material and discursive (Lenoir, 2010: xv). Rheinberger's concepts also foreground and grasp the dynamics of scientific practice and knowledge production in a more general sense. In comparison, in qualitative studies the "experimental system" is established in the process of writing, when new connections, ideas, or arguments are being developed in compliance with scientific methods and the utilization and enactment of theories and discussions in the field (Rheinberger, 1997: 222–229).

However, the way I understand the samples builds not only on Rheinberger's (1997) way of seeing the production of, and loop between, both epistemic and technical objects and things. Knorr Cetina (2001: 190) has also worked on objects that are "at the center of the research process". The biobank samples are prepared to be used both as material and as data, and to be used for different purposes: to gain knowledge of treatment outcomes, to develop diagnostics, and so on. Knorr Cetina (2001: 185) writes that the defining characteristic of knowledge objects is their "lack of completeness of being and their nonidentity with themselves"; they are "characteristically open, question-generating and complex" and thus carry in themselves the dynamic nature of research (Knorr Cetina 2001: 185, 190). This resonates with Rheinberger's (1997) theorizing. The work of these authors helps to illustrate that the samples are "technical objects" of an industrial scale, but still allegedly carry the future-oriented potential of objects of knowledge making. Thus, a certain level of uncertainty and flexibility is needed for research and knowledge-building purposes. Knorr Cetina (2001: 190) argues that "epistemic objects are always in the process of being materially defined, they continually acquire new properties and change the ones they have". Moreover, when it comes to naming these objects, "a stable name is not an expression and indicator of stable thinghood" (Knorr Cetina 2001: 193). Naming is therefore "a way to punctuate the flux, to bracket and ignore differences, to declare them as pointing to an identity-for-a-particular-purpose" (Knorr Cetina 2003: 193).

Cambrosio et al. (2009, 515) have argued that in biomedicine "new genomic tests are hybrid tools: simultaneously commercial products and clinical service, laboratory tests and medical devices, biological results and clinical indications". In a sense, this is also descriptive of the potential inscribed in biobanks – their "standardized flexibility". As argued earlier, in this field objectivity is not something pure or genuinely true, but more a matter of shared conventions and compatibilities. Cambrosio et al. (2006: 192) maintain that "what counts … is not whether or not the results produced by a particular laboratory are true, in some absolute sense, but whether or not they are compatible (within conventionally determined statistical limits) with results produced by other laboratories". This links to standards, but also to scientific discoveries and how they are built in the interplay between shared conventions and new possibilities (Rheinberger 1997: 76).

Conclusions

The biobank samples can be seen as delineating the past from a future to which biobanks are contributing; from the grass-roots level to the newest applications of medicine, everything is organized, standardized, rationalized, and made effective (see Williams, 2017 for a similar discussion on umbilical cord blood banks) without institutional or organizational barriers. The old way is non-standardized and unprofessional, which means that it is lacks clarity; it is not known and impossible to evaluate what has actually taken place during a sample's processing and storage. At the same time, biobanks continue on from the past and build on it; there have been medical collections before and samples have been used for medical research for ages. This talk of a new, distinctive quality can be seen as a legitimizing discourse, one of the roles of expectations (Beckert, 2016; van Lente, 2012). Furthermore, biobanks now transfer and translate old medical archives of information and biological samples to connect pharmaceutical companies, academia, and clinics.[24]

"High quality samples" is a notion that covers a variety of different kinds of samples (skin biopsies, blood, bone marrow, cancer tissue, etc.) said to share the characteristic of a specific level of quality that hinges on the recorded history of the sample and the availability of added health-related data. It is claimed that, eventually, with the help of standardized and quality-assessed samples, a more accurate understanding of diseases and a faster translation of the results to clinics will become reality. Nonetheless, it has been suggested that not only standards are problematic (Bowker and Star, 2000b; Lampland and Star, 2009; Star, 1990); samples are as well. Maybe there will now be better conditions for accurate replication; however, if something has not been replicated it does not necessarily mean it is false, just that it cannot be replicated in these particular conditions for reasons that often remain unknown. Standards produce boundaries in terms of what is included and what is excluded, consequently eliding the messiness that might in the end have been crucial (e.g., Webster and Eriksson, 2008: 109). For example, as the case of "junk DNA" (e.g., Biémont and Vieira, 2006) has demonstrated, what is considered important to scientific practice is prone to change. In this sense, standards and centralized sample collecting might pose a challenge to epistemic diversity and how the multiple kinds of needs of researchers can be taken into account (Leonelli, 2016: 55).

Inside of the notion of the high quality sample a lot seems to be going on in terms of quality: particularity and universality, old and new, amateur and professional, prospective and past. Biobank samples are indeed very different from "everyday notions of material things" as Knorr Cetina (2001: 193) has pointed out about epistemic objects. Thus, the reconfiguration of how biomedical research is organized through biobanks is connected to ideas about the fundamental building blocks of scientific knowledge and the most basic

24 A table of the proposed value of Finnish biobank collections is presented in a report by expert group appointed to evaluate the integration of biobanks (Ministry of Social Affairs and Health, 2016: 10), see Appendix 4.

entities of the collections: the biological samples as liquids, blood, and tissue, together with data. The potential and possibilities are in-built into practices that are referred to in terms of quality: the constitutive actions of a sample (standards / technical object) are at the same time the way to the future (flexibility / epistemic thing).

Indeed, a high quality sample is something to be used, but its usability is bound to the circulation, documentation, standardization, and protocols to which it has previously been subjected. Ultimately, this is needed in order for biobanking expectations to materialize. The biological sample must meet both clinical and industrial standards that are now framed as a requirement for the academy as well. However, no one can anticipate the needs of future research. What will a high quality sample be in 10 or 20 years? These samples carry the hopes and indeed capabilities of today, mirroring the temporality of visions of the future that are based on today's knowledge and understandings. Understandings of the usability of different kinds of samples are continually developing and changing, even though the rhetoric of "high quality samples" remains the umbrella under which changes in samples and sampling techniques are being reconfigured and reset. The "value" of the samples for specific settings remains in the hands of researchers. What is interesting in the end is how a "high quality sample" can remain as flexible as this chapter has demonstrated is possible, alongside the simultaneous portrayal of new, prospective collections as more professional, standardized, and credible.

Biobanks, therefore, are playing their part in building and strengthening certain conventions that serve as references for the evaluation of biomedical research. In other words, the quest for standardized sample quality can be understood as exemplifying negotiations over how to create objectivity and universality in biomedicine through shared conventions (e.g., Cambrosio et al., 2009: 653; Keating and Cambrosio, 2003: 3). Yet, at the same time, what is valuable in the samples is far from stable: for example, sometimes the new prospective collections hold the greatest value, sometimes the older.

To summarize: high quality samples must be both standardized and flexible to be used and to qualify as evidence in research. Flexibility, referring to the "uncertain character" of the "boundaries and qualities" of these entities (Knorr Cetina, 1999: 136) is important. Because biomedicine is constantly moving and searching for the new, the potential for these samples to be framed in different ways is about keeping pace with progress and adapting to the current scientific culture. From this it follows that if a biobank collection can be made to fit with new understandings and the developing technologies of the future, it is all the better for biobank activities. Additionally, samples in the collections must be flexible in terms of whether they will be used as wet samples or pieces of digitalized information, whether they will be part of a reference population or targeted diseased population, whether they will be utilized in academia or in the industry, and so on. The sample itself is also a very different thing when it is a piece of tissue in a freezer with the inherent potential to generate data, and when it is a sample with data attached that is actually being used in different settings. At

the same time, the iteration of biobanks, and their goals, practices, and self-understanding, is continually taking place (see also Helén, 2013; Ong, 2016; Williams, 2017).

5. The population(s) of Finnish biobanks: "homogeneous Finnishness" in the making of future medicine

Biomedical research produces, shapes, and enacts populations in the name of health (e.g., Epstein, 2007, 2008; M'charek, 2005; Montoya, 2011; Reardon, 2009), while biobanks provide access to the multiple populations biomedical research practice requires. Neither the research nor the reference populations of biomedical research are necessarily dictated by the borders of nation states; rather, they are "made" as Gannett (2003: 990) puts it, or practical matters as M'Charek (2005) has similarly shown. Despite this, national rhetoric is often used when biomedical research and its potential are publicly presented. On the web page of the FinnGen research project, which utilizes biobank samples, it is stated that "[i]mportant discoveries could be found on a single sample from any one of Finland's 500 000 biomedical pioneers". The project aims, therefore, both to collect and genotype[25] samples in order to benefit Finns and the whole world through Finnish samples (www.finngen.fi/en). Curiously, while biomedical science in practice is very much an international endeavor, there still seems to be room for *nations*. As shown by Benjamin (2009), Gibbon (2016) and Ong (2016), the need for 'national' samples in part arises from the need to secure the benefits of personalized medicine for the populations in certain nation states and geographical areas, especially if these populations have the risk of being understudied (see also Epstein, 2007). However, at the same time, these aspirations are often related to the economic benefits biomedical research and innovations are expected to bring to national economies (Cooper, 2008; Fortun, 2008; Ong, 2016; Sunder Rajan, 2006; Tupasela, 2008; Waldby and Mitchell, 2006).

Finland's Genome Strategy is one example of national rhetoric that combines the health and wealth of biomedical promise. It also represents an ongoing innovation-policy-level effort to promote Finland as the place to be for biomedical research (Tarkkala et al., 2018). The strategy was written to ensure "that, by 2020, genomic data will be effectively used in healthcare and in the promotion of health and wellbeing", as well as to make Finland "into an internationally interesting partner in genomics research and genomics-related enterprise" (Ministry of Social Affairs and Health, 2015: 3). In the strategy the Finnish population and its unique genetic composition are stressed as follows:

25 Genotyping is more cost-efficient than sequencing. For genotyped information to be as usable as possible, the requirement is that the samples are genetically of Finnish ancestry, the idea being that in a genetically homogeneous Finnish population one could fill in the missing variants with the help of mathematical modelling (Fieldnotes, 2018). Indeed, the homepage of FinnGen study states: "The project will also develop imputation methods that enable achieving near-complete genome variant information without whole genome sequencing. The unique history of the Finnish population makes this a realistic aim. (https://www.finngen.fi/en/node/27)"

> The genetic structure of the Finnish population provides us with a unique possibility to function as pathfinders and early utilizers of genomic data. By combining genomic and health data we can identify connections of genetic makeup to the health of the population and the effectiveness of treatment in a manner which would be difficult or impossible elsewhere. (Ministry of Social Affairs and Health, 2015: 12)

This chapter focuses on the populations stored by Finnish biobanks, specifically in terms of what kind of uses are envisaged for them, and how a homogeneous population, accessible through biobanks, can figure as a national advantage in the first place. Indeed, in the Genome Strategy, the "relatively homogeneous" genetic heritage of the population (Genome Strategy, 2015: 13) frames Finnish biobank samples as offering unique opportunities for R&D (see also Kääriäinen et al., 2017; Ministry of Employment and the Economy, 2014, 2016), simultaneously mobilizing a certain part of population in the name of national interests (see also Jasanoff and Kim, 2009: 123). Nevertheless, the way this genetically homogenous, and therefore unique, population is made to matter – through its "Finnishness" in innovation and the science policies favoring personalized medicine exemplified by the Genome Strategy – is slightly mismatched with how biobank samples, and medical research populations stratified from biobanks, seem to matter for research. Interestingly, the value of Finnish genetic uniqueness was not raised in the interviews I conducted. My informants told me that what matters in biobanks is the potential for the samples to be used for multiple purposes and as parts of differently stratified, multiple populations. This tension is the point of departure for this chapter.

In what follows, I analyze the malleability of populations in biomedical research, contrasting it with the rhetoric that presents and highlights Finnish population samples as especially valuable. In this analysis, biobank samples have a dual role: on the one hand, in innovation rhetoric and strategies seeking a competitive edge, they are framed as carrying particularly valuable, unique, national characteristics; on the other, they are samples of human origin with additional data that can potentially be used for multiple research purposes in the future, a potential tied to the social and institutional history of the country. A similar approach highlighting the twofoldness of imaginaries and infrastructure can be found in Erik Aarden's (2017) study on the case of the closure of the Singaporean Tissue Network (STN), in which he shows how biobanks serve "as both an infrastructure for knowledge production and expression of an imaginary of the sociopolitical benefits of research" (Aarden, 2017: 753).

In this study, the claims made about stored (potential) research populations are seen both as a way to create a competitive edge for the national innovation environment, and as illustrating the requirements scientific practice is expected to have of the populations it uses. The populations which are stored seem to be conditions of possibility for both the dual goals of personalized medicine: health and wealth (Tarkkala et al., 2018).

In this chapter, then, I do not concentrate on the commercialization, commodification, or economic value of human biological materials (Cooper, 2008; Parry, 2004; Sunder Rajan, 2006; Tupasela, 2006b; Waldby and Mitchell, 2006). Instead, I follow a strand of research that attends to how populations are made to matter in biomedical R&D: both in terms of what it is envisaged that biomedical R&D expects from biobank populations, and also what Montoya (2011: 194) calls bioethnicity, which "refers to the resultant product of the ways ethnicity comes to be constructed as a meaningful for scientific research". The concept operates "at the confluence of biology and society" and

> recognizes that distinct biological races do not exist in humans and that all knowledge derived from racialized populations is in fact the social histories and life conditions of those population pressed into service of biomedical discourse (Montoya, 2011: 201).

Indeed, in Finland, as I show, social and institutional histories and life conditions are part of how Finnish biobank samples and stored populations are expected to be valuable for biomedicine. The analysis in this chapter attends to the ways biobank collections and the samples of the population(s) they contain are framed as national, "unique" and offering a competitive edge in international biomedical research markets. This actually highlights Finnish society more than its genes and even leads to a sort of naturalization of the society through the "Finnish" samples. In what follows, I first briefly discuss how populations have been studied by STS scholars in ways that are relevant to my analysis and present the background for the populations in Finnish biobanks. Second, I sift the claims that a specific population can provide a competitive edge, examining how the understanding of the Finnish population as genetically unique first developed and how genetic homogeneity has been contested. Then I discuss the balance between biobanking and the utilization of genomes as national and malleable in my research materials and, finally, how Finnish society is positioned as what makes the Finnish biobanks valuable to, and usable by, biomedical R&D. In terms of data, this chapter utilizes presentations, scientific literature, reports of innovation, and interviews with experts, researchers, and clinicians. I also use openly available published materials such as radio and newspaper interviews, wherein Finnish homogeneity and its meaning for research and society are discussed. I analyze innovation policy documents, presentations, and other written materials, including my fieldnotes and recorded interviews in which researchers raise the issue of unique populations. I discuss these materials especially in relation to ideas, histories, and understandings related to the homogeneity of the Finnish population and society.

Populations for competitiveness and research

Medical research populations have been a central topic for STS scholars. Attention has been paid, for example, to the way populations are formed and understood in contemporary biomedical research, and the consequences and political and social implications of practices

that concern populations. In this literature, many scholars have pointed out that despite attempts in genomic medicine to abandon such terms as "race", "ethnicity", and "ancestry", they still continue to figure in the field (Benjamin, 2009; Epstein, 2007; Fujimura and Rajagopalan, 2011; Goodman et al., 2003; Hinterberger, 2012b; M'charek, 2005; Meloni, 2017; Montoya, 2011; Pálsson, 2007; Shim et al., 2014; Tupasela and Tamminen, 2015; Wailoo et al., 2012; Williams, 2018).[26] One concern in these discussions has been whether biomedical research will provide individually tailored treatments for different groups of people equally (Epstein, 2008; Lee, 2012). For example, Benjamin (2009), Gibbon (2013), Ong (2016), Coopmans and Hua (2018) as well as Tarkkala and Tupasela (2018) have shown how the use of racial and ethnic categories or claims about the uniqueness of a population can be used in biomedical research to secure the needs of underserved populations or to secure competitiveness – or both. In her book, *Fungible Life*, Ong (2016) presents the case of Biopolis in Singapore, which is an initiative aimed at constructing infrastructure for "stratified medicine", which, while meeting the needs of investors and collaborators, also secures benefits for "Asian" bodies and, thus, "Asia" (Ong 2016: 14).

Reflecting the competitiveness in global research markets, a number of countries frame their populations as offering exceptional potential for biomedical research, innovations, and development. According to Hinterberger, "the selling points of DNA collection projects are articulated in a variety of ways depending on a range of political, economic and cultural contexts" (Hinterberger, 2012b: 529). Indeed, Tupasela (2016b: 48) has pointed out how populations become brands in biomedical research (see also Benjamin, 2009), which "helps to identify the ways in which biobanks seek to leverage the sample collections they have onto international research markets". Populations become brands through processes that begin by highlighting heritage, identity, and authenticity, and tying them to a certain geographical location, thereby generating both differences and similarities between populations. Scientific work on the genetics of specific groups produces the means to make claims about these populations and their potential (Tupasela, 2016b: 49).

In the search for partners, collaborators, and funding, countries have tried to show exactly how a specific geographical area or population can provide unique possibilities for research and innovations (see Tarkkala and Tupasela, 2018). In Finland, too, the health sector has been recognized as a strategical area for further development, as throughout the economic recession since 2008 the export in health technology has been constantly growing (www.teknologiateollisuus.fi; Ministry of Employment and the Economy, 2014, 2016; Ministry

26 The concepts of population, race, and ethnicity can be contiguous, sometimes overlapping, sometimes drawing apart. Wade has addressed the topic of "how academics know when they are looking at something called 'race'"(Wade, 2014: 587) and M'Charek has pointed out how race is made relevant in certain practices without there being one clear definition of what a race is (M'charek, 2013). Several scholars have discussed the relations between the concepts race and population; see, for instance, Reardon (2009), TallBear (2013) and Thacker (2006).

of Social Affairs and Health, 2015).[27] This kind of national effort to be competitive in terms of biomedical R&D[28] is not unique (e.g., Reardon, 2017: 94). There are, and have been, similar attempts to become hubs or centers for biomedical research and innovation – and personalized medicine – in Iceland, Estonia, Scotland, Denmark, Sweden, Great Britain, Taiwan, and Singapore, among other countries (Bell, 2017; Cool, 2016; Fan et al., 2008; Fortun, 2008; Ministry of Health and Danish Regions, 2016; Ong, 2016; Reardon, 2017; Waldby, 2009). In the course of this search for investment, different kinds of unique populations[29] are being presented to biomedical research as valuable (Benjamin, 2009; Lee, 2012; Montoya, 2011), with the advantages of heterogeneity also being underlined (see Fletcher, 2004; Gibbon, 2016; Kent et al., 2015; Ong, 2016; Sunder Rajan, 2006: 165). Whether a population is homogenous or heterogenous, it can be claimed to offer unique potential (see also Fortun, 2008). This has been presented as "population branding" for biomedical research markets (Benjamin, 2009; Tupasela, 2016b). Additionally, as Petryna (2009b: 14) has pointed out, the choice of location for clinical trials is more an "economic and political" than scientific decision.

Other scholars have concentrated specifically on how populations are achieved in laboratories and scientific work in practice. M'charek (2005) notes that populations can be produced in multiple ways.

> [They] might be a product of family names, of laboratory practice and routines, or of genetic proximity distance. It could also be a product of race, national boundaries of genetic markers and their specific clustering in different population. This makes clear the "problems", or rather the variety, in the practice of *population*. (M'charek, 2005: 46, emphasis original)

According to M'Charek (2005) populations that are technical and operationalized in a laboratory serve in genetics as a reference to an individual and therefore, "neither the individual nor the population are inherently 'biological.' Rather they are *effects* of technologies and routines applied in scientific practice" (M'charek, 2005: 21, emphasis original). Indeed, as discussed in the previous chapter, the process of standardization – along with data harmonization – is part of how suitable populations for different research settings and usages in science are constructed and operationalized in the first place (see, e.g., M'charek 2005).

27 The value of exports in the field of Finnish health technology was 2.2 billion euros in 2017, with a 5.3% growth in comparison to 2016. In total the value has increased fivefold during the past two decades. (www.teknologiateollisuus.fi)

28 Moreover, in Finland there was already an interest in the utilization of the genetics and health care data before the founding of the biobanks in the 2010s (see, e.g., Tupasela, 2006a, 2007).

29 In fact, my informants said that all populations are unique (Fieldnotes, 2015), which suggests that claims about uniqueness are prevalent in the field of biomedicine.

Populations play a key role in the initiatives conducted in the name of personalized medicine, including biobanking. Hinterberger (2012a: 74) reminds us that despite promises of personalized medicine promoted at the level of individuals, human genome research is driven primarily by "the comparison of groups and populations", which is why some prefer to use concepts such as precision medicine or stratified medicine. Consequently, what is personal or individualized in personalized medicine, is based on reference populations that render individual results meaningful (e.g., Nowotny and Testa, 2010: 35). Reference populations are important because differences between individuals can be identified only when similarities within a population are presupposed (M'chareck, 2005: 21). For this reason, according to Shim et al. (2014), researchers need to use their populations strategically, "by actively working to *produce* homogeneity along some dimensions in their study populations and heterogeneity along other" (Shim et al., 2014: 581 emphasis original). This homogeneity can be achieved in research in multiple ways. For example, Montoya (2011: 93) points out that for research on diabetes the "homogeneity of Mexicana *admixture*" was produced; that is, homogeneity and heterogeneity are "'jobs' to be accomplished" (Shim et al., 2014: 588) and populations and their homogeneity or heterogeneity are "pragmatically constituted" to meet the requirements of the research question (Pálsson, 2007: 206). The way populations are formed in science is by no means a unified or straightforward activity; rather, it is about establishing a "fit for purpose" setting, case by case (Fieldnotes, 2017).

In practice, the forming of populations often hinges on institutional and societal practices such as censuses, various registers, and so on (see, e.g., Hinterberger, 2012a; Rose, 2003: 77), as the data that is needed in research is usually collected by nation states. Ong (2016: 13), for example, demonstrates that, in Singapore, multiethnic population data, now reassembled to be an advantage in the field of genomics, are based on "existing forms of racialization and racial accounting in the nation's official classification of its citizenry", which are in turn based on "ethnic heuristics inherited from British colonial race typologies" (Ong, 2016: xix, 13). Similarly, according to Montoya, the "words that describe groups" in biomedical scientific research "are inherited from outside the labs" (Montoya, 2011: 43). It has been pointed out that, while genetic difference is of importance for genomics research epistemically, "both ethnicity and race are compelled to accommodate structures of informatics and information" (Thacker, 2006: 135). However, STS scholars have reminded us that the participation of science and technology in the constitution of nationhood is crucial (Jasanoff and Kim, 2009, 2013, 2015; Winickoff, 2006: 99–100), something also taking place in national genomics (Hinterberger, 2012b; Kent et al., 2015; Tamminen, 2010; Tupasela, 2016a; Tupasela and Tamminen, 2015; Wade et al., 2014).

Finnish biobanks and their sample collection

Biomedical sample collections always form populations and all biobank collections exhibit traces of inclusion and exclusion connected with whether the collection is, for example, epidemiological, clinical, regional, disease-specific, or based on family histories. Biobanks

always come with some kind of understanding about what is a "good population" (Rose, 2003) for biomedical research, along with questions about the population of a given biobank, how it is constructed, and who is included (Prainsack, 2007). Tupasela et al. (2015a: 2) have argued that not only do biobanks utilize the populations from which they draw when defining and characterizing themselves, they simultaneously give rise to these constructed populations through the "identification, collection and distribution of samples and data" (Tupasela et al., 2015a: 2). Prainsack (2007: 86) has also pointed out that biobanks often "preserve the boundaries of existing" collective identities and thus can be seen as "repositories for the 'genetic components' of the collective body".

In Finland, most biobanks are clinical and collect prospective samples regionally; consent for this is asked of patients who receive specialized clinical care in hospitals. Alongside the six regional clinical biobanks, there are four nation-wide biobanks in Finland: THL (National Institute for Health and Welfare), which stores the epidemiological population cohorts; the disease-specific biobank for hematological diseases (FHRB); the biobank of the Red Cross Blood Service; and the biobank of private health care provider, Terveystalo. As mentioned in previous chapters, many older clinical collections and the population cohorts of THL, collected and stored before biobank legislation was put in force, have been transferred into research resources through biobanks with related data. The biobank legislation made this possible without requiring informed consent, which is otherwise mandatory.[30] The older clinical collections that were transferred to biobanks in Finland are based on the kind of population these biobanks also aim to store in the future. In general, Finnish clinical biobanks want to "capture all comers" (Fieldnotes, 2015), which means that, ideally, all patients attending a hospital also participate in a biobank. Similarly, the disease-specific FHRB works on the principle that "every patient is a research patient" (Fieldnotes, 2013), thereby rendering visible the goal and need for large quantities of samples. The reasoning goes that when samples are collected from all patients, they will represent people from different age groups, with different kinds of diagnoses and disease outcomes. Moreover, such sampling is considered socio-economically non-biased as all patients, whatever their socio-economic background, have allegedly received the same kind of treatment, medicine, and care in the same regional hospitals responsible for specialized care. This results in a situation where the samples are constructed as representing a sort of homogeneous Finnishness produced by the institutional structures of health care. Moreover, when biobank participation takes place in a public hospital, the biobank sample collection is believed to cover the Finnish population thoroughly, which in turn is also seen as a requirement for conducting proper research on diseases that affect a given population, in this case that in Finland (i31, 2013).

As already noted, biomedical collections always have sample criteria and ideas of inclusion and exclusion, whether implicit or explicit (Busby and Martin, 2006; Epstein, 2007;

30 For more on transfer of old samples into biobank collections, see the Introduction and Soini (2016).

Oikkonen, 2018; Prainsack, 2007). Yet Finnish clinical biobanks seem to welcome all patients as donors and participants,[31] without excluding certain groups or subpopulations of the country, such as the minority groups of Saami, Finnish Swedish, or Roma. A contrasting example can be found in Taiwan where the biobank project required deliberate balancing of different ethnic groups and their subsequent representation in the collection so that the biobank could be considered as storing the population of the country (Tsai, 2010). However, the Taiwanese are also described as homogeneous (and weak linkage disequilibrium potentially advantageous) (Fan et al., 2008: 245). What is more, in Finland, some Finns are presented in biobank materials as more homogeneous than others. For example, the collections of the biobanks of Eastern Finland and Northern Finland (Borealis) seem to store an even "more" distinctive population than others in Finland (Salmén, 2017; Sosiaali- ja terveysministeriö, 2015; http://www.oulu.fi/university/node/38474).

Unique and homogeneous? The Finnish population in and for biomedical research

> A combination of coincidences has finally made this [Finnish] population one that, out of proportion for its size, has by example shaped research in human disease genetics. (Kere, 2001: 103)

The scientific literature has referred to the Finnish population as "one of the best-studied genetic isolates" (Peltonen et al., 1999: 1913). Indeed, in Finland, geneticists have played an important role in explaining how the Finnish population, as genetically unique, initially developed. The research on so-called Finnish Disease Heritage (FDH) has been especially important both for interpretations about more general population history and for forming an understanding of the scientific potential and opportunities offered by unique genetic heritage (Tupasela, 2016a, 2016b; Tupasela and Tamminen, 2015). FDH refers to a group of monogenic, rare diseases that are overrepresented in Finland (Chheda et al., 2017; Norio, 2003a; Norio and Löytönen, 2002). In the studies on FDH it was identified that the population structure of Finland – "a consequence of the isolation and enrichment in a number of settlements regions established during the 1500s" – was also the reason behind "the emergence of particular rare diseases among the Finnish population" (Tupasela, 2016a: 123); it thus became possible to claim "these diseases as particularly Finnish" (Tupasela, 2016a: 137). The other side of the coin, as Tupasela (2016a, 128) has pointed out, is that studies on FDH, through concentrating on certain diseases and "their related historical trajectories", has turned them into "explanations of where and how people and families came to inhabit the land". Therefore, identifying the disease heritage was also about the creation of a "common origin of the population" (Tupasela, 2016a: 128) and about the "formation of national identity and unity" (Tupasela, 2016a: 121). Thus, in Finland, as well

31 The ones participating in the cohorts of THL are invited to participate in the study. The Red Cross Blood Service biobank recruits and invites blood donors to participate in a biobank.

as elsewhere, studies of genetic ancestries have opened up yet another space in which to imagine belonging (Oikkonen, 2018).

The concept of FDH was presented for the first time in the Finnish Medical journal, *Duodecim*, by a medical doctor and specialist in hereditary diseases, Reijo Norio, in 1972 (Meskus, 2009: 82; Tupasela, 2016a: 123). From the outset, the genetic uniqueness of the Finnish population was seen as an opportunity for research, giving rise to an obligation to work on this exceptional material as long as it is there (Meskus 2009: 82-83). Finnish diseases identified as rare were even described as "rare fauna in rare soil" (Norio et al., 1973). Nowadays around forty rare diseases are counted as comprising FDH (see http://www.findis.org/heritage.html, for their representation as "Perheentupa steps"); not all of them are unique to Finland, but they are overrepresented and "enriched" in the country (Tupasela, 2016a: 123, 137). At the same time there is lower carrier-frequency in some diseases, such as phenylketonuria, tay-sachs, thalassemia, cystic fibrosis, and sickle-cell anemia (Kääriäinen et al., 2017; Norio, 2000: 89–94).

The scientific success in disease heritage research has led to the understanding that it is possible to conduct successful and even pioneering R&D in a small country such as Finland (Kääriäinen et al., 2017; Kere, 2001; Peltonen, 1997; Peltonen et al., 1999; Wheelwright, 2005). Indeed, the genetics of the population, and the associated research benefits it is considered to offer, have been important for a number of academics in their scientific careers (e.g., de la Chapelle, 1993; Hästbacka et al., 1992; Kääriäinen et al., 2017; Peltonen et al., 2000; Wang et al., 2014). Today, innovation policies and strategies, with their public presentations, underline that Finnish biobank samples – and the Finnish population as a source of samples – are particularly good for research. This claim rests on the idea of the homogeneity of the genetic heritage of Finns, stabilized in studies on FDH which was then extrapolated into "the uniqueness of the rest of the population" (Tupasela and Tamminen, 2015: 412), and likewise labeled biobank collections and their current potential for personalized medicine with the aim of opening up new contexts for the use of homogeneous genes. Thus, the genetic homogeneity of Finns is built on the past of Finnish medical research, as imaginaries often are (see Jasanoff, 2015b: 329). More generally, many of the concepts that were used to describe FDH, against a backdrop of settlement history, such as "population isolate", "bottleneck effect", and "genetic drift" (Norio, 2000, 2003a, 2003b, 2003c), are also used to describe Finnish population history.

Consequently, the history of settlement and its bottleneck effects – as the main causes of the homogeneity of the population – figure in scientific and strategy papers concerning the potential Finland may nowadays offer for biomedical R&D (Ministry of Social Affairs and Health, 2015; Peltonen et al., 1999). Tupasela (2016a: 138) has already noted that studies of Finnish population history and Finnish disease heritage can be seen as

> part and parcel of a broader push in Finnish science policy to develop biomedicine and draw on the uniqueness of Finnish population. In this sense, the population and its unique genetic characteristics were seen as an important part of nation-building in the form of national innovation policy. (Tupasela, 2016a: 138)

Thus, "FDH and population genetics in Finland" are more widely illustrative of the ways populations become brands and potentially productive in biomedical R&D (Tupasela, 2016b: 61).

Contesting homogeneity and origin imaginaries

FDH has played a crucial part in the formulation of "a specific vision of Finns as homogenous yet European" (Tupasela and Tamminen, 2015: 412). However, in this process only certain individuals and groups have served to represent the population (Tupasela and Tamminen, 2015; Tupasela, 2016). Tupasela has described this as genetic romanticism, thereby referring to the scientific mobilization of certain populations and their genetic heritage which unifies certain "populations within politically and geographically bounded areas" and shows them as representatives of, in this case, Finland (Tupasela, 2016a: 121).

There are, and could be, however, other depictions of the Finnish population than that of a genetic homogeneous isolate. The postulated homogeneity of Finns has also been contested. There is, for example, such a significant difference between people from the eastern part of the country and those from the west that it raises the question of whether a population based on these two groups can be described as homogeneous at all (Lappalainen et al., 2006; Palo et al., 2009; Salmela, 2012). This difference is significant despite the fact that the whole Finnish population shows less diversity than other reference populations (Lappalainen et al., 2006; Palo et al., 2009; Salmela, 2012: 11). According to Salmela (2012: 11) "the genetic distance between eastern and western Finns was greater than between for instance the British and northern Germans. In fact, western Finns were genetically equally close to Swedes than to eastern Finns." Moreover, some are considered genetically more distinct than others – for example, those who originate from the area of Kuusamo (see Chheda et al., 2017: 477–478). Additionally, based on nuclear DNA, Finns have been identified as genetically more distant from Finnish Saami than they are from other "Europeans" (Lahermo et al., 1996). During the past decades differences have also been posited between the Swedish-speaking and Finnish-speaking populations of Finland (Virtaranta-Knowles et al., 1991). Following this, the crucial point is the sampling: Who will be chosen to represent Finns in a study design (see, e.g., Lek et al., 2016; Oikkonen, 2018)? And with whom are Finns being compared in order to produce the notion of their uniformity? In oral communication, researchers often point out that eastern populations are rarely used as references in this context, with "European" samples being preferred due to conceptions related to the availability of samples of appropriate quality. Indeed, a recent

study on genetic variation among Uralic-speaking populations, of which Finns are part, has shown traces of a common demographic history (Tambets et al., 2018).

Tupasela and Tamminen (2015: 420) write of FDH and population studies in Finland:

> [They] serve the medical community to distinguish the Finnish population historically, geographically, but also genetically from both non-Finns, as well as Finns who are not deemed authentic or original. This process of discrimination leads to a type of purification of the population that distorts, both the perceived genetic composition of a geographical location, but also exaggerates the national uniqueness of populations. (Tupasela and Tamminen, 2015: 420)

This aspect of research populations highlights the culturally appealing ideas of belonging and origin. Amy Hinterberger (2012b) has demonstrated that French Canadians have been foregrounded as the original population in the Quebec area, whereas others, such as "Quebecians" are seen as heterogeneous "immigrants". In her book, *Native American DNA*, TallBear (2013: 6) writes that the idea of ancestral populations "require[s] the assumption that there was a moment, a human body, a marker, a population back there in space and time that was a biogeographical pinpoint of originality". This, she argues, "seem[s] to be at odds with the doctrine of evolution" (TallBear, 2013: 6) in which biology is seen as constantly in a process of change. Indeed, ancestral DNA in particular is often culturally and socially interpreted as establishing a point of origin for belonging to "the imagined ethnic, racial, regional, or national community" (Oikkonen, 2018: 73). Oikkonen (2018: 115) touches on these paradoxes of population genetics and foregrounding of DNA of a certain kind as follows: "Evolutionary origins, then, appear to reside inside each of us, but in some of us they are assumed to be purer, less tainted by mixture, and thus more valuable for the scientist or the community."

Isolated populations and the challenge of multi variant diseases

As mentioned above, the Finnish population as a genetic isolate has been utilized in genetic studies for decades. The way Mendelian diseases are associated with a single gene has been an especially fruitful area in which to work in Finland as certain diseases are prevalent in the population, while the level of homogeneity has enabled effective detection of disease-causing genes (Chheda et al., 2017; Peltonen, 2000: 66; Zara, 2015).[32] However, with genome-wide association studies (GWAS) and those of complex, multi-variant diseases, working on homogenous populations is no longer unanimously considered efficient (Visscher et al., 2012: 8). For example, homogeneity may create long linkage disequilibriums, meaning that the area of genomic loci associated with a certain disease may easily become too wide, resulting in potentially inefficient research work (Thompson et al., 2010: 133): described as "finding a needle in a haystack" by an expert in an article

32 For the benefits of the homogeneous population isolate for linkage mapping, see, e.g., de la Chapelle (1993) and Hästbacka et al. (1992).

by Tarkkala and Tupasela (2018). Additionally, the sample sizes that population isolates and homogenous populations can offer are too small for many research settings. For these reasons, the usability of homogenous populations and population isolates has created concern (Ong, 2016: 39–41; Visscher et al., 2012: 8).

Perhaps the reason why talk of a genetically homogenous population did not come to the fore in interviews concerning the establishment of Finnish biobanks over the years, was that informants stressed the need for quantity, drawing attention to the developments in methods, technologies, and scientific needs as the drivers for biobanking (see also Lee, 2012: 167). A key goal for biobanks has been to provide both *quantity* and *quality* (Fieldnotes, 2017), which are considered prerequisites – conditions of possibility – for meaningful research results. In an interview this move towards the demand for quantity was described as follows:

> We started to wonder how we can grasp these more common diseases, like blood pressures and fats and such, Alzheimer and so on. And then it was purely mathematical to calculate that we need huge numbers of samples. We need these large collections because there won't be a single factor to explain these; they will be outcomes of multiple factors. (i34, 2013).

With this kind of goal in mind, the Finnish population, described as "equal to the population of south London" (i10, 2012) was considered by interviewees to be too small for any significant findings; therefore, international projects and collaboration are necessary for good research on both rare and common diseases (i10, 2012).

This is also one of the key factors in the FHRB, as hematological diseases are relatively rare. It was considered inefficient to collect samples for just a single study – and the national level might mean that still more samples are needed. A clinician (i31, 2013) suggested that that one probably has to combine Finnish samples with, for example, samples from other Nordic countries; merely collecting samples from Finland would take too long and be inefficient. "This", he added, "is the inevitable corollary of getting any results" (i31, 2013).

What is important in enabling research is the ability to circulate data and combine it with collaborators' data sets. As Finnish geneticist, Juha Kere, wrote in regard to establishing biobanks in 2007:

> As we have in Finland an excellent tradition of high quality clinical and epidemiological studies, the future looks bright for our researchers. However, the small size of the national population restricts in a natural way the amount of our data. This is why Finnish clinical researchers and epidemiologists should actively aim to lead and coordinate international collaborations. (Kere, 2007: 865)

This extract, like many of my interviews, indicates that there has not been a sole emphasis on genetically unique Finnish samples among biobank proponents (see also Sosiaali- ja terveysministeriö, 2007). From this view biobanks were initially, and still are, all about remaining relevant in the international field of biomedical research (see Tarkkala and Tupasela, 2018; Tarkkala et al., 2018).

There are also numerous international projects where the need for quantity is manifest. For example, the All of Us initiative in the USA aims to collect at least one million samples, and the stores of samples and data that arguably should be collected and brought together keep growing. Whole countries have already been framed as "cohorts" (Frank, 2000) and it has been envisioned that in 20 years there will be one billion sequenced genomes (Schatz, 2015). It was mentioned in interviews that ten or a hundred samples might previously have been regarded as enough to analyze candidate gene associations linked with hereditary diseases. Today, however, common variant associations require vast numbers of samples as the effect size will be significant only after perhaps 10,000 samples have been analyzed (i40, 2015). Often the call is for upwards of 100,000.

Kere (2007: 864) also suggests that scientific findings in complex disease research which are based on a single collection have been increasingly hard to publish; conclusions should be drawn from bigger, combined data sets, preferably from different countries. Similarly, Montoya (2011: 167-168) shows that the results of a diabetes study based on a Mexican population living in the US close to the border between USA and Mexico could not be published before replication in other populations. This results in "general" instead of population-specific findings. It also signals that the scientific publishing system sometimes works to hinder the publication of results that are meaningful only for very restricted populations,[33] or to underline the needs of specific groups whose health could be improved through socio-economical and socio-political decisions, for instance.

The question of benefiting all populations is also a concern in Finland (Kääriäinen et al., 2017), but efforts to demonstrate the potential that Finnish samples have for biomedicine through their particular genetic uniqueness remain ongoing. Scientists are still working to show the usefulness of the Finnish population for GWAS studies aiming to identify more complex, common variant diseases (Chheda et al., 2017; Kääriäinen et al., 2017; Lim et al., 2014). In these efforts, the isolated population, its genetic heritage, and the possible cues and shortcuts it may offer for scientific discoveries are stressed (see e.g., Kääriäinen et al., 2017; Palotie et al., 2013), especially the rare variants enriched in the population (see e.g. Flannick et al., 2014; Kallio et al., 2009; Lim et al., 2014; Wang et al., 2014). Even though there might not be enough research material in terms of number of samples, it is now being suggested that the Finnish population offers a fast and inexpensive route to verification, producing findings that should later be validated in a larger and more heterogeneous

33 This touches on the issue of potential false positives and negatives, which I do not discuss here in detail.

population (see also Tarkkala and Tupasela, 2018). When the goal is speed and efficiency, a special advantage of homogenous populations is that they are considered less "noisy", providing cleaner results (see, e.g., Shim et al., 2014: 590).

Thus, the Finnish population has been reinforced as especially valuable with a rhetoric of homogeneity that is a vital element in how it is branded, and the national population calibrated, to meet the needs of global biomedical R&D (Benjamin, 2009; Tupasela, 2016b; Tupasela and Tamminen, 2015). However, this simultaneously foregrounds certain types of research expected to be in the interest of the pharmaceutical industry: drug development based on enriched rare variants (Tarkkala and Tupasela, 2018).

Interestingly, however, the benefits of "homogeneity" are about to disappear, and now is the time to act. In a radio interview, Kimmo Pitkänen, director of a biobank, claimed that the ability to detect "small, genetic variations in the genome a lot more easily than in other populations in the world" is "one of the most important benefits in Finland that we still have" (Pekkinen, 2015). He then went on to say that utilizing this benefit swiftly is a priority, since there is a fear that other countries with larger investment capital will "outstrip our competitive edge", thus indicating that homogeneity is only a brand to utilize for the time being (see also Ministry of Social Affairs and Health, 2015). A discussion with another biobank expert revealed the concern that after, say, Britain and the US have potentially managed to collect their registers, data, and samples, "the money will go where the system works!" (Fieldnotes, 2015). Thus, the ability to utilize Finnish genomes in research is one that follows not only from the samples themselves.

The multiple and malleable: biobank populations

Despite my discussion so far, the populations stored in Finnish biobanks are not always seen as "Finnish" in the sense of genetic homogeneity. Quite the contrary. When I conducted interviews and talked with people about what makes biobank collections usable and valuable for biomedical research and development, my informants mainly mentioned data and the possibilities to combine and stratify the right kinds of populations for a given research setting (see also Shim et al., 2014: 581). The need is for very specific samples and data from those patients who can be assumed to share a disease-causing "mechanism" in which researchers are interested (i20, 2013). Reflecting this, when discussing what makes a Finnish biobank competitive in biobanking, one of my informants mentioned the capacity to stratify multiple populations, also stressing that it requires the existence of the right kind of data:

> For us it is, for example, the clinical data. … That we do not just give breast cancer samples but we can say that this patient was of this and that age, and she had a breast cancer that was R2 positive and estrogen receptor positive. In addition, she has been treated like this and the disease responded to this but not to that. That is the thing! There are breast cancer samples around the world, but that is not enough. Research

> questions are so specific these days. And we are probably the only ones who really can … stratify the right samples. (i31(2), 2015)

These different kinds of populations serving disease-specific research were not connected with population homogeneity in the interviews. In fact, it turned out that the production of stratified populations and cohorts is one of the roles of biobanks, since, due to the legislation, they have the right to re-contact donors, if donors have consented to it (see also Wyatt et al., 2019). This was described with the following example:

> If a mutation has been found, and we can see that our patient has it and is alive, and we have a sample that has been tested in a biobank … then the biobank has the right to re-contact this person and ask whether the person wants to participate in this clinical study. Then the person can say yes, no, or maybe, but it is of course not the biobank who conducts the clinical trials. (i35, 2013)

In other words, when the biobank can re-contact consenting patients who prove willing to participate in a clinical study, the next stage no longer involves the biobank but can be agreed directly between the patient and the clinical research organizations and pharmaceutical companies running the trials. Thus, the biobank might merely be the conduit to accessing the right kind of population, not the provider of the samples per se. A professor and the director of the Finnish Comprehensive Cancer Center wrote in 2017 that this right to re-contact is a crucial factor in making clinical studies more efficient, since seeking out, pooling, and stratifying the right patient populations can be done effectively through biobanks (Carpén and Helander, 2017: 594).

In this example, genetic uniqueness is not necessarily of importance at all; rather, it is the way data is handled and utilized that speeds up processes. Indeed, genetic uniqueness might even have to be contested, as emerged in a discussion with a biobanker, who said, "We have to say to our potential customers and collaborators that we are not that unique!" (Fieldnotes, 2015). The biobank expert in the previous example said that genetic uniqueness is not even true of their collection and that the rhetoric works against them. This is not only because the homogeneous population comes with a rough internal divide, but also because there is concern over whether results obtained from "unique" Finnish samples can be replicated: that is, whether such samples are usable. As Pálsson (2007: 55) writes, the problem with small populations is that "generalizations for other populations may not hold well, and, moreover, homogeneity may not allow for the genetic variety needed to research the genetics of a complex disease", a topic which has already been touched on in this chapter. Anu Jalanko, a key actor in the Finnish BBMRI and THL biobank, was interviewed on the radio in 2015. When the theme of genetic homogeneity was raised, she commented that until now the Finnish genetic heritage has not prevented collaborations; rather, Finnish researchers with their samples and data have "fit into" international, collaborative research projects (Mattila, 2015). In the same interview, she addressed the possible benefits of homogeneity, saying

that there is a belief that it could be utilized in today's biomedical research, even though "we do not have good examples yet" (Mattila, 2015). This interview excerpt suggests that the branding (Benjamin, 2009; Tupasela, 2016b) of the Finnish population as genetically unique because of its homogeneity, simultaneously forces biobank actors to modify the claim to show that actually the population is not so homogenous as to prevent meaningful research collaboration with international researchers and partners (Tarkkala and Tupasela, 2018): biobanks do not store just *one population*. In this sense, biobanks are in a situation where, on the one hand, they draw on the uniqueness of the local population – especially constructed in the studies on FDH – and, on the other, they simultaneously deconstruct the same uniqueness through the multiplicity and malleability of their populations (see also Tarkkala and Tupasela, 2018; Reardon 2017: 114 for a Scottish case).

What follows, in terms of population branding, is the more fluid rhetoric about being merely *relatively* homogenous, because too much homogeneity would possibly position Finns as outliers:

> Actually, we think that for marketing purposes you should not highlight that we are complete freaks. We should say that we have these certain strengths that make this and that possible, but it needs to be validated in some other population then as well. Because it turns a bit in the direction that if you find a marker in this odd population, then… who cares? Like big pharma, globally… But instead it is just the route to verification in a larger population. (i1(3), 2016)

The Genome Strategy (2015: 13) also refers to Finns as "relatively homogeneous", which is sometimes formulated by saying that the Finnish population is perhaps not too homogenous, but quite homogenous, or that Finns are *Europeans, but just a bit different* (Fieldnotes, 2018). In this, the role as Europeans is important in that it offers the promise of the possibility of further generalizations and similarity with larger populations. Similarly, Lakoff (2012) has discussed the significance of Argentinian DNA passing as "European", while Gibbon (2013) shows how "Brazilian cancer genetics research focused on European ancestry becomes something that reflects transnational research agendas and simultaneously confirms Brazilian mesticagem" (Gibbon 2013, 116). The latter concept refers to the way genetic ancestry in Brazil is crucially about race mixture, which, "strongly tied to national identity", is both contested and reinforced in Brazilian cancer genetics, as well as being presented as a special and unique resource for both national and international research (Gibbon, 2013: 109).

In Finland, collaborators with biobanks are often interested in using Finnish registers and clinical data and the possibility of combining the two;[34] that is, the samples are

34 Indeed, in 2004, in the text of biobank proponents, it was stated: "In addition to the health registries useful lifestyle- and life environment -data can be found of the numerous other registries; 17 national registrar sustain in Finland over 70 (!) official registers that biobanks can utilize. (Käpyaho et al. 2004, 7)"

not necessarily interesting for their research settings. Crucially, the different kinds of requirements for samples and biobank data mean in practice that "the population" of a biobank cannot be defined narrowly: it is not a single entity.

A population isolate as a competitive edge – reproducing the story of Iceland?

Appealing to the significance of a genetically homogenous population for research is old news. As I have shown in this chapter, it has been common in Finland for decades, for example in FDH research (see also Tupasela, 2016b), but it also reflects how biobank collections have been framed elsewhere as valuable for future medicine because of homogeneity and the availability of register and genealogical data, especially in Iceland (Fortun, 2008; Pálsson, 2007; Rose, 2003; Winickoff, 2006). In the late 1990s Iceland's unique population was foregrounded as an advantage in the early phase of the biobank plans and Iceland was portrayed as an "ideal context" (Pálsson, 2007: 55). Like today's Finland, Iceland was to benefit from its small, isolated population and its unique history, as well as from "the detailed genealogies available and accuracy and completeness of disease diagnoses" (Pálsson, 2007: 55). Both Finland and Iceland are thus illustrative of how biomedical collections come with links to social and institutional settings and histories (Busby and Martin, 2006).

Sitra, an independent but state-bound Finnish innovation fund that participated in the preparation of the Genome Strategy, has prepared a slideshow "Finland – your testbed for next generation research and medical innovation". The presentation, available on the Sitra homepage, consists of over 50 slides that can be utilized for the purposes of advertising Finland (Sitra, 2015). Key researchers and experts in the field often use them in their presentations to highlight the biomedical innovation potential of the country. I present three slides here that show the connections between the rhetoric of specific genetic heritage and features of Finnish society with which genetics travel. The first slide (Fig. 1) illustrates how the term "genetic isolate" is being used as a Finnish specialty in connection to genomic data and biobanks. In the lower part of the slide the link between specimen and digital data is stressed, and, with the sample number being potentially 6.8 million, this clearly works to advertise the usability of the old sample collections too, not just the prospective.

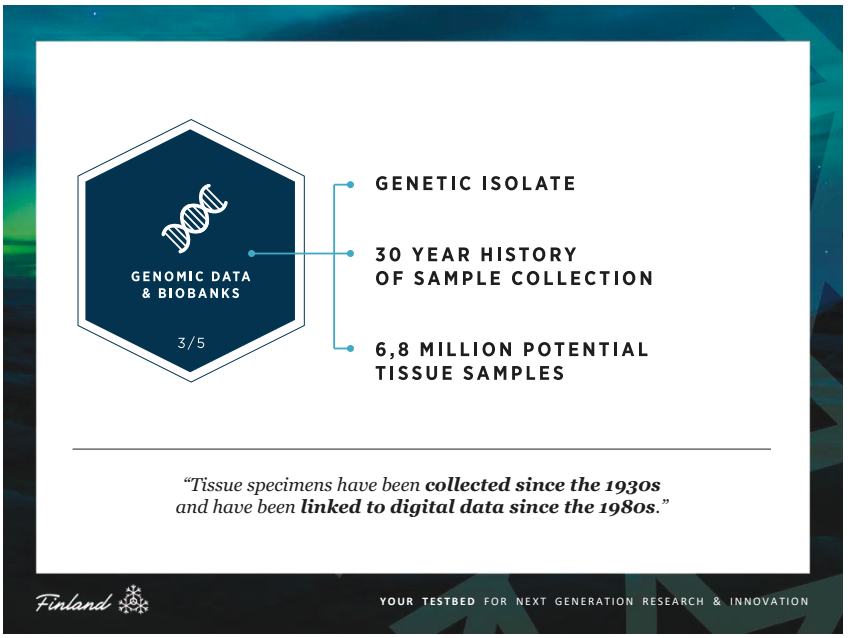

Figure 1: Slide from the slideshow, "Finland your testbed for next generation research & innovation", by Sitra.[35]

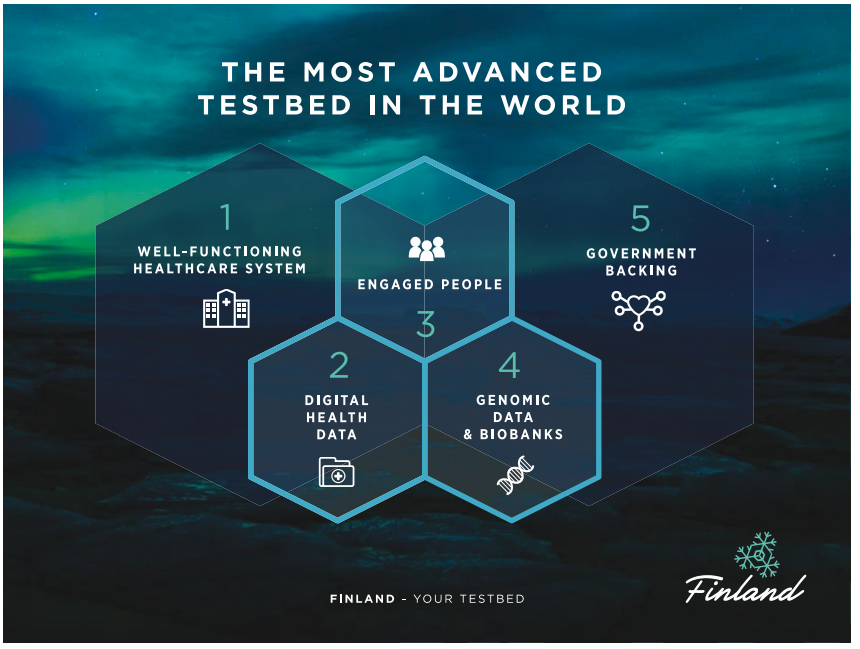

Figure 2: Slide from the slideshow "Finland your testbed for next generation research & innovation", by Sitra.

35 In 2018 this slideshow was updated and the current version shows even greater emphasis on the institutional environment than the version utilized for analysis in this study.

The second slide (Fig. 2) shows Finland as the only place in the world to provide precisely the kind of circumstances and environment biomedical R&D seeks: as "unique" (see also MSH 2015). The slide lists its genetically isolated population as one of the important features of the Finnish "test bed", but this is just one factor among others that include health data, data registers, and institutional environment and practices. This combination of societal factors such as registries and genetics can also be found in scientific articles on the usage of isolated populations in genomic studies in Finland and more broadly (see, e.g., Zeggini, 2014: 83). As with the Finnish population, the Icelandic population and Iceland as an environment have also been framed as a particularly suitable environment for biomedical research and development because of genealogical information available, its registers, the educated population, the public health care system, and genetic homogeneity (Fortun, 2008; Pálsson, 2007; Rose, 2003). Iceland's resources, such as the "Icelanders' DNA, genealogies, and the phenotypic data" were expected to "create a uniquely powerful tool for conducting genetic linkage studies as well as allelic association studies" (Winickoff, 2006: 85). Nonetheless, one biobank expert said in an interview that what distinguishes Finland from Iceland in the current situation is that the homogeneity in the former is connected to relatively big population (i1(3), 2016). He admits that Icelanders "might be more homogenous as a group", but instead of numbering only hundreds of thousands, Finns – "perhaps not as homogeneous but almost as homogenous" – can be counted in millions (i1(3), 2016).[36]

Figure 3: Slide from the slideshow "Finland your testbed for next generation research & innovation", by Sitra.

36 Nonetheless, Chinese genetic diversity, for example, has been said to offer "several Finlands and several Icelands" (*Nature*, 1998).

The third slide (Fig. 3) exemplifies how the whole Finnish environment is presented as "the most advanced testbed in the world" (Sitra, 2015). Here the coupling of genomic data and biobanks with Finnish society is explicit, without a link to genetic uniqueness. One can see that the government and its policy is presented alongside a "well-functioning" healthcare system. Obviously, here it is Finnish *society* being presented as an advantage. Similarly, Aarno Palotie (Fieldnotes, 2017) noted in his studia generalia lecture on "tricky Finnish genes", that it is not only the genes or health care data which make Finland competitive in biomedical R&D; rather, the "organized society", "developed regulation", and the efforts by policy makers to gain from health data are emphasized. A representative of pharma noted similarly that "we do have a lot better legislation than in other Nordic countries". Therefore, what differentiates Finland from its Nordic competitors is said to be the legislation: the regulatory environment (i41, 2015) that strives to be enabling.

Another thing to point out is that just as the samples, as pieces of tissue or drops of blood, are said to be nothing without the attached data of the donor (see Chapter 4), so too, in this respect, the Finnish population seems to be of value to research only together with its environment. The speed of delivery, as elsewhere, such as in Iceland, is essential (see Rose 2003). In Finnish branding the Finnish environment has been considered to have an advantage over the competitors due the health care data that are already in place (see, e.g., Ministry of Employment and the Economy, 2014: 15). One does not need to wait for disease outcomes. Thus, it is now or never: the "window of opportunity for exploiting Finland's strengths will be open for a few years at best" (Genome Strategy 2015: 3). What no one seems to mention in the slideshow, however, is the welfare state. It is the welfare state history that has created path dependencies that can be monetized in the present (Rose, 2003). Indeed, in regard to pharmacogenomics and its potential in Iceland, Hilary Rose (2003, 77) has written that there is a certain irony involved:

> [P]otentially immense innovation, actively pursued by global pharmaceutical companies and venture capital, requires as its precondition a universal health care system. Only the old welfare states have universal health care records. Not for the first time does the relationship between the organizational structures of health care provision and the development of genetics come into visibility and importance. For pharmacogenomics, only the old welfare states offer what they speak of in their depoliticized language as a "good population". (Rose, 2003: 77)

Welfare states have traditionally provided a universal health care system and therefore comprehensive registers and data. Not even the work on Finnish Disease Heritage, which led to the understanding of the genetic uniqueness of Finns, would have been possible without the "modernization project of Finland and the subsequent construction and implementation of the Finnish welfare state system during the 1960s and 1970s, which made it possible to study rare diseases to such an extent" (Tupasela, 2016a: 138). Currently, these welfare state structures continue to serve as sites for data and sample collecting and

are increasingly open to research and secondary uses;[37] along with this latter development, data collecting has even intensified (see also Hoeyer, 2016, for a Danish case). Indeed, the background of the welfare state and the way health services and registers have been organized institutionally play enabling roles in both developments (see also Oikkonen, 2018: 202).

Ultimately, based on my interviews and the other data collected, it seems that the most important aspect of "Finnishness" for its research potential is the already collected data.[38] The welfare states are known for having been eager to collect data and utilize it to improve population health and social welfare (see, e.g., Alastalo, 2009; Pálsson, 2007: 113), in the course of which they have generated vast registries and "big data" (Fieldnotes, 2016). So, it seems that societal characteristics are to be capitalized on just as they were in Iceland, where the highly educated and cooperative population treated in the public health care system of a welfare state was seen as a "good population" for biomedical R&D (Rose, 2003: 81), while the deCODE and Health Sector Database were framed as valuable and the whole of Icelandic society an exceptionally good place for research (Ong, 2016; Pálsson, 2007). Even the citizens are "engaged" people, trusting of research and medical professionals, and supportive of science, something especially evident among citizens of Nordic welfare states in European surveys (European Commission, 2009, 2010a, 2010b, 2014). Similarly, in a radio interview, a biobanker admitted that the population stored in their biobank and in Finland is "uniform", however in the end it all comes down to the fact that it is "possible to get samples at all", referring both to people's readiness to participate in the first place and to the fact that the samples and clinical data can be combined (Heikkinen, 2013) – once again underlining how samples can be used for biomedical research only together with the data (see Chapter 4).

The natural resource of a homogeneous population – society as unique

As discussed above, the genetic uniqueness of Finns that has been significant for the careers of many biomedical researchers seems to be simultaneously a story about Finland's socio-historical and institutional past. The rhetoric of genetic uniqueness is essentially linked to the whole society; there is a willing population, a legislative, enabling, and competitive environment, and a health care system that produces and collects data – thus, a favorable

37 On Finnish health data environment more widely, see, e.g., Lehto and Neittaanmäki (2017)

38 In the national electronic archive of patient records, on 31st December 2015, there were 301,198,512 files pertaining to 4,752,516 persons (Fieldnotes, 2016). In Finland, the national electronic archive of patient records (Kanta) has been operating since 2010, but patient records have been archived since the early 20th century and in electronic format for three decades (Tarkkala et al., 2018). Social science research showing how populations are attached to certain political and institutional structures to start with see Rose (2003), Hinterberger (2012a), and Kohli-Laven (2012).

institutional environment (see, e.g., Ministry of Social Affairs and Health, 2015; Tupasela et al., 2015b); so much so that the "'Finnish population' is a product of social, cultural, and political forces as much as of the actual genetic characteristics carried in the cells of Finnish citizens" (Oikkonen, 2018: 201–202). Indeed, in 1999, Finnish researchers wrote:

> The example of Finland shows how successful research of genetic diseases has been based on well-recorded population histories, the efforts of skillful clinicians and high quality health care. These advantages have produced reliable diagnoses and excellent population and health care registers, but even more importantly a high level of basic trust by the population of genetic research and consequent high participation rates in genetic studies. (Peltonen et al, 1999: 1920.)

As mentioned above, there is nothing new in collecting and utilizing data from populations with the goal of improving health; what is new is that these data depositories are increasingly open for innovation and R&D purposes, for example, through biobanks (Tarkkala et al., 2018). Therefore, I especially want to stress the links between health-care data related visions, people's bodies, and the institutional and social history of the country, since it is a combination of these elements that comprises the "Finnishness" that is believed to attract interest and offer research potential. Simultaneously, when "Finland" is advertised in this way, a specific population living in a particular society is reassembled and recombined, offering potential as "bits of information" (Ong 2016: 15) which are simultaneously biological and social. As Montoya has also pointed out, the "social, historical, political, and economic conditions that make populations intelligible are always already part and parcel of DNA research" (Montoya, 2011: 63) and a "necessary part of the exchangeability" of the samples of given populations (Montoya, 2011: 151). In 2004, proponents of biobanking underlined the priority of health data over homogeneity, writing:

> A lot more important [than homogeneity] for our national biobank initiative is the work on public health that has been carried out in Finland over the years. This has resulted in exact and trustworthy registers about the factors and incidents that have affected the health, lifestyle and living environment of each citizen. (Käpyaho et al., 2004: 7)

Another interesting perspective emerged in an interview with Leena Peltonen-Palotie in 2007, in which she highlights how there are many homogeneities at play and homogeneity is "not only restricted to our genes":

> For common public health problems, the comprehensive records that Finland has kept of its citizens are an advantage. The personal identity code that has been in use for decades, the public healthcare system, and various electronic records that can be made accessible to researchers provide valuable research infrastructure. And the homogeneity of Finns is not only restricted to genes, our lifestyles and diets are

> also relatively similar throughout the country. What's more, epidemiologists have gathered data related to them for decades. (Paavola, 2007)

This extract shows a curious mix of the social, societal, genetic, and biological at play, both in terms of bodies and data registries. The isolated population of Hutterites, for example, has also been seen to offer similar benefits due to the "communal" way of living, which "reduce[s] environmental and lifestyle heterogeneity" (Thompson et al., 2010: 137), further reflected in the samples. In the previous reasonings about what is unique in Finland as a research environment and what is unique in "Finnishness", biology and the social are mixed, and the institutional history of Finland seems to play a key role, which foregrounds certain Finnish bodies over the others even when most biobanks have been collecting samples in an apparently open way aimed at "capturing all comers".

This seems to suggest that socio-historical characteristics are inscribed in the samples. A nation that lives in a homogenous way and receives homogeneous treatments and diagnoses produces homogeneous data. That is, diagnoses and treatments have presumably been based on the same criteria, as all doctors have been educated in the same system, which is now to be seen in the unique characteristics of patient records and registers. In a similar vein, Tupasela (2016a) has described how collecting national epic poetry into the Kalevala ("national romanticism") culturally mobilized a national identity, creating an understanding of a homogenous cultural tradition of oral poetry, much like studies on FDH created an understanding of a common genetic origin ("genetic romanticism"). However, in the case I present here there is a certain romanticism concerning the lifestyle of the national population, and how this lifestyle penetrates the samples and data registers. As Winickoff has argued in relation to Iceland, the way deCODE successfully appropriated "cultural tropes and resources re-imagined Iceland, while simultaneously" it constructed "a future for it" (Winickoff, 2006: 89).

The following insight comes from a professor who answered a question concerning Genome Strategy's goal of attracting international collaboration at a public event:

> We have a lot that is unique, and we have our own special genetic heritage; we are our own isolate that is special and exceptional in terms of research. Our lifestyle is homogenous and our medicine is homogeneous compared to many other countries. We are sort of lab mice [some say, but the professor does not like this metaphor himself]; we have components that separate us in terms of habits, registers, and health care systems from others; it makes our nation unique. (Fieldnotes, 2016.)

Similarly, the director of the biobank of Eastern Finland, Arto Mannermaa, said in a radio interview in December 2017 that the population of Eastern Finland is not only unique genetically, but that their disease burden is higher in comparison to the general population and their diet is also one of a kind (Salmén, 2017).

The views discussed in this chapter make it clear that genetic uniqueness never stands alone. There are several characteristics that are mixtures of the social and biological, such as the digitalized disease outcomes based on laboratory results that allegedly exhibit similar diagnosis and treatment of patients, a belief in similar diets and lifestyles shared by the population and, obviously, the migratory history of (some parts of) the country. These are indeed to be seen in perceptions concerning biological samples and the laboratory results which are then written in digitalized format into the databases. Just as in "epigenetic mode", according to (Meloni, 2017: 401, emphasis original), history penetrates "the *content* of the sample", similarly, in the case of Finnish databases and population, it seems that the "lifestyle" of the population is now a crucial part of biobanks and the samples they store. Moreover this discussion is also about the close connection between biology and histories of human societies and local social policies (Haraway, 1997; Montoya, 2011; Subramaniam, 2014). Indeed, in Finland an imagined Finnish way of life in a certain institutional environment is now naturalized in the form of information in the samples and their attached data.

Conclusions

Biobank population(s) in Finland provide a condition of possibility for personalized medicine on two grounds: first, through the uniqueness utilized in the making of a competitive edge, and second, through the malleability that caters to multiple research settings and needs. In this chapter, I have paid attention to the ways unique population, genetic homogeneity, and Finnish social and institutional histories figure and are employed in how the population is made to matter for biomedical R&D. The social and institutional history of Finland, linked to the biomaterials through records and registers, is emphasized as significant when Finland is advertised, introducing a curious mixture of biology and institutional and societal elements to the rhetoric. This leads not only to efforts to capitalize on Finnish bodies and institutional practices, such as data collecting and register keeping, but to rhetoric wherein Finnish health data and therefore bodies as data sources are regarded as natural resources and a national treasure.

In Finland, two factors are highly relevant to biobank and genomic data: first, the conflicting needs both to establish homogeneity and to dilute and negotiate it; and, second, the stabilization of societal institutions and registers that takes place as a result of this movement. Crucially, genetic resources, such as those in biobanks, are about moving things into new assemblages, while concomitantly building the national economy's potential and also imagining a "nation". As Ong (2016: 13) reminds us, the Singaporean way of classifying populations for administrative purposes, based on a specific national, colonial history, is now part of what is made available for R&D as valuable data infrastructure.

Furthermore, a nation such as Finland that is imagined as having lived in the same way in the same place for generations, eating the same food and receiving the same kind of medical care, is framed as having lived in a controlled environment. This excludes, for

example, a large number of Finns whose backgrounds lie elsewhere. At the same time, there are voices saying that only Finns are interested in the things "meaningful for us Finns" (see also Jimenez-Sanchez, 2003: 295–296 for Mexican example). So, if we need the research that is based on the "Finnish population" to secure benefits for "the Finns" (Kääriäinen et al., 2017), we are left with the question of whom we are really talking about. To whom are these results potentially useful? Finns as they were imagined to be in the 1960s? People whose grandparents lived in a certain area? What is currently valuable and unique in Finnish samples also leads to ask whose samples are really wanted in the collections. Whose samples are valuable and why? Whose are not? Am I the wrong kind of donor in terms of the national economy and competitiveness, but possibly just the right person to be in a stratified population for a more specialized setting? This is something to ponder because, while the data, samples, lifestyles, and Finnish institutional environment are rhetorically and strategically packed together, at the same time it is a certain kind of Finnishness that is framed as valuable for biomedical research markets. Simultaneously this Finnishness promises the benefits of personalized medicine to Finns. Benjamin (2009: 350) points out that there might also be a difference "between what donors think their DNA represents and what their tissue is made to represent in the framework of national genomics". In Finland this might give rise to discussions of what identifications or differentiations are being consolidated and enhanced in the populations of genomics (Simpson, 2000: 5). The underlying ambiguity in the practices, enactments, technologies, and methodologies related to populations provide space for many different kinds of cultural and political alternatives based on populations (Oikkonen, 2018: 214).

Simultaneously, in biobanks, with their goals of personalized medicine and a healthier nation, different combinations of individuals and populations are potentially mixed and stratified in multiple ways. As there is a constant interplay of reference populations and individuals, biomedical projects cannot escape the interdependencies they create between people as biomedicine moves forward to produce knowledge that will eventually serve targeted communities, groups, and individuals (Nowotny and Testa, 2010: 35).

As with Singapore, the way biological and institutional features intermingle in how the Finnish environment is presented as unique for biomedical research can be understood through the lens of pluripotency (Ong 2016). This is a concept that grasps the contexts and ways populations are reassembled for science and innovation, and how this process becomes intermingled with politics, society, and culture, as well as how new alliances and assemblages are formed. Pluripotency is a property of the institutional milieu that is being created for biomedical R&D, not only a property of samples, cells, or DNA (Ong, 2016: 152). Crucially, Ong's (2016) conceptualization of pluripotency resembles Helén's (2016) redefinition of Adriana Petryna's (2009) concept of experimentality: things are being moved to new contexts and into new assemblages in the name of maintaining expectations, which is exactly what happens when nation states and national economies try to benefit from genomics (see also Tarkkala et al., 2018).

6. Biobanking, translational expectations and regulatory objectivity

> We were and still are tremendously enthusiastic since finally we can truly foster this – move this translational medicine forward. For that we need a biobank. (i31(1), 2013)

As the quote above shows, translational medicine is a word that has often been connected to biobanks in Finland as well as elsewhere (see, e.g., Gaisser et al., 2008). The concept was discussed at the events and public lectures I attended, and it has also appeared in medical literature on the topic (e.g., Altman, 2012; Bornstein and Licinio, 2011; Butler, 2008; Collins, 2011; Wehling, 2008; Woolf, 2008; Zerhouni, 2005a, 2005b). While in recent years it has been related to efforts to pursue personalized medicine, it is more descriptive of a way to work and organize activities carried out between private and public actors and institutions, and research and clinical care (e.g., Mittra, 2015; Mittra and Milne, 2013b), with an emphasis on fostering closer and faster translation of research results into clinical care and allowing clinical needs to drive research.

Promoting translational medicine numbered amongst the main goals of the first biobanks in Finland, whose operations were expected to encourage care and research to intertwine and overlap, with biobanks themselves being increasingly utilized in clinical care. Examples of this expected hybridity of clinical care and research, the translational medicine of biobanking, are visible in the empirical material I collected when biobanking was in its infancy. In this chapter, then, I discuss how everyday clinical care produces data that are expected to be usable for both clinical and research purposes (see also Hogle, 2016), while pointing out that a range of practices, for example in oncology, simply do not fit with the idea of a clear boundary between clinical care and research. Indeed, Keating and Cambrosio (2003: 323) have argued that, in biomedicine, innovations and routines are often intertwined and co-produced. Biobanks are founded in a world where numerous boundaries, such as those between "clinical and research laboratories" have in many places already "become porous" (Cambrosio et al. 2009: 515).

In this chapter, the focus lies particularly on the goal of translational medicine, as it was understood during the early years of Finnish biobanking. In what follows, I unpack the notion of translational medicine to cast light on the medical landscape in which biobanks participate and to which they contribute. However, the analysis is specifically concerned with my interest in how biomedical knowledge is produced and enacted in hybrid or potentially hybrid practices. I address how research and care are seen to figure together, overlap, and yet also remain separate in the biobanking context, examining this from four perspectives: first, the potential to develop individualized cancer treatments in the context of disease-specific cancer biobanks; second, the stratification and validation of populations in clinical biobanks; third, the issues related to the validity of potential secondary findings;

and fourth, the utilization of clinical data analytics. The disease-specific biobanks specifically addressed in this chapter are the Finnish Hematology Registry and Biobank (FHRB) and the Helsinki Urological Biobank (HUB), both of which were founded in close collaboration with clinicians who could thereby increasingly contribute to research, while addressing clinical needs. The fact that these biobanks were the first to operate had its effect in how translational cancer medicine gained a leading role as an example of what can be achieved with biobanks in terms of individualizing treatments.

I begin by briefly discussing the concept of translational medicine and translational research, although the analysis is more concerned with expectations about what the translational medicine of Finnish biobanks could possibly become. I then move on to describe the biomedical landscape – characterized by regulatory objectivity – in which biobanks operate and translational medicine is being developed. I then examine biobank potential for translational medicine based on interviews, fieldnotes, and publicly available materials such as newspaper articles; this is followed by the presentation of empirical examples. These examples illustrate that the needs of knowledge-building in biomedical research articulate the contingency of boundaries between care, research, laboratories, and clinics and the benefits of hybridity. I also use the empirical material to reflect on the regulatory environment with its implications for knowledge production. My main argument in this chapter is that the ways biobanks were expected to enhance clinical care indicate the perceived need for *hybridity in knowledge production* of contemporary biomedicine. There seems to be a need to "alter the boundaries between existing institutional arrangements" (Brown et al., 2006: 3), pointing to the constantly moving and co-produced scientific and regulatory contexts. That is, the expectations presented in this chapter tend to illustrate how biobanks have been seen as a possible solution to this kind of situation: enabling something that otherwise is not easy to accomplish in biomedical clinical practice.

Translational research and translational medicine

Biobank actors and proponents often showed audiences at their public lectures and presentations an image (see Fig. 4) of a deep chasm with a lab researcher on one side, a clinician on the other, and the skeleton of a patient on the valley floor (Fieldnotes, 2015). The picture is meant to illustrate of the need for translational medicine. It represents the current situation, the "valley of death" (see Butler, 2008), with biobanks providing conditions of possibility for bridging the gap between clinics and research so that patients will no longer drop into the valley to die (Burke et al., 2010: 790; Marko-Varga, 2013). Furthermore, the bridge from bench to bedside would not only be one-way; there would always be a loop from bench to bedside and back (see, e.g., van der Laan and Boenink, 2015: 32). According to Mittra and Milne, this "feedback loop"[39] back and forth between bench and bedside

39 Another element to be added to characteristics of present translational research is the growing importance of bioinformatics (Cambrosio et al., 2014; Douglas, 2014; Levin, 2014).

Figure 4: Valley of Death (Reprinted by permission from Springer Nature: Nature, Butler, copyright [2008]).

characterizes present efforts (Mittra and Milne, 2013a: 6), while the adverb "back" in "back from bedside to bench" rejects "the unidirectional model of translation" underlining that "both the clinic and the laboratory can be the starting points of a successful translation" (Cambrosio et al., 2014: 14–15). Indeed, in translational settings, the expectation is that clinicians and clinical needs could increasingly contribute to and guide research (see also Lander and Atkinson-Grosjean, 2011).

The concepts of translational research and translational medicine seem to escape precise definition and their meaning and coverage has shifted over time (see, e.g., Crabu, 2018; Keating and Cambrosio, 2012; Kraft, 2013; Martin et al., 2008; Vignola-Gagné and Biegelbauer, 2013). However, currently they are often used in the field of biomedicine to refer to activities aiming for new therapies and diagnostic tools by bringing academia, health care, and the pharmaceutical industry closer together (e.g., Bornstein and Licinio, 2011; Mittra and Milne, 2013b; van der Laan and Boenink, 2015; Vignola-Gagné and Biegelbauer, 2013). In this sense, translational goalsetting departs from a situation which is seen to consist of "many poorly integrated activities distributed throughout the academic, governmental and private sectors" (Blumberg et al., 2012: 38). The increased collaboration

between public and private institutions is expected to result in faster translation of research findings into patient care (Wainwright et al., 2013: 43). Furthermore, biobanks have been seen as playing a "central role in providing raw data that is used in fundamental and translational genomic research" (Gaisser et al., 2008: 94).

That being said, translational medicine is also a notion acknowledging that biomedicine has failed to fulfill its promises to date, but is about to do so under this label (see, e.g., Burke et al., 2010: 789; Butler, 2008; Lenfant, 2003; van der Laan and Boenink, 2015: 33, 41). Sunder Rajan and Leonelli, for instance, argue that the emergence of translational medicine indicates that "too much research in the life sciences has failed to advance human health, either because it is esoteric in nature or, more commonly, because institutional structures in which research is conducted do not facilitate its transformation into health outcomes" (Sunder Rajan and Leonelli, 2013: 463). Thus, actual improvements in patient care are now required. As I show, biobanks were presented as exemplifying this kind of paradigm shift in terms of close contact between research and patient care, especially during the first half of 2010s in Finland.

However, at the same time, it has been pointed out that scientific discoveries do not transform into clinical applications overnight, even under the label of translational research (Contopoulos-Ioannidis et al., 2008: 1299). The new technologies cannot provide outcomes as fast as desired because the prerequisites for the translations must be built first (Mills and Sykes, 2010). Yet Mills and Sykes write that there is an ethos of quick solutions and, furthermore, "there is impatience politically, scientifically, and socially to generate a sense of progress" in the "endeavor to translate genetic knowledge into disease mechanisms and treatments" (Mills and Sykes, 2010: 2). This tension between expectations and actual results was also reflected in my interviews, with many informants considering that the path from knowledge to its actual use in health care is too seldom found. Science policy, public research funding, and the need for scientists to contribute successfully to innovations – elements which relate to translational objectives more widely – were often stressed (e.g. Kohli-Laven et al., 2011; van der Laan and Boenink, 2015). The issue of scientific prestige has also been discussed in the literature as one of the problems with sustainably conducting translational research in the academy, which does not reward this way of working (e.g., Bornstein and Licinio, 2011; Butler, 2008; Mills and Sykes, 2010); therefore, research incentives also need to be envisaged and put in place.

Biobanks were established in a situation of increased pressure to produce utility, do it fast, and with scarce funding, as Finland was faced with a severe economic recession during the early 2010s. Consequently, translational medicine is also "shaped by science policy" that has as its goal "apply[ing] science for the benefit of the society" (Meslin et al., 2013), something already visible in the efforts to build biobanks in the first place and then pool sample collections into biobanks and biobank networks, especially during the past decade.

Translational research and medicine have both been addressed by STS scholars from different viewpoints (e.g., Aarden, 2016; Douglas, 2014; Friese, 2013; Keating et al., 2016; Lander and Atkinson-Grosjean, 2011; Levin, 2014; Martin et al., 2008; Mittra and Milne, 2013b; Nelson et al., 2013; van der Laan and Boenink, 2015; Vignola-Gagné and Biegelbauer, 2013; Wainwright et al., 2006, 2013). Many have critiqued the way innovations are expected to take place in translational medicine and research (e.g., Martin et al., 2008; van der Laan and Boenink, 2015). Previous work has shown that translationality in medicine is a challenging task, not a straightforward innovation pipeline from basic research (T1) to ever more practical solutions and all the way up to the level of population health applications (T4) (on the route from T1-T4 in translational medicine, see Khoury et al., 2007; for more hybrid understanding of translationality see Lander and Atkinson-Grosjean, 2011; Martin et al., 2008; Wainwright et al., 2013). Van der Laan and Boenink (2015: 46) have suggested that translational research can be seen as "a nexus (or web) of many translational moments", since it is not meaningful to label all the work and multiple efforts in many different places by many different actors with the single designation of "translational research"; Lewis et al. (2014: 397) have also underlined the multi-directionality and multi-modality of translations. This is not, however, the main focus of my analysis, which is, rather directed at what the expectations of translational biobanking – underlining the close contact of research, clinics, and public-private partnerships – reveal about knowledge production and its needs in highly regulated biomedical contexts.

Regulations as constitutive of knowledge production

Conceptually, my analysis is rooted in the understanding that biomedical practice is built on thoroughly regulated processes and practices in terms of knowledge production, its translation, and its application in the clinics (Cambrosio et al., 2006; Cambrosio et al., 2009; Cambrosio et al., 2017; Keating and Cambrosio, 2003). This applies, for example, to objects generated in the field of biomedicine, and also how they become linked to conventions and routines (see, e.g., Hogle, 2009). Bourret (2005) has demonstrated the constitutive role played in the work performed in cancer genetics by regulations, which are not only top-down restrictions, but act "as a condition of possibility for the definition and performance of the activities that [they] regulate" (Bourret, 2005: 43). The underlying assumption is that new knowledge needs "regulatory objectivity" to be applicable and valid, thus an absolute truth is not the key to making knowledge production work, but the compatibility of results from multiple sites (Cambrosio et al., 2006: 192). That is, regulatory objectivity connects a wide array of instruments, people, regulations, technologies, and so on into a "form of *institutional* action" in which shared conventions play a key role (Cambrosio et al., 2009: 655, emphasis original) . Cambrosio et al. have noted:

> The conventions produced by regulatory objectivity create the conditions for a clinical objectivity that relies on the existence of entities and protocols produced

> and maintained far outside the intimate encounter between the doctor and patient. (Cambrosio et al., 2006: 189)

Bourret (2005: 59) has further pointed out that in cancer genetics clinical decision-making is collective, and activities are not based only on the expertise of doctors or the generation of bio-clinical data; instead, "they signal an extension of a collective turn to medical judgment and medical decision-making" (Bourret, 2005: 59). That is, the "locus of expertise" nowadays lies in the collectives that are "collaborative clinical and research networks, groups devoted to the drafting of guidelines and recommendations, and clinical consortia consisting of variously specialized clinicians, biologists, epidemiologists, statisticians and biometricians" (Bourret, 2005: 62). In practice, biomedical kits and tests are used at the clinics for clinical decision-making, thus containing expertise in clinical settings (Bourret et al., 2011). Similarly, Turrini has pointed out that, in this kind of environment, which produces and applies knowledge, "the production, circulation, and interpretation" of any new biomedical entity "requires a multi-layered biomedical platform which involves intimate and dynamic connections between equipment, tools, concepts, medico-scientific guidelines, biotech companies, databases, health services, and so forth" (Turrini, 2014: 119). This also sums up the complexity of the anticipated translational biobanking and its dense entanglements with social and political environments. In this kind of landscape, then, biobanks are meant to play their part in the "collective production of evidence" (Cambrosio et al., 2006: 190), which is also deemed significant for the different layers of translational medicine: from bench to bedside and possibly back. Moreover, Keating and Cambrosio (2003: 332) argue that biomedical innovation is "as continuous as it is undirected and surprising", thereby indicating that mundane activities, discoveries, and innovations are in constitutive relationships with each other.

The multiplicity of coordinated conventions and regulatory layers contribute to, enable, and constrain knowledge production. The case I present for analysis here is rooted in this wider landscape where everything from reagents to legislation matter, although, the Finnish Biobank Act (2012, in force since September 2013) as regulation specifically serves as a reference in the analysis. The legislation was expected to come into force first, and only after that would biobanking activities in Finland start. It was anticipated that the Act would solve uncertainties and offer a clear regulatory landscape in which to operate, but ambiguity remains in terms of interpretation (see also Stephens et al., 2013), even when the law offers scope for action. Especially important in the legislation and its eventual interpretation are the following points: first, the objective of the act was "to support research that utilises human biological samples, to promote openness in the use of these samples and to secure the protection of privacy and self-determination when processing these samples" (Biobank Act, Section 1). Since there was no mention of patient care, this was later interpreted as preventing the use of biobanks in patient care – an interpretation that fixes the boundary between the two rather than acknowledging the ambiguity of the distinction in the first place (Cambrosio et al., 2018).

Secondly, in Section 39, the legislation allows individuals the right to access their own data. This includes the "right to receive, upon request, information concerning his or her health as determined based on a sample" and information on the significance of the findings (Biobank Act, Section 39). Moreover, a connection between biobank and patient could also be established through the use of samples for diagnostic purposes if necessary, since the legislation states in Section 13 that the transfer of samples to a biobank "must not jeopardise the provision and implementation of patient care", which was taken to indicate that the needs of diagnostics and clinical care come first.

Thirdly, in relation to stored samples and data, Section 3 of the Act states that "biobank research means research utilizing the samples contained in a biobank or information associated with them for the purposes of promoting health, understanding the mechanisms of disease or developing the products and treatment practices used in health care and medical care". This came to be regarded as a sample-centric definition of biobank research, and interpreted as preventing the utilization of the clinical data of participants who have already given their consent to participate, but who have not yet been sampled. As the sample is usually taken on the following visit of the consenting person to the clinical laboratory, there might be a long gap between when consent is registered and when the prospective sample is collected and stored (if older samples from the same person have not already been transferred to the biobank). Additionally, there are many visits to hospitals from patients whose care does not require sampling, and therefore there might not be a visit to a laboratory where sampling for the biobank takes place (Fieldnotes, 2015). Interestingly, this has prevented the utilization of the data of these participants, even when they contain information based on other samples taken – for diagnostic purposes, for example. In addition, over the years discussion of the utilization of biobanks in patient care has shifted increasingly to issues regarding secondary findings and individuals' receiving their data from biobanks. This is a significant shift, as it has displaced an earlier emphasis on how a clinician would use data in clinical care and in informing care (Fieldnotes, 2017). The Biobank Act and its different interpretations are at the heart of the regulatory environment[40] of Finnish biobanks, framing the relationships between research, industry, and clinics, and determining the operations of biobanks. This is so even though the Act is not always unanimously interpreted (see also Tupasela and Liede, 2016).

Biobanks and their potential for translations

During the first years of establishing biobanks (in the meaning of the Biobank Act) in Finland, the vision of fast translation to patient care was an explicit goal (see, e.g., Sosiaali- ja terveysministeriö, 2015: 36). It was claimed that research-based benefits would accrue more swiftly to the patients and new ways to use research results to inform care would become possible. In 2013, I interviewed a professor involved in biobanking initiatives

40 Other important laws for biobanks are the Personal Data Act, Medical Research Act, the Act on the Status and Rights of Patients, and Act of the Medical Use of Human Organs and Tissues.

who saw translational research in biobanking as offering more for patients than provided by their giving samples (i22, 2013). He added that during the time the Biobank Act was being prepared, the role of patients had changed. Initially, biobanks were meant to be for researchers, which raised "concern" as it seemed that patients should "consent voluntarily to something which does not bring anything back to them" (i22, 2013). During the years in which the legislation was being prepared, medicine progressed, with genome sequencing, for example, becoming available; this meant that the "benefits of biobanking could be returned" to clinical care (i22, 2013). He went on to say that, at the time of the interview (2013) when the legislation process was coming to an end, the draft of the Finnish Biobank Act had provision for the data to go back to the patient, which is a "premise for a functioning translational biobank" and the way to go (i22, 2013). He felt it was important that in Finnish biobanking a research-oriented path, where "nothing is returned to a patient", should be avoided (i22, 2013), once again referencing the loop back to bedside from the bench (Mittra and Milne, 2013a). Some informants stressed that university hospitals should allow for translational research since so much tax payers' money is used in them, while a clinician / researcher (i2(1), 2012) claimed it was the responsibility of clinicians to be involved in translational efforts; they have charge of clinical care and its further development, for which biobanks were a necessity. However, despite these expectations the Act was eventually interpreted so as not to allow biobanks to be utilized in patient care, a topic to which I return later in this chapter. Thus, this expectation was not fulfilled.

Another important area of biobanking in which the potential of translational medicine have been presented is cancer care and cancer research, which are often identified as the forefront of personalized medicine. This also relates to visions of a genomic era of medicine more widely. Among others, Guttmacher and Collins envisioned in 2005 that "it will become the standard of care to sequence cancer patients' tumors and use that information to refine prognosis and guide therapy" (Guttmacher and Collins, 2005: 1400). This notion was also reflected in the establishing of disease-specific cancer biobanks in Finland when biobanking officially started and the FHRB and the HUB began to operate.[41] At that time, the need to get new tools for patient care were stressed in both projects, and both biobanks had strong links to the clinics (Mirtti and Rannikko, 2012; Pitkänen and Porkka, 2012). For example, the hematological biobank, which was launched as a national effort to serve translational research and to contribute to improvements at the clinics (e.g., Fieldnotes,

41 In Finland the HUB and the FHRB were formed in 2011-2012 and were from the beginning built to meet the requirements of planned biobank legislation, simultaneously drawing attention to cancer. These two biobanks started first as independent research projects, but with the aim of turning later into biobanks in the meaning of the law. One later became the National Biobank for hematological diseases, according to the original plan. The other, the Helsinki Urological Biobank, merged in 2016 with the Helsinki Biobank, the clinical biobank of the Helsinki and Eksote hospital districts, which simultaneously meant that they needed to accept that their sample collection and storage could not continue as extensively as during the first years of the HUB as a project funded by TEKES – Finnish Funding Agency for Technology. Previously they were able to collect urea, tissue, and blood over the course of the treatment.

2013), was framed as part of the care of all hematological patients (Pitkänen and Porkka, 2012), implying that it was perceived to be at the interface between clinic and research. Indeed, in Finnish biobanking the personalized medicine approach to treat cancer and tailor treatments accordingly (e.g., i30, 2013) was among the identified translational possibilities. This also echoes translational medicine's role as one of the key framings of biomedical oncology since the 1990s (Keating and Cambrosio, 2012).

When the HUB and the FHRB started, and later with the Auria and the Helsinki Biobank, cases of individualized cancer treatments were often shown as concrete examples of what is both new and achievable with the help of biobanking (Fieldnotes, 2013, 2015, 2016). However, while it is anticipated that individualized care can be achieved with the help of biobanks (somewhere in the future, biobanks being one of the building blocks in this development), in practice biobanks neither organize nor provide individualized care. Yet, in the beginning of biobanking operations, one often got the impression that biobanks were supposed to be part of the way cancer treatments were being individualized (e.g., Lehtinen, 2013; Repo, 2011; Toivio, 2016; Vierula, 2011). For example, on November 11th, 2016 an article in the biggest Finnish newspaper, *Helsingin Sanomat*, stated:

> Individualized treatments are furthest along in hematological diseases. Blood samples from leukemia patients are collected to a biobank. If disease recurs a new blood sample is taken and compared to the first one. Then it will be seen if that precise form of the disease could be treated with one substance out of the selection of 500 medicines. By now 10 patients have been treated this way. Bono says this is the best treatment Finnish medicine can offer. (Repo, 2016)

Similarly, in 2016, a professor noted in a lecture that biobanks can be used "as a tool for translational research" (Fieldnotes 2016). He described how he had "utilized biobanking to understand ovarian cancer and to develop its treatment" and improve the life expectancy of the patients. Indeed, this "unofficial biobank study" from 2011 – when there were no biobanks in Finland in the meaning of the Biobank Act – was presented as illustration of "the future prospective biobank studies" (Fieldnotes, 2016). Thus, the actual link to biobanks was the potential demonstrated by the study, as no biobank was involved officially. In 2013, a hematologist showed in a presentation his own research as an example of how "a biobank can be utilized for targeted, individualized treatment of patients" (Fieldnotes, 2013). This makes it sound as if biobanks or biobank samples – of the FHRB, for example – were already being utilized and put into use at the clinics, even though in this case the individually tailored treatments and thus personalized medicine were being developed[42] in a separate drug screening research project, described in more in detail below. Thus, what was presented as biobanking or biobank-related was not biobanking as Finnish legislation defines it. That is, the drug screenings were shown in presentations about the topic and in

42 Whether it is even possible to consider research being "done" in a biobank instead of a biobank's "contributing", "supporting", or "participating" in research activities is another concern.

connection to biobanking because they reflect the "capacity of what can be achieved with a biobank" (i32(2), 2016). A similar goal to utilize individual drug screenings was also part of the HUB efforts (Mirtti and Rannikko, 2012: 2498), where special attention was paid to methodologies and technology development to enable this kind of translational medicine.

In the following four analytical sections, I address the possibilities and potential for translational medicine that biobanks were seen – and presented – as offering. These four sections highlight aspects related to individualized cancer treatments, stratification and validation, secondary findings, and data analytics.

Individualizing cancer treatment through a drug-screening project

Even though individualized treatments were often exhibited in the presentations of biobank proponents as examples of biobanking (or its potential for personalized medicine), in hematology an independent research project with its own samples was being developed. In this project, patients with Acute Myeloid Leukemia (AML), who were identified as "difficult cases" could participate in the development of personalized medicine through drug screening (i1(1)2012). This was described as experimental research and, according to a clinician and researcher, it should also be framed as such, "even though it is also part of patient care, because it guides the way we choose medicines we use" (i32(2), 2016). According to the clinician, it was considered "ethical" to do it this way:

> These projects for individualized treatments are very specific and if we aim to apply results to guiding clinical care then the patient is entitled to know specifically what is being done with her/his samples and what it will possibly mean in the future: that is, more specific information than the general biobank consent formula provides. (i32(2), 2016)

The drug screening project worked as follows. First, using samples from patients with a poor AML prognosis, the cancers were individually screened for sensitivity to different medical substances; then, based on this information, researchers try to come up with a more efficient treatment for the patient than they could otherwise offer. The aim is, and was, to find and test off-label uses for medicines and combinations of medicines already on the market (i10, 2012), something which has been identified as a "promising avenue" in the search for "multiple targets and multiple biochemical pathways implicated in any given cancer" (Keating and Cambrosio, 2012: 327). By October 2013, the hematologists had conducted this kind of testing on over 80 patients and, for over a third of them, an option to the standard treatment was found. However, only some of the patients had actually benefited from the change, because the human body and its metabolomics comprise a different environment to the research bench. Despite this, all the responses were informative, not only about the treatment but also about the disease itself.

In this kind of constellation, the drugs used ex-vivo can be seen as "informing materials" (Vignola-Gagné et al., 2017) in hybrid knowledge production. Vignola-Gagné et al. (2017: 2) argue that anti-cancer drugs, such as those utilized in the drug screening project, are in fact "instruments for exploring cancer pathways and mechanisms that lead to new biological, pathological, and therapeutic insights into the etiology and evolution of cancer". Indeed, in the drug screening efforts of the hematologists, the

> possibility to profile cellular responses to an extensive collection of anti-cancer compounds enables a systematic means to repurpose existing drugs to new indications, identify druggable vulnerabilities in various types of cancer cells and functionally investigate cellular pathways behind drug sensitivity or resistance. (Yadav et al., 2014: 1)

In other words, their efforts have not only developed a new way to choose the medicines used in patient care, but have also resulted in a growing knowledge of what leads to drug sensitivity and drug resistance, which might help to identify predictive biomarkers, a topic discussed later in this chapter. In addition, as already noted, new substances with potential for use in the treatment of the patients as well as a growing knowledge of the mutations behind leukemias are further favorable outcomes. A clinician / researcher describes the drug screenings as follows:

> We search for a response to medical substances experimentally, and we do not know what we are targeting, which might result in a situation where we have to take a look at the patient or his/her samples from another angle, to see whether there is some other target the medicine has an effect on even when the primary target is not discoverable. (i29, 2013)

The kind of twofold practice attached to "informing materials" illustrated by this case has led "to an increasing permeability of the boundary separating research from care" (Vignola-Gagné et al., 2017: 2). Not only are existing medical substances being repurposed to be utilized in the treatment of patients, but they are also being used as "informed materials" in research to gain knowledge of cancer, which also reflects how "no bright lines can be drawn between contemporary biomedical knowledge and the tools used to generate that knowledge" (Vignola-Gagné et al., 2017: 20). Vignola-Gagne et al. (2017, 20) go on to say:

> Drugs, in other words, and the companies producing them cannot be reduced to a mere epiphenomenon of contemporary biomedicine: they are an essential component of what and how we know. (Vignola-Gagné et al., 2017: 20)

The drug screenings are also part of the landscape of genomic medicine, where the goal is to change a molecular understanding of cancer into a clinically "actionable" one (Nelson et al., 2013). The sequencing results and their actionability "are centered on molecular hypotheses about drug action" and, therefore, actionability is not only about potential clinical actions,

but also about "a shift in the types of evidence on which clinicians can act" (Nelson et al., 2013: 425).

The traditional staging of tumors used in pathology is no longer considered sufficient; rather, tumors need to be staged on a molecular basis (i38, 2013). Cambrosio et al. (2017: 162) have also argued that "previously homogeneous categories, such as breast cancer, are replaced by a number of diseases whose specificity is based on their reaction to different therapies". This acknowledgment that all cancers are one of a kind is part of the translational landscape of more individualized treatments and the use of medical substances as informing materials (see, e.g., Keating and Cambrosio, 2012; Vignola-Gagné et al., 2017). The molecular way of approaching cancer acknowledges that "100 leukemias can be 100 different diseases" which will require "100 different treatments as well" (i11, 2012). This necessitates experimental research based on off-label uses of medicines or "drugs still under development", something seen to intensify connections between routine and experimental spaces (Nelson et al., 2013: 424). Moreover, once diseases are classified on a molecular basis, the "molecular information of the patient" based on patient's material samples, must be available (i22, 2012), as it is the only way to know "what the patient is" (i14(1), 2012). According to one professor (i22, 2012) whom I interviewed, this is what changes the character of medicine, diagnostics, therapies that are offered, and the way they are developed. In other words, as Kohli-Laven et al. have argued, it involves a "redefinition of biology, genomics, and medicine in relation to one another and to treatments and patients" (Kohli-Laven et al., 2011: 488).

Nowadays, cancer is understood as a genetic disease (i38, 2013), which you can study in order to make predictions based on the genome. "That is what makes cancer therapy a completely new therapy not comparable to other disease areas", said another professor (i38, 2013), highlighting the possibility of tailoring individualized treatments by combining different medical substances once the individual mutation has been identified. This is also why cancers have been identified as at the forefront of personalized medicine (see, e.g., Collins and Varmus, 2015; Varmus, 2006), which is probably why they are so often used to represent personalized medicine more widely, with biobanks among its conditions of possibility.

A prime example of moving the understanding of cancer through "genetic and biochemical mechanisms" (Varmus, 2006: 1162) into patient care is probably *imatinib* (Gleevec), a medicine used to treat patients with Chronic Myeloid Leukemia (CML). It is a protein tyrosine kinase inhibitor, which closes down the pathways of cancer, making CML for many a disease that requires life-long medication (Ely, 2009: 305; Varmus, 2006: 1162–1163). That being said, this kind of success is relatively rare. However, the case of *imatinib* demonstrates that the solution to treating malignancies such as cancer is "breaking into the malignant behavior of a malignant cell" (i11, 2012), also seen in the drug screenings. Moreover, as in knowledge production, there is a two-way street in the utilization of informing materials.

Cambrosio et al. (2017: 169) argue that therapies for BRCA2+ type breast cancer, based on the substance *trastuzumab*, that target "specific receptors on the surface of cancer cells" have also turned the receptor into a predictor "of response to a specific treatment" (Cambrosio et al., 2017: 169). Thus, the receptor is not only targeted with the substance, but also acts as a predictor of the treatment outcomes. The way drug screening and utilization of informing materials produces knowledge, on the one hand, and guides treatment decisions for patients with poor prognosis and no response to standard treatment on the other, illustrates how care and research are inseparable in the development of individualized cancer treatments. Thus, drug screening can be regarded as a way to work at the border of research and care (e.g., Majumder et al., 2017; Pemovska et al., 2013).

This work on the border was not always in sync with the expectations I encountered when conducting interviews about how biobanks actually could and would be utilized in patient care. For example, it was not completely clear for the clinicians in hematology, who were not researchers themselves, what kind of element in patient care the biobank was actually, rather than potentially, going to provide. This was also reflected in how other informants, not so closely connected to the disease-specific biobanks of FHRB or HUB, had understood their efforts and goals. For example, i6, an expert in biotechnology, and i16, a professor involved in another biobank project, said:

> Biobanks are the sort of things that were meant for research use, but like in the cases of leukemia, the data has been utilized in the care of individual patients. (i6, 2012)

> At least in the hematological biobank … I have understood that they can use the sample of a patient to inform the care of that patient, to make the treatment better, improve follow-up, and so on, and at the same time they gain knowledge to improve the care of similar future patients. (i16, 2013)

Similarly, a clinician who was involved in initiating biobank routines and practices in the hospital in which she worked, said that biobanks were warmly welcomed as part of the routine care of their patients. I asked her why biobanks were considered in connection with care and not research. She first admitted that when biobanking was regarded as part of care, it secured the continuity of biobank activities in terms of funding, since the hospital districts pay for care; secondly, she stressed the possibility they offered to help individual patients:

> If a disease does not respond to care as we had hoped, we can dig up the sample and do further research, which usually we would not be able to do. That is … the reason why they are [about patient care] … It is quite experimental or, let's say, it is experimental care … but in that situation we don't have other options anymore. (i13, 2012)

Indeed, there are now expectations of a patient sample, which is considered to increase treatment options for patients with poor prognoses. The focus in this kind of practice would be on "patients who require immediate medical attention" (Nelson et al., 2013: 411); it also demonstrates links with the molecular landscape of developing individualizing care and treatments (see also Beaudevin et al., forthcoming). In the past there were no samples available from the different stages of disease, something which is now an important part of the FHRB sample collection. For the clinicians, the possibility of storing samples from different timepoints of the disease, and being able to go back and gain information on the course of their patient's disease is crucial. It was said stated by a professor / clinician involved in biobanking that sample collecting "links to their everyday clinical needs" (i3, 2012); moreover, it was something they "should already have been doing for a long time" (i3, 2012).

However, one clinician (i13, 2012) also pointed out that clinical utility and research utility are two different things: that is, samples were expected to be more accessible in terms of care than in terms of research. Research was expected to require more thorough and more regulated evaluation and permission protocols: a research plan needs a permission and ethical evaluation before anything can be done.

> How easily can we get the samples to treat the individual patient? I do not think it will be a problem because it is [part of the] care of that patient. But for research you need the permits. (i13, 2012)

Interestingly, care and research figure as distinctive areas even when often in practice their difference is not clear cut (Boeckhout and Douglas, 2015; Cambrosio et al., 2018). Another clinician pointed out that there truly was a possibility to use hematological biobank samples for care because, according to the legislation, in Finland biobank samples cannot compromise diagnostics, so when it is considered necessary the samples stored can be used for diagnostic purposes (see Biobank Act, Section 13). For example, a clinician / researcher describes what happens when specialized analysis is needed which a clinical laboratory is not able to provide.

> We can go back to the sample and answer the clinical question of whether this is a myelodysplastic syndrome, a certain subtype of T-ALL, which requires a different kind of treatment. We have done only few of these. … These are the kind of questions that a clinical laboratory can't answer. In some ways it is research, but then again it is about this personalized medicine side of our practice. It is information we need in order to treat the patient. (i32(1), 2013)

The development of individualized care also invokes the stratified populations of biomedical research. Vignola-Gagné et al. (2017: 12) argue that in the world of "mechanism based" therapies, "statistical noise has been turned into a signal and a possible niche

market for otherwise failed drugs". They go on to describe the context of clinical trials where "the transformation of statistical outliers into valuable experimental research subjects is emblematic of the changes introduced by the combination of targeted agents and sequencing" (Vignola-Gagné et al., 2017: 12). This is also something to keep in mind in relation to the efforts of hematologists who are researching statistical outliers that do not respond to standard care, while simultaneously trying to offer better treatment to these patients. In this mode of developing individualized care, the patients who were treated were those with poor prognoses and for whom the standard care was insufficient. This also means that the cancer being treated was, in this phase of the disease, possibly more complex and mutated than it might have been in the beginning; with these late mutations only temporary responses to the screened medicines are possible. In the future, clinicians are expected to base their treatment decisions increasingly on molecular analyses of differences between an older and allegedly "healthy" sample, and a sample taken for the purposes of diagnostics (i22, 2013).

Biobanks for stratification and fast validation

There is also a second and overlapping method of potentially building knowledge in the hybrid setting of clinical care and research, in which the key is to stratify patient populations and search for a biomarker, complemented by an eventual fast validation with the help of biobank samples. In this second method, results from drug-screening or other kinds of research, not specifically cancer related projects, could be verified and validated efficiently using the bigger populations accessible through biobank collections. For this to be possible, the data generated in clinical practice as well as the data resulting from analyses done in research must allow for stratification. A clinician / researcher describes this as follows:

> In the world of acute leukemias, classically during recent years the whole genome of a patient has been sequenced, and when a certain mutation was found, we would know its predictive significance. Then we could take from maybe 1,000 patients a small amount of biobank sample, do targeted sequencing on each one, and see how many of these patients have the same mutation. In this way we could build the knowledge that, OK, this is the predictive significance of this mutation; then after that we could create a research setting in which we could study whether these patients would benefit from allogenic stem cell transfusion, for example. And then we would get that information and take that into consideration in the treatment of the future patients, and we could check for this mutation right at the beginning. … In the bigger picture this is what utilization of a biobank can be. (32(1), 2013)

Indeed, "the most important thing in a biobank", one biobank expert stated during a public presentation, is that "now that we have the biobank, we can search for similar patients and get the validation that what works for this one patient also works for others" (Fieldnotes, 2013). In a sense he too was describing the loop and circulation of data and research that the hematologists have in mind. A hypothesis from a more basic research setting could

be quickly and efficiently validated once there are enough samples and data in a biobank. Again, the sheer number of samples is one important factor in how translation from bench to bedside can take place. It is possible to test new things quickly when there is no need to spend time collecting samples (e.g., i23, 2013).

Eventually hematologists also started to conduct drug screenings on earlier mutations, but without using this accrued information to inform care, as it would have meant experimental care from the beginning (i32(2), 2016); information based on drug screening of earlier mutations in a specific research project was primarily collected to be utilized at a later point when there are "huge amounts of genome data, huge amounts of drug screening data" (i32(2), 2016). Then it becomes possible to search for meaningful connections, to see whether it could be better predicted which kind of treatment the patient's disease requires, what kind of outcomes could be expected, and which medical substances would be of use (i32(2), 2016).

> This connecting of drug screening with genome data is at its best a hypothesis generator. If we can use the tailored information for the benefit of individual patients, but on a larger scale, we could identify, for example, new indications for already existing drugs, biomarkers for certain medical substances, which factors predict response to the treatments in certain patients – and it is here that the platform will be at its best. (i32(2), 2016)

This kind of hypothesis generation was linked more widely with the goal of personalized treatments; when there are samples from the same patient at different time points and in different stages of disease, new possibilities open up. This kind of biobank collection can be utilized in the search for predictive biomarkers that change during the follow-up period, potentially allowing predictions concerning disease outcomes (i14(1), 2013). The samples from different time points will eventually provide the possibility to see "things in a new perspective", allowing the researcher to know the pathogenesis and perhaps even build targeted therapies (i25, 2013). These expectations were also raised in relation to other medical conditions besides cancer, even when cancer was used as an example.

The sensitivity of biomarkers is an advantage in clinical work and they are therefore sought after. As described by a clinician, the markers "see" better "than the microscope, whether the disease is going to relapse" (i23, 2013), which, if known while blood samples and bone marrow are still in good condition, makes it easier to treat even a relapsed cancer (leukemia) (i23, 2013). Another expectation was that biobanks can help in pharmacogenomics and stratifying patients to ensure that they are using the right medical substances. According to an expert working for pharmaceutical industry (i41, 2015):

> Even an expensive medication is cost effective, but this does require that the right patients are the ones using it as it should be used, and that those who will not benefit

> from it do not use it. And here biobank and biobank studies and results, and the diagnostics that are enriched because of biobanking… it all helps in finding the right patients… stratification, that is a big thing! (i41, 2015)

One often-used illustration of the benefits of stratifying was the case of a clinical trial that failed because only 2 of 100 participants benefited from the substance being tested. However, for these two, the outliers, it was the right medicine and it is important to know why. Thus, if these two shared some characteristic that meant that the medicine worked for them, it is possible that it could be highly successful, in the same way as *imatinib* in the treatment of CML has shown that even a highly selective drug – one that "targets smaller populations in which it can demonstrate superiority" (Keating and Cambrosio, 2012: 319) – can be a huge commercial success (see e.g. Keating and Cambrosio, 2012). It is reasoned that biobanks might offer speed and efficacy in terms of drug development, and benefit pharmaceutical companies because they could help in stratifying patients who might be expected to benefit from a new drug in the first place (i30, 2013). This links back to the discussion of hybrid forms of knowledge production, where "biomarkers are used to stratify patient populations for clinical trials", underlining that disease categories are changing and molecular medicine matters (Cambrosio et al., 2017: 179), as does the experimental clinical care patients might receive in these research settings.

Additionally, biobanks are more generally expected to deliver risk profiles and hypotheses. As already pointed out, biobanks are seen as hypothesis-generating machines (i30 and i31, 2013) because biobank data can reveal associations and relations to certain diseases more generally and then hypotheses could be made about why, for example, certain diagnoses seem to go together.

> Actually, you can test and create different hypotheses [with a biobank]. If you want to understand the disease of the patient and you believe in this molecular medicine, then the secrets of the disease can be revealed based on the samples, and that is why the samples are necessary. (i30, 2013)

One clinician / researcher (i25, 2013) stressed, however, that before you can have a rational effect on a disease you have to know how it arises and develops. He observed that there is still lot to be done and that the path to individualized treatments is still in its infancy.

> For example, the acute leukemias and how they arise: it is a big group of different diseases and almost every patient has most likely a disease of their own. For now, we are not so advanced diagnostically or in treatment that we could treat all patients individually; that possibly would be quite a nightmare if we tried to do that. That is still distant, but in hematological diseases, for example, it would be good if we found markers that correlate with treatment response … or with the prognosis, so that we could use something other than the standard treatment for those who have a poor

> prognosis. And then use the standard treatment for those with a better prognosis. (i25, 2013)

Yet another clinician pointed out that the potential role of biobanks in patient care is probably not direct, saying that, for many, they do not provide anything clinically significant; rather, biobanking is an aspect of the modern way of developing care in university hospitals (i29, 2013). This again brings us back to the ambiguities of biobanks' being a part of care and yet not being a part of care.

The challenge of secondary findings

The third way that a biobank could be meaningful to the clinics is connected with secondary findings, information that might accrue if a patient has agreed in the consent form that a biobank can contact him/her if something significant and actionable comes up. The possibility of returning results straight to patients from biobanks or based on biobank studies was, however, often questioned. Even though sequencing, for example, was said to be conducted in the same professional way in the research center and in the clinical laboratory (i22, 2013), and biobanks come with the promise to align research and care, many still considered it inappropriate that findings produced from biobank samples should inform clinical practice, at least without further validation. One professor stressed in an interview that the quality of data and analytics varies too much; some labs are "top-notch", but some are just "collaborators somewhere" (i16, 2013). The point is that "a slight mistake does not matter that much" in research, but to give that information to patients could possibly cause problems (i16, 2013). The credibility of different actors varies and what qualifies for use in the clinics and what is produced in clinical routines is presumed to differ from what is provided by research (see Crabu, 2016 on how a clinic adapts to the epistemological needs of research).

One clinician / researcher (i2(3), 2016) said that it is not the core idea of biobanks to use results to inform care in a routine manner, as one would "give blood or iron" to a person with low hemoglobin, largely because of the probably inconsistent quality of analysis performed in different labs. He felt that validation of findings so as to qualify them for clinical care was something to be left to the consideration of regulators (i2(3), 2016). The need to be careful when applying research results to the treatment of patients follows not only from issues related to sample quality and regulation, but also from the fact that biology is filled with complexity and its "truths" are far from absolute. As a clinician put it, medicine "is not physics" with "exact natural laws", and a single study is never enough to change treatment protocols (i35, 2013). Moreover, there are always subtleties involved in data quality, and often there is a need to connect with those who actually know the data and circumstances of their production (see, e.g., Aarden, 2017; Leonelli, 2016; Levin, 2014). This situation was reflected in the interviews, especially in relation to epidemiological cohorts and other older collections that have been moved to biobanks:

> If you lose control of who's doing something with your samples and data, it's inevitable – we have seen it so many times worldwide – that the level of analysis and information goes down, since they do not know the cohort, yet they are drawing conclusions from it. And since they don't have tacit knowledge about what they should *not* be doing, it is of course a bit dubious… As we know that in biology and medicine there are not many truths that could not be otherwise; if you just twitch them a bit you might end up having slightly silly results, which no one has published before. And this… this is not beneficial for anyone if you use data or samples in ways they were not meant to be used. (i24(1), 2013)

Another way that a biobank might return data to an individual is if the person uses the right to request his/her own data directly from the biobank. However, data are not just there, ready to be used; they require work and do not just flow from place to place (Leonelli, 2016): not from lab to lab, or from lab to clinic, or from biobank to participant. This is why concern with the quality of data kept coming up, and was also linked in interviews to the quality of original samples which might have been suboptimal, such as broken RNA with some intact molecules. A professor involved in the work of establishing biobank networks and data-sharing described it as problematic when this kind of sample-based information is turned into numerical, digitalized data.

> It does not say in the data that this RNA was a bit poor. The data get so easily disconnected from the sample history. Then you start to compare the data with 10,000 other data sets and how can you or anyone else say that a bit less attention should be paid to this one here? Should you just exclude it? And here you have the kind of mistake in the research process which researchers know very well, and this plays its part in [the considerations] that research results should not be utilized in patient care or move into patient files. (i34, 2013)

These are important questions for biobanks that aim to share not only samples, but also data produced in different research projects by different actors. Finnish biobanks specify data returns as a prerequisite for access and collaboration. In Chapter 4 this was referred as being part of how biobank samples "gain interest", yet sending information back to the biobank from research is not an easy task (Leonelli, 2016). Consequently, in terms of how the latter connects with care everything was rather vague, something further complicated by the fact that no sample transfers had yet taken place.

> At the moment we have still not resolved how data should actually return to the biobank. And then how much the information from the biobank actually moves into clinical use… we have not yet considered that very much. (i32(2), 2016)

Another important part of research culture, already discussed, is whether you trust the quality of others' work (see also Stephens et al., 2011). Both a professor and a director of a research institution (i38 and i39, 2013) highlighted that in the academy there is now

the need for clear "procedures, quality controls, validation standards, documentation standards" to be followed, "like [in] the pharmaceutical industry", without sloppiness (i38, 2013). That would be the missing piece in enabling the building of the "bridge to the other side" (i38, 2013): that is, translational medicine. For example, when it comes to drug discovery or establishing a new diagnostic tool, it could reach the bedside of the patient, but only if everything is "highly standardized, highly validated, highly reproducible" (i38, 2013). The discussion went on:

> i38: And it helps the pharmaceutical industry to gain confidence in what academic research is doing and enables them to incorporate elements such as devices, assays, and ideas much earlier in their portfolio. And that helps everybody to save time and money.
>
> i39: The typical way up until now is for the pharmaceutical company to license some research results from academic partners, and they do the same from the beginning. They repeat exactly the same experiments. Because…
>
> i38: They don't trust [academia]. (i38 and i39, 2013)

Indeed, the alignment of quality between clinic, research and pharma (see Chapter 4) is central for translationality to feed into clinical care (cf. Crabu, 2016). A clinician told me during one discussion that the belief that quality varies often comes up in seminars related to biobanking. However, she continued, the quality "might be the same if everything is done in the same way", but people have not generally "thought this through, they are still so enticed by research" (i35, 2013). At the same time, whether the quality of samples can ever truly be aligned between the variously regulated areas of research, patient care, and development, remains uncertain despite efforts made in this direction. Moreover, for secondary findings to be actionable clinically, it would require that clinics were ready to receive this kind of information, either through the patients themselves or the biobanks, and had practices and care pathways planned so that everyday clinic life could cope with it. A secondary finding becomes part of clinical care only after it is utilized and appropriated – a practice that is still in formation.

Everyday life of the clinics as knowledge production

> What do biobanks foster? They support translational medicine and clinical research, improve health care, samples, data and research foster the evaluation of the efficacy of treatments, identification of new drug targets, development of biomarkers and new ways of setting up clinical trials, their recruitment and the transition to personalized medicine. (Fieldnotes, 2016)

Biobanks came with expectations of cutting-edge individualized therapies, but alongside the capacity and potential they offer in the field of cancer care, other clinical improvements

were also anticipated, as the quote above from a presentation in a biobanking seminar demonstrates. Often it was argued that biobanks are crucial to understanding the processes and efficacy of publicly funded health care (i40, 2015). Utilizing this information was considered translational, too, the fourth aspect of translational medicine in this analysis, since the better utilization of clinical data turns the ongoing everyday life of the clinic into potential part of research (see also, Hogle, 2016). Van der Laan and Boenink (2015: 38) write that this kind of translational research could result in "new approaches or methods", "knowledge of the human body", "medical applications", "improvement of clinical practice", "benefit for the individual patient" and "improvement of public health". They point out that successful translation follows from multiple efforts in different fields, alongside re-shaping and changes in practices, habits, and responsibilities (van der Laan and Boenink, 2015: 38). Expectations about the possibilities resulting from using already collected data more efficiently to help patient care came up in the interviews several times. A clinician who had been active in the founding of biobanks said that translationality in biobanking not only involves the movement of findings "from bed to bench and from bench to bed", but also "using already existing data in a new and more efficient way for the benefit of patients" (i35, 2013). This was seen as a practice that is still in its early stages; nonetheless, biobanks were pictured as part of "research on the health care system and development" (i22, 2013).

Another dimension of biobanking that links to clinical and patient data is the way it allows for quality control and the provision of information about the efficacy of treatments and disease outcomes; obviously, it is important to eradicate treatments that do not produce the effects they are supposed to produce, whether in cancer or other diseases.

> As a byproduct of biobanks, we have now started to build better ways to utilize the whole patient record system in research, and once it is utilized in research, we can utilize it in the evaluation of our own operations. … Like, for example, knowing how new treatments and medicines have really affected disease outcomes will make easier to test new treatments in the future. (i30, 2013)

Moreover, it is hoped that biobanks will initiate cultural change at the clinics. Indeed, the clinician mentioned above (i35, 2013) said that biobanks, per se, already improve the quality of clinical diagnostics, because collecting data for the needs of analytics forces the clinics to improve their routines and practices in regard to patient records, which were currently "a bit in the direction" of sloppy (i35, 2013). Another informant, commenting on the usability of already existing patient clinical data, noted that some diagnoses are inherently messy since, for example, underdiagnosed diseases are often classified in patient records as more general diseases (i40, 2015). In a similar vein, the need to change the mindset behind clinic operations also came up in the interviews. Again, the quality of data, and how data and information could be appropriated to meet the needs of its different and changing contexts, was crucial; another recurring topic of complaint was the current state of IT systems. Often

hospital IT systems were considered incapable of collecting information systematically, as one informant observed (i22, 2013). Another concurred, saying:

> Our biggest problem is the state of our IT systems. These different systems do not discuss with each other, and the systems are filled with information which we cannot access as desired and in a simple manner, and we cannot connect it with other kinds of information. (i2(1), 2012)

What the data contain and their usability is yet another constantly raised issue. Whereas in the previous quote the biggest perceived problem was the state of IT systems, the same informant claimed about four years later that the "biggest challenge" was collecting clinical data and building the link between samples and clinical data. This was so because clinicians outside of clinical IT structures arguably collected data important for research, highlighting that clinicians have an understanding about the kind of data that is really needed to undertake meaningful research. This situation was seen to "create tensions over who can utilize that information" in the future, since, as implied at the beginning of this chapter, there are no incentives for those who have collected data based on their own expertise and activity to share their data with others through biobanks (i2(3), 2016). It was even queried whether a big clinical biobank could provide the required expertise to be able to discuss their samples and data with collaborators in detail, since the needs of research are expected to be highly specific. As a clinician / researcher explained:

> They [biobanks] do not have experts on different diseases. In that sense they cannot evaluate what would be the most profound clinical information related to a specific disease. That is where we clinicians in our specialized areas are the experts and we know that. We have research projects [in which] we have collected data for years. We have the knowledge … So, to foster these things, do we collaborate with other researchers or companies as we did earlier? Or do we donate for one reason or another our data to the biobank, which can then collaborate with [other researchers and companies] … And if we do this, what's the incentive for us? (i2(3), 2016)

Exemplifying this problem, a particular pharmaceutical company wanted to gain access to the HUB's data, but encountered difficulties with the existing data structure. The data on medicines used could not be provided from the hospital's IT system, while other data in which the pharmaceutical company were interested were deemed "impossible to pick from any register in a simple way" (i2(3), 2016). This also relates to the regulatory environment wherein biobanks operate. As already mentioned, one of the challenges for biobanks has been the fact that legislation has not allowed the use of donor data if there is no biological sample of the consenting donor stored in the bank.[43] This was identified as an obstacle

43 With the consent of the donor, the biobank can access his/her data, but the sample is taken the next time the patient would visit the laboratory anyway, so that sample donation does not cause any extra burden to the participant. This means that the chronology of prospective samples and consent differs from what legislation seem to expect (Fieldnotes, 2015).

for some collaborations soon after biobanking commenced, as many had no interest in the samples themselves, so there should have not been any need to wait for them to be taken. Diagnostic development can take place based merely on data that have already been collected that carry the stamp of previous samples taken from participants – highlighting again the thin line between samples and data (see Chapter 4). As a professor involved in biobanking observed:

> We can improve and develop our diagnostics; we have there [in the database] something like 30 million laboratory results from a two-year period, and if we get the lab results, let's say from the past 10 years, then we have 50 million lab results which we can connect with patient records in a way that was impossible before. (i30, 2013)

Disease-specific biobanks in an uncertain regulatory environment

The case of FHRB and its development into a national, registered biobank for hematological diseases is illustrative of the need for more hybrid clinical care and research. This is inherent in how translational medicine was expected to become reality with a potentially thin line between care and research. This would have opened up spaces for action that were needed, but not considered possible before. From its founding the FHRB has been about samples and data. The idea of biobanking was linked to the process of founding a register, since biobanking was considered a modern way to develop patient care. Initially, the effort to create a national register on hematological diseases followed from the poor usability of existing IT systems. Indeed, even before the idea of collecting samples emerged, hematologists had started to plan and prepare a national register in which to collect information on hematological diseases systematically – mostly with the aim of improving care, but research needs were also acknowledged (i3, 2012). The national register on hematological diseases was seen as a statistical instrument able to provide information about "the incidence of these diseases, the average age of the patients and the survival rate" (i11, 2012). In a sense the register started as an independent study whose goal was to improve care through better knowledge of treatments and responses (i32(1), 2013). It was expected to provide systematic information on regional differences in the incidence of disease, in responses to treatments, and thus "whether the patients are in an equal position in terms of the care they receive" (i11, 2012). A biobank, on the other hand, as a collection of biological samples linked to the national register, was seen as a contemporary way of bringing patient care, hematology, and research activities to the next level.

Thus, despite biobanks' being perceived as the "missing link" (i22, 2013) which would bring cancer care into the 21st century (Niederhuber, 2010), hematologists started by creating the structured data collection, since samples are not usable without attached data that carry information on disease outcomes, responses, and treatments (see Chapter 4). Once the register was in place, they added sample biobanking (i3, 2012). However, the register listed patients who had only consented to participate in the register, but not the biobank, since

the register was supposed to be comprehensive, but biobank sampling was only for new patients. This resulted in blurry boundaries between the register and the biobank, although one clinician (i13, 2012) stressed that she specifically welcomes the register into their routines since now she can follow the treatments and disease outcomes of her own patients:

> I am interested in the register data of my own patients. So that I know how we have done and how we will do, what kind of treatments we have, and then compare that to others as well, how they are doing. (i13, 2012)

Yet, since the legislation is taken to forbid the use of research results for care, it eventually became a problem that the FHRB had a register that included patients who were not all biobank participants, but which had the aim to inform care decisions. Hence, the FHRB needed to reorganize their activities. They had to compile another register, since the original contained participants from whom samples had not been collected. Moreover, as already discussed, legislation was interpreted as not allowing the utilization of biobank data and results in patient care, contrary to earlier expectations and interpretations. What followed is that hematologists now have a hematological register of all the patients who have given their consent to be part of it, and a separate biobank register of the patients who have consented to biobank sampling. A clinician / researcher describes this maneuver as follows:

> Now that we have this hematological register which is linked with the biobank, we have to keep it separate. And then we have this Finnish hematological register, which operates similarly as the FHRB register has operated, in that all doctors and nurses are eligible to examine the information stored there – of course only that of the patients in their own hospital districts – and also feed information into the register. Now we have to sort of build a parallel FHRB register on the side. (i32(2), 2016)

This structure of having a separate register partially enables the translational work that was envisaged as taking place through biobanks, because the register can be used to inform patient care and support decisions. Moreover, often the data fed into the register are the same data which are being fed into the separate biobank register, including many laboratory results taken as part of clinical care. Data based on separate research projects conducted outside biobanks, such as drug screening, are also accessible through the register:

> In the setting of a research project we sequence all acute leukemias at the clinic; we perform exome sequencing, drug screening… And that information returns to the hematological register and the clinicians can utilize it from there. (i32(2), 2016)

Thus, research and care meet in hematological clinics through the register, not the biobank. Indeed, as Kohli-Laven et al. (2011: 488) have argued, "new technologies" in biomedicine emerge "through the artful management of regulatory norms and organizational partnerships" (Kohli-Laven et al., 2011: 488). Nelson et al., (2013: 419) also note, in relation

to making cancers actionable, that sequencing in these kinds of settings often creates regulatory unclarity, since the aim is "to produce information that will change clinical decision-making", while the results come from a "space of uncertainty at the interface between research and routine". Consequently, "regulat[ing] clinical actions based on these results" can be an issue (Nelson et al., 2013: 419).

To merge or not to merge? Implications for knowledge production

After the biobank legislation came into force in 2013, a big clinical biobank was founded in Helsinki. However, instead of merging with it, hematologists wanted to retain their own national biobank for a number of reasons: firstly, they considered that because it had the status of a joint, national project owned by the national association of hematologists, it would possibly create bad blood between different clinics if they suddenly became part of Helsinki Biobank; secondly, since their biobank financing was built into municipal invoicing, the funding situation allowed them to remain separate; thirdly, joining a bigger, more general clinical biobank would have compromised their highly specialized sample collecting and sample processing. Thus, it was important to stay independent:

> With that we guarantee that we truly are national, but in addition we can now collect… Our sample collecting differs completely and radically from all the other biobanks; not that there is a contradiction, but other biobanks concentrate on collecting large volumes of samples from large populations. We concentrate in something completely different. We collect such high-quality samples, and no other biobank is planning at the moment anything like collecting bone marrow and so on so that we can use defrosted living cells in research... (i32(2), 2016)

Indeed, the FHRB would have not been able to continue their extensive sampling as part of the Helsinki Biobank. As early as October 2013 a hematologist said in a presentation that "we need focused, disease-specific biobanks", underlining that "population biobanks may not be useful for more detailed research settings" (Fieldnotes, 2013). Even though, as mentioned in Chapter 4, biobanks store "high quality samples" usable in as many settings as possible, they cannot meet the requirements of all. In Finnish clinical collections, the new, high-volume, prospective samples of large populations are mainly blood samples. I asked one informant, a cancer clinician / researcher, what those blood samples would mean for research, and he answered that, without a link to old, pathology cancer collections, they have very limited use (i32(2), 2016). Luckily for researchers, these older collections are now in the biobanks. Still, the general blood samples[44] in clinical biobanks are not adequate for use in the specialized settings in which hematologists are interested.

44 It is expected, though, that the samples will eventually qualify as "liquid biopsies", showing again how expectations adjust and adapt to new situations. Eventually, just a blood sample might be enough.

> To study cancer, you must have primary sample of the cancer tissue. … But the answer to why we have not merged with anything is that we have the feeling that our scheme, our system, which we have built, is excellent for hematological malignancies and a one-size-fits-all approach does not function for us. And that is what the big biobanks are at the moment. (32(2), 2016)

Consequently, as already noted, biobanks are not always needed for translational medicine even though they are often presented as a prerequisite. For example, drug screening requires such high quality samples that it is not meaningful to use just any samples. A clinician considered that drug screening also requires flexibility and speed as one has to be able to perform the screening when the patient needs it. This has been something to actualize swiftly in independent research projects (i29, 2013).

Unlike the FHRB, the other disease-specific biobank, HUB, did eventually merge with the Helsinki Biobank. This was of necessity, since they started as a project with funding for three years and eventually the project came to an end. Bornstein and Licino (2011: 1567) have argued that there are "strict separations of revenue streams for hospitals on the one hand and for research resources that fund biomedical science on the other" and that this "fundamental split between research and daily clinical practice clearly reduces the efficiency of the translational initiatives that many nations seek to launch" (Bornstein and Licinio, 2011: 1567). A biobank expert / clinician told me that the number of samples that the HUB managed to collect during its three years of independent operation, was "usable but not enough" (i2(3), 2016).[45] What they had to compromise when joining the bigger biobank was their specialized and extensive mode of collecting samples from all different time points (with diagnosis, remission, relapse, care, medications, etc. inscribed in the samples themselves).

> In the HUB we tried to collect samples extensively from a smaller patient population, so that we could monitor the development of disease and see how treatment affects it. In these big collections maintained by universities or university hospitals we don't have such a possibility; instead there is a goal of collecting one or two samples per patient so that one gets at least the basic information. (i2(3), 2016)

45 The homepage of the Helsinki Biobank writes about this collection that, "During the years 2012-2015, 1976 urological patients were recruited to donate their blood, urine and tissue samples into the HUB Biobank. Most of the samples have been collected from prostate cancer patients but other urological cancers are also represented. There are 27 628 single samples that have been collected at the time of diagnosis and on follow-up visits. Number of prostate cancer patients with blood and urine sample taken before and after surgery as well as tissue sample collected in the surgery: 390." (http://www.hus.fi/en/about-hus/helsinkibiobank/Sample_Collections/Pages/default.aspx)

After the merge, urologists came up with an idea that sounds familiar. Since they were "surprised when we realized that the Biobank Act forbids the use of results based on biobank samples directly in patient care" (i2(3), 2016), a research proposal in which the aim was to collect samples prospectively from the patients was prepared. As described by a clinician / researcher:

> On Monday we left a study for ethical evaluation, in which we seek permission to utilize analyses done with these new methods, such as sequencing and these individualized drug screenings, so that the treating doctor could, if needed, use this information in the treatment of the patient, if the doctor considers it reasonable and possible. (i2(3), 2016)

Thus, in a sense, it sounded to my ears as if they were trying to establish the kind of translational instrument they had tried to build few years earlier with the biobank (see, e.g., Mirtti and Rannikko, 2012). This time it was a research project, but one that could be utilized at the clinic, if necessary, for individualizing care. However, this way of working in which clinical practices become increasingly experimental is not easy to regulate. In terms of developing individualized care, regulations could quite concretely be the condition of possibility preventing, constraining, or enabling new knowledge. However, when the new knowledge is built in these emerging flexible settings where patients' diseases are being treated at the clinic, are providing information about the disease, and also generating data for further studies, the complexity is significant (see e.g., Kerr et al., 2019; Nelson et al., 2014).

Conclusions

> The main aim of the HUB is to maximize the value of its biospecimens and data by facilitating the translation of basic research innovations into clinical care and thus improve outcome of patients with urological disorders. (https://www.fimm.fi/en/)

> Biobanks are one tool with which this translationality can be built. It starts from the fact that it is challenging to do translations without human samples. And that is what biobanks offer, sample of human origin. (i40, 2015)

In the early interviews with people connected with the two cancer biobanks, the topics of individualized care and the utilization of individual patient data in clinics were often raised. Analysis on the whole data set from a wider perspective identified four recurring themes in my informants' approaches to translational medicine, each illustrating clinical needs that a biobank would come to fulfil, each also negotiating the relationships between care and research in their own ways: individualizing treatments, stratifying populations for fast validation, secondary findings, and data analytics. However, as the cases of the FHRB and the HUB demonstrate, these ideas have required reorganization. Biobanks have had to adapt to the legislative and institutional settings in which they operate, which has had an

effect on what can be done in terms of research and care, and how the hybridity of these practices is addressed. Indeed, "regulatory activities do not simply act on pre-existing practices or entities, but contribute to creating the objects they regulate" (Cambrosio et al., 2017: 178) – and this takes place on many levels of regulations and conventions.

Consequently, as time has passed, biobanks have generally been perceived as less a part of the landscape of "from bench to bedside" than of "from bedside to bench"; in other words as research biobanks rather than as offering translational potential as clinical biobanks. One clinician involved in founding a biobank and pursuing individualized cancer treatments had come to see biobanking in a more research-oriented way in recent years, although he admitted that only few years earlier he "most likely" had the "opinion of utilizing biobank research results in patient care" (i2(3), 2016).

> With biobanking we can nowadays produce biological findings that explain things, and basic rationales, but we cannot take that into the treatment of individual patients. We can use those findings to find mechanisms that explain some diseases in a bigger patient population, or why not in a specific population, but we cannot use that information in the treatment of that individual patient. Period. It seems to be like this. (i2(3), 2016)

In October 2016 it was stated in a HUS (hospital district of Helsinki and Uusimaa) press release that "Biobank activities are guided by law and the samples will be used for research only" (HUS, 2016), meaning that biobanks were being promoted as a research biobanks. Indeed, to a large extent, they have come to be generally understood as a "resource for human samples" (i40, 2015). Of course, the rearrangements and changes in the biobank context were not the first that actors had to come to terms with. For instance, a prospective collection had already been a clinical need before biobanks were developed, and one clinician (i2(1), 2012) had tried to establish this kind of instrument in 2000-2001 after receiving permission to collect samples from patients with urological cancers for prospective use. However, the cancer surgeries were then moved to another hospital where they did not have functioning sampling processes and facilities (i2(1), 2012).

Kohli-Laven et al. (2011) argue that different legislation at the European level creates a fluid situation, "leaving researchers no choice but to pursue ad hoc arrangements and other forms of tinkering that, on the one hand, create multiple obstacles to the development of bio-clinical projects but, on the other hand, provide a degree of flexibility and open-endedness" (Kohli-Laven et al., 2011: 505). In a similar way, researchers in Finland have sought, and continue to seek, ways in which they can continue their research. Today, the legislation is still under development and new personalized medicine initiatives have started with the goal of finding ways to bring benefits to the patients. Even biobank proponents have again started to argue that biobanks are not "only for research" (Laitinen et al., 2018). However, given the hybridity involved in settings where new knowledge is currently being produced,

or where it could be produced, the role of clinical samples and data, for example, in knowledge production remains an interesting issue. It seems to require further sociological attention to the regulations and practices in this field, while understanding research and care as ambiguous practices – as objects of study – rather than as strictly separated fixed entities (see Boeckhout and Douglas, 2015; Bourret, 2005; Brown et al., 2006; Cambrosio et al., 2018).

7. Conclusions: on the biobank samples and data in promissory biomedical knowledge production

Research interest has driven this study of the early years of Finnish biobanks towards promissory biomedicine and its prerequisites: that is, the making and molding of "the limits of what is considered as possible" (Jacob, 1982: 9). In it, I have addressed efforts to reorganize the collecting, processing, storage, and dissemination of biological samples and data for research and development purposes. The establishment of biobanks has had the dual goals of making the same research materials available for public and private actors and of offering the perceived requirements for science to proceed and medicine to develop. The case presented opens an empirically rich view onto biomedical research and its possibilities and prerequisites, conditions, and constraints. I have been interested in expectations, future-making, and imaginaries on the one hand, knowledge production and its requirements, on the other, and the entanglements between these two dimensions.

During the first half of the 2010s, the vision of how biobanks would pave way to personalized medicine was discussed in terms of three constituent elements: first, the understanding of high quality samples as a fundamental starting point for valid, reproducible research; second, the populations biobanks provide and stratify to meet the expected needs of biomedical R&D (in quest of both health and wealth); and third, their potential to enable work in hybrid settings where care and research overlap, the goal of translational medicine. Whether these aims and directions truly represent a revolution in biomedical science, and whether biobanks meet these expectations, remains to be seen; it is not self-evident that the transformation that is imagined and promoted in the practices of today will eventually be realized.[46] As Borup et al. (2006: 290) observe, an inevitable side effect of such expectations is often disappointment, "accompanied by serious costs in terms of reputations, misallocated resources and investments".

Personalized medicine is a key imaginary of biobanks (Tarkkala et al., 2018): a sociotechnical imaginary, according to Jasanoff and Kim (2015), who address how science and technology are likely to play central roles in our understandings of what should be achieved in our societies and by what means. The sociotechnical imaginary of personalized medicine is a vision in which individuals are treated, rather than averages, with greater accuracy, utilizing genomic data alongside phenotype data, and with an emphasis on prevention. Regulations and policy geared towards personalized medicine are being developed in interested countries, on the expectation that economic wealth will follow alongside of health benefits.

46 The biobank collections have already been put in use, and many biobanks list the research projects that utilize their biobank samples on their internet homepages (see, e.g., the homepage of Auria biobank). Furthermore, based on the biobank collections there are already promising results, for example in the field of pharmacogenomics, and new projects are being developed (such as the P6-project) with an idea to return data to the participants (Fieldnotes, 2018). Still, it remains to be seen which promises to the patients will materialize.

The concept of sociotechnical imaginaries grasps the relationship between expectations, science, and technology and their embeddedness in society. Personalized medicine as a sociotechnical imaginary, then, is collective, both locally and internationally, shaping both national and multi-national policies and scientific endeavors. In Finland this imaginary is put into action and fused in practice through biobanks (Tarkkala et al., 2018).

This study has investigated the ways in which biobanks are conditions of possibility for personalized medicine. Situated in a landscape of shared conventions and practical and regulatory arrangements, biobanks are crucial constituents of what can be understood as solid biomedical research, knowledge, and clinical practice. As Keating and Cambrosio (2003: 332) argue, regulation is the "condition for the production, circulation, and interchangeability of novel entities and practices". It is not top-down ordering, but "grounded in the procedures of internal quality control and, especially, external quality assessment" (Keating and Cambrosio, 2003: 332). The concept of regulatory objectivity underlines the collective production of evidence of which biobanks could be part by organizing and providing standardized samples and attached data. Moreover, regulatory objectivity highlights the connections between clinics and "other socio technical domains" (Cambrosio et al., 2006: 196–197). In this study, understanding biobanks as a condition of possibility for personalized medicine links imaginaries with concrete biobanking initiatives that operate in a field characterized by shared conventions and regulatory objectivity. This allows us to see that biobanking is constrained and conditioned by various layers of activities, practices, policies, regulations, and stakeholders, which all have implications for the kind of knowledge production and implementation that is possible in the first place.

In what follows, I briefly review the main themes examined. I then discuss the most recent developments in Finland, which have emerged as part of the landscape of personalized medicine and have thus become linked to the same imaginary, shaping it and the role of biobanks in the process (see also Tarkkala et al., 2018). I also review the main argument in this dissertation, with theoretical reflections on the developments presented in analysis and conclusions.

A review of the main themes

Analytically, this study of biobanking was organized around three key notions, the first being the high quality of the samples biobanks claim they now store. Professionalization of sample processing and storage, as well as standardized operating procedures meeting the quality of clinical laboratories, were portrayed as key characteristics of these biobank samples in comparison to the past, when samples were collected according to each researcher's own preferences. To qualify as befitting the different research needs, samples need to have a recorded history and come with the data of the donor. It was assumed that, with this known history and the samples' appropriate use, increased reproducibility and a faster translation of findings to clinical care than under earlier "messy" sampling methods would follow.

The latter were seen as characteristic of academics, who were perceived as uninterested in preanalytical procedures – something that for pharmaceutical companies and clinics is not an option. Ideally, biobank samples align clinics, the industry, and academics to work on the same materials that could qualify for the use of all. Sometimes, however, old samples from earlier collections are also regarded as of high quality, possibly because of their greater bodies of attached data on disease outcomes and so on. Furthermore, developments in methods and technologies are perceived as partially overcoming challenges related to the quality of older samples. Indeed, quality-assessed old material can sometimes be considered better than new, prospective samples.

The notion of high quality samples relates to the requirements and contemporary re-organization of biomedical research, and future-oriented, promissory medical science more widely. It is a notion that encompasses numerous paired elements: particularity and universality, the national and international, old and new, same and different, amateur and professional, prospective and past, concrete and potential. Biobank samples are indeed very different from "everyday notions of material things" as Knorr Cetina (2001: 193) has pointed out about epistemic objects. Reasoning concerned with high quality samples has crucially been about the samples' being both flexible and standardized. In this sense, the samples have been framed as qualifying for scientific knowledge production, because "standardized flexibility" along with a solid foundation in previous work comprise the basic dynamics of scientific knowledge production in orchestrated settings: while something new might emerge, it is always based on a high degree of the previously known (Rheinberger, 1997). Samples must be stable on the one hand – that is, standardized, documented, and known – while allowing for multiple uses and the production of new knowledge on the other. Eventually, of course, the latter might become part of the previously known and, in its turn, elementary for future novelties (Rheinberger, 1997). There are no intrinsic components or fixed identities in high quality samples (e.g., Knorr Cetina, 2001); rather, quality as a distinguishing feature of biobanks is a crucial characteristic of the reorganization of biomedical research and its attendant promises. It also connects to the reasons why biobanks are presented as necessary for the development of personalized medicine, and eventually, to how flexible the biobank and its operations and stored materials need to be in order to stay relevant in the developing and forward-looking field of biomedicine.

The second theme concentrated on the dual explanations of why the populations of Finnish biobanks could be of interest for the international biomedical R&D enterprise. I specifically address the malleability of research populations in the face of the multiplicity of expectations related to personalized medicine: not only those concerned with health, but also with innovation policy and competitiveness, in that Finnish biobank samples are "branded" as especially valuable in the search for foreign investment. In order to create a competitive edge in biomedical R&D, the population stored in Finnish biobanks is framed as distinctive due to its uniqueness as a "genetically homogeneous population". According to Tupasela (2016b), this kind of branding makes value claims by highlighting the heritage,

identity, and authenticity of a certain population in a given geographical area, utilizing scientific work on genetics in order to do so.

On the one hand, it is imagined that international investors and collaborators are interested in utilizing the genetically homogeneous background of Finns, a product of Finnish biomedical research that has developed a specific understanding of wider population history alongside medical knowledge. Foregrounding homogeneity has promoted certain types of research, specifically in the field of drug development and the identification of drug targets, but has also raised questions concerning the validity of the claim. Further, if the claim is valid, does the claimed uniqueness constitute a population with Finnish ancestry as outliers who do not offer generalizable and reproducible results? Does it prevent participation in international collaboration? On the other hand, therefore, informants also highlighted the potentially multiple populations of Finnish biobanks that can be stratified and pooled to offer highly targeted research settings.

Imaginaries of what is valued and sought after in research populations by biomedical researchers, as well as the interplay between national and international interests, are reflected in ideas about the kind of populations Finnish biobanks could and should offer to the field. The claims made about stored populations can be seen both as a way to create a competitive edge for the national innovation environment, and reflecting the requirements scientific practice is expected to have of the populations it uses. This explains one tendency to underline the societal rather than the genetic features when framing the samples as unique, which suggests that, in fact, the valued homogeneity lies in the huge amounts of data that have been collected during the history of the welfare state: data that present "unique Finnishness" as residing in the long-term homogeneous lifestyle and homogeneous medical practice of the country. The kind of "Finnishness" that is rendered visible is co-configured alongside reasoning about the usability of the samples wherein data play a crucial role, and relations between tissues, bodies, data, and institutional environment are at stake. Some scholars have suggested that biobanking and medical databases reproduce imaginaries concerning nations, and builds and reinforces imagined communities (Busby and Martin, 2006). In the Finnish case the innovation rhetoric concerning the population stored in registers and biobanks is not primarily framed as potentially multiplicitous, and the question of who belongs to the population of biobanks in Finland has not been publicly debated (cf. Tsai, 2010). Wade, too, reminds us of the social significance of the populations studied in genetics when stating that "they are connected to complex networks of people and practices" (Wade, 2017: 43) that extend beyond the laboratories. Just as the Finnish Disease Heritage was accompanied by an understanding of Finland's population history – traces of which can now be seen in the political framing of genomics – the way genomics ties and connects different elements together is, and continues to be, a task for STS scholars (see Wade 2017: 51). One obvious question following from the Finnish example is whether the presentation of Finnish samples as especially valuable for biomedical R&D naturalizes

social policy and institutional history in some way. And what kind of relations between the social and the biological are promoted in ideas about populations?

The third analytical chapter and lens through which this study has approached biobanks is the translational medicine that biobanks were expected to facilitate: from bench to bedside and back, according to the slogan. As I noted, the Biobank Act was initially seen to enable the participation of biobanks in the care of patients, with the specific case of cancer treatments and diagnostics serving as an example of the potential offered by biobanks. Eventually, however, the Act was interpreted as preventing biobanks from informing and taking part in clinical care, since this was not mentioned as a legislative purpose (Fieldnotes, 2017). Moreover, the discussion was increasingly framed as an issue of secondary findings, which understands "care" and "research" as fundamentally distinct areas.

It had also been hoped that biobanks would facilitate translation through health and clinical data analytics. Clinicians, for example, expected to be able to follow the disease outcomes of their own patients better, while it was anticipated that clinics and hospitals would eradicate inefficient treatments with the now available data. However, this was also something that the legislation was interpreted to prevent, since it was written in a sample-centric manner that prevented data being used unless it was attached to a sample – and certainly not for clinical purposes. Ultimately, biobanks do not participate in translational medicine as a straightforward result of hybrid knowledge production, but, rather, via a more traditional and much longer path from research to clinics. This is perhaps not a surprise given the high degree of regulation of medical research and clinical practice. Therefore, what a biobank is and what it does differs from early ideas implying and suggesting they would promote greater hybrid practice between clinical care and biomedical research and development. However, the regulation of such a development would be a major challenge.

The impetus to overcome boundaries between public and private, care and research is still alive, but currently more often outside of biobanks and directed towards other projects and initiatives. Nonetheless, biobanks are trying to re-establish the idea of merging research and care to secure the continuance of their practices and to develop operations further. Whereas in 2016 it was stated in a press release by the hospital district of Helsinki and Uusimaa (HUS) that "the samples will not be used for any other purposes than research" (HUS, 2016), in June 2018 a group of biobank professors wrote a joint letter to the *Helsingin Sanomat* stating that "it is a great misunderstanding that biobanks have been established 'only' for research. Clinical biobanks in particular are being integrated into patient care" (Laitinen et al., 2018).

Imaginaries, regulatory objectivity, and biobanks

My choice to describe biobanks as conditions of possibility is not only based on how the notion empirically fits with the language that surrounded me while doing this study.

It is also based on the literature that emphasizes shared conventions and practical and regulatory arrangements as crucial constituents of solid biomedical research, knowledge, and clinical practice. Indeed, perceiving biomedical practices as characterized by regulatory objectivity highlights the degree to which biomedical results, methods, and technologies are conditioned and collectively achieved. From my point of view, labeling biobanks as conditions of possibility links practices with imaginaries such as the sociotechnical imaginary of personalized medicine.

New technologies and innovations are always produced in relation to the expectations that boost them. The cases of the two disease-specific cancer biobanks, and the founding of Finnish biobanks more broadly, demonstrate the hybrid knowledge-building that contemporary biomedical research is said to require, and also that the pursuit and achievement of personalized medicine through biobanks is flexible. Biobanks as prerequisites for personalized medicine are malleable according to different interpretations: firstly, of what makes the samples in biobanks valuable and usable; secondly, of what Finnish biobanks provide to global biomedical R&D in terms of populations; and, thirdly, of the links to clinics with which biobanks are endowed.

Consequently, the search for new possibilities in medicine, and how a biobank might meet the requirements of these possibilities, is an experimental field. Helén's (2016) redefinition (originally Petryna, 2009a, 2009b) of the concept of experimentality attends to the maintenance of expectations and the opening of new prospects (see also Ong, 2016). By claiming to meet the various needs of biomedical knowledge production, biobanks participate crucially in the *maintenance of expectations and sociotechnical imaginaries*. Imaginaries, as Jasanoff argues, "build on the world as it is, but they also project futures as they ought to be … [moreover] imaginaries get built into the hard edifices of matter and praxis" (Jasanoff, 2015b: 323; see also Borup et al., 2006: 285-286 for a similar discussion within the sociology of expectations). This study – and the expectations which it addresses – focuses on rearrangements and re-purposings connected with expectations and imaginaries in particular settings such as biobanks (see also Tarkkala et al., 2018).

Of course, it is to be expected that not everything connected with biobanks could be planned in advance. Adjustment, iteration, and development are always part of initiating new practices and actions, and numerous institutions from hospitals to policy and research institutes, as well as methods and technologies, need to be coordinated in order to achieve sufficient mutual understanding for biobank operations to run smoothly. As has been argued, the components of biomedicine, enacted in complex settings "ranging from basic biological research to clinical treatment", need to be constantly re-aligned (Kohli-Laven et al., 2011: 508): that is, the functioning of this field requires constant attention (see also Stephens et al., 2013).

My argument regarding the interplay between biobanks and personalized medicine as a sociotechnical imaginary claims that *biobanks and what they are continually change as new elements, actors, regulations, and developments are linked to the endeavor to realize the imaginary of personalized medicine* (see also Tarkkala et al., 2018). In short, a biobank, both as an idea and in terms of operations, needs to be flexible and ready to transform in accordance with what is regarded as a valuable population and what is seen as the potential of its collection, whether the latter is based on old or new samples, or how the samples can be utilized in care. In other words, "biobanking" *is shaped in the interplay of making and maintaining expectations*, many of which are related to often uncertain efforts to align different fields and human and non-human actors to produce a smoothly co-operating and compatible environment (see also Hedgecoe and Martin, 2003: 330). In this project, other interest groups, such as policymakers, participate with biobanks in defining their role and position in the quest for personalized medicine.

Iteration, rearrangements, and management of the future in Finland

In Finland during the 2010s, expectations that had initially pertained to biobanks were increasingly being discussed under the broader rubric of personalized medicine (Tarkkala et al., 2018). That is, new initiatives, new actors, and new policies were considered necessary to future medicine, and biobanks became merely a part of this landscape. In practice this can be seen in the strong political push to establish the Genome Centre in Finland which, in the Genome Strategy (2015), was identified along with biobanks as a central tool for bringing individualized treatments and the utilization of genomic data and genomic knowledge to the clinics (Ministry of Social Affairs and Health, 2015). While the slogan, "every patient is a research patient", used to imply biobanking (Fieldnotes, 2015), by 2017 this kind of reasoning reflected a wider context of personalized medicine initiatives in the country, such as the Comprehensive Cancer Center FICAN (Carpén and Helander, 2017). Indeed, the Comprehensive Cancer Center and Neurocenter are to be founded, with the government backing these efforts as part of what is called their initiative for personalized medicine (see http://stm.fi/yksilollistetty-laaketiede).

It is unclear what these new openings in terms of institutions and regulations mean for biobank operations. When the work to set up the Genome Centre commenced no one seemed to know exactly what the Centre would be (Fieldnotes, 2016), although the project was pursued by a team of experts under a mandate from the Ministry of Social Affairs and Health. Another interesting point is that initially it was unclear what the Genome Centre could do in terms of research and care that biobanks would not have been able to do with some legislative adjustments regarding the use of data in clinical care. One source of ambiguity between the role of the Genome Centre and that of biobanks was that until now the biobanks have stored the genome data derived from the samples in their collections, which have comprised an essential part of the "sample as data". However, if the Genome Centre were to store the genome data, practical matters of access and ownership had to

be solved. Indeed, while I was wondering what, exactly, the Genome Centre would be, one expert sniffed, "We already have a genome center! We have the biobanks! But these politicians do not understand this" (Fieldnotes, 2017).

This changing and developing regulatory and institutional environment leaves space for uncertainties about the role of biobanks. Indeed, with the establishment of the Genome Centre, which will provide genome data for health care, and legislation allowing for secondary use of health data, it seems that all that is left of the various expectations of biobanks is that they will provide the human samples to be used in research that can be built on public-private partnerships. It is not clear however, whether the potential link to potential patient care that is now increasingly based on the Genome Center will actually speed up the process of utilizing genomic data in health care settings. It has been suggested that these new openings and the changes in institutions and regulations related to them might actually slow down developments. In the field of stem cell science, for example, a "policy landscape" with a vast number of "recommendations, regulations, guidelines, and legislation" has resulted in unclarity, ambiguousness, and contradictions instead of "clear path for translational medicine" (Meslin et al., 2013: 4). Given the high stakes of offering good quality care for patients, however, slowing down rushed clinical applications is, of course, not only a bad thing.

Simultaneously, the many different layers of regulation, starting from the reagents and technological devices used, all the way to care protocols and further, are also crucial constituents of knowledge production in biomedicine (e.g., Keating and Cambrosio, 2003). To regulate biobanking and biomedicine in a relevant manner, especially when the different layers of regulation feed crucially into the kinds of knowledge that can be achieved, is a challenging task. The changes which the idea and imaginary of biobanks underwent during the time of their establishment in Finland, make it clear that science policy and regulation are also vital matters of scientific knowledge. For example, the way drug screening in individualized cancer treatments produces knowledge in a hybrid setting challenges legislation that presupposes clear boundaries between care and research, as well as samples and data.

Given that the field of biotechnologies is, as Brown (2003:4) describes, "synonymous with the language and imagery of futuristic breakthroughs" that are "spilling over with heated aspirations, promises, expectations, hopes, desires and imaginings" (Brown, 2003: 4), it is perhaps understandable that expectations and future-making were what caught my attention during the early years of Finnish biobanking. In biobanking what is being done, and what can be done, are not in sync with early promises and perceived potential (see also Brown and Webster, 2004: 182). This is hardly a surprise; people do not generally expect revolutionary results to happen overnight. Nonetheless, what is said – expectations – generates interest and leads to new openings and initiatives that mold, shape, reformulate, and restrict the outcomes of previous future-makings, even in the counterproductive

ways exemplified by biobanks' being reduced to the role of offering samples and access to populations.

Additionally, regulatory processes that have an effect on biobanks include the aforementioned genome legislation that goes hand in hand with the Genome Centre, the amendment of the biobank legislation, and legislation for the secondary uses of social and health care data, to name a few. One area which is especially difficult to regulate (apparent in the proposal for the new biobank law in spring 2018) is the distinction between samples and data. Since the goal of making data available for secondary uses is being strongly promoted by the government, the use of health care data that is also based on samples retrieved in different ways through research or care is still being reconfigured. The plan is that there will be a new, national, and centralized unit to process and combine data, including health care data, for secondary uses, despite the fact that it was precisely this that was considered one of the key tasks of biobanks: to connect data from different sources and make it available for research and development purposes. The new law concerning secondary uses might leave biobanks, by definition, as merely providers of human samples. Yet the new projects, initiatives, and processes being instituted in this field lead one to ask whether they are the most efficient and meaningful way of attaining the set goals, or whether they result in inefficiency, making difficulties for the development of personalized medicine and biobanks in the long term.

Ultimately, despite the developments that seem to suggest that biobanks are mere repositories for the samples, in practice it seems as if data will be the main product of biobanks. This was acknowledged during the process to amend biobank legislation which started, interestingly, immediately after the legislation was put in place (the idea being that it is better to have poor legislation than no legislation, since the process bringing the law into force took so long that the legislation was in many ways outdated by the time it became law). In many ways, the focal point of personalized medicine-related initiatives is currently data, as sample-based data connects with the donors' other data, whether health or register-related. Furthermore, this package of data carries previous research results to new contexts; therefore, biobank participation (or possibly non-consent) is crucially a matter of data handling, an appreciation of data security, the privacy of participants, and the economy related to data circulation (see also Reardon, 2017).

Indeed, I witnessed the growing role of data myself. Suddenly it was not enough simply to amend biobank legislation. Instead, there were several processes, both legal and institutional, to allow for the increasing use of the data collected by the welfare state in the course of decades. The enthusiasm for big health data and the possibilities of data-driven medicine have shifted the political emphasis on innovation from biological tissue samples to health-related data in the years since the biobanks commenced practical operations (Tarkkala et al., 2018). Even the webpage of BBMRI demonstrates the change. In 2015 on BBRMI.FI it was stated that their "[a]im is to establish samples of human origin as the

foundation of research and development practices" (www.bbmri.fi); by early 2016 the formulation had changed: "The major goal of BBRMI is to develop a research infrastructure that will facilitate high quality research use of comprehensive collections of biological samples and associated data" (www.bbmri.fi).

Since 2015, the Upgraded Life Festival, an event for start-ups in health technology, has been hosted at the Biomedicum[47] on the campus of the University of Helsinki, where the Institute of Molecular Medicine can be found right next to the Meilahti Hospital Area and Helsinki Biobank. During the four years from 2015-2018 the festival has offered a prime example of the small shifts in the landscape of health tech and related expectations. During the first years the scale of companies and start-ups that were present went from chaga mushroom products and health apps all the way to biobanks and genomic medicine. However, by 2018 the shift of focus was clearly away from health apps to providing services, data management, analytics, and more, while the fair presenters were people representing innovation environments and ecosystems. Whereas individual biobanks might have had their own stands in previous years, this time regional innovation environments were presented: not only countries such as Great-Britain and the Netherlands, but also Finnish cities, hospital districts, and their initiatives such as Kuopio Health, The Health Capital Helsinki, and the Life Science Accelerator concept from Turku. Allegedly ecosystems, and biobanks' part in them, are what speed up research, and encourage the development of care, public-private collaboration, and the utilization of health data for the benefit of all the participants. Biobanks, however, are clearly not the sort of ecosystems that were presented at the event. The notion of ecosystem seems to reflect the new ideal of health care and clinical care development and public-private collaboration. Reardon (2017: 178) has argued that during the past decade there has been a "quick shift [in genomics] from inspiring goals and purposes – saving lives – to management-creating platforms, algorithms and data analytics". Similarly, according to Mittra (2015: 195),

> we have witnessed a prolonged period of experimental policy initiatives, commercial strategies, and major organizational restructuring, as a direct result of new biology and its promise of numerous benefits and value to industry, medicine, and society. (Mittra, 2015: 195)

Ilpo Helén (2013) uses the concept of experimentality to explore developments such as those discussed above, suggesting that there is a constant need to tinker, to connect new openings, ideas, and projects into the complex assemblage of future making; whether previous efforts have yet been fully initiated or results achieved does not seem to be of importance. Resonating with this, Alan Petersen (2009: 05.1) has argued that expectations of realizing the promises of innovations "can be difficult to sustain over the longer term" and, therefore, they "need to be supported through various reiterative practices, including the management of public representations". Similarly, according to Fortun (2008: 47),

47 In 2014, it was held for the first time in Otaniemi, Finland.

success in genomics comes to those "who can continually rearrange software, hardware, wetware and inforware into hybrid combinations that create new intensities, perform new biological effects". Crucially, he goes on, "completion isn't promised by genomics, future becomings are" (Fortun, 2008: 47).

Concluding remarks

> The dimension in which success and failure takes place in the world of genomics is that of time. A strategy must be fruitful before it becomes outdated, and its value decreases as other understandings take shape. (Rabinow and Dan-Cohen, 2005: 189)

Given that biomedicine is in constant search of new openings, the biobanking of today is by necessity not the same as it was first envisaged and constructed. Therefore, my central claim in regard to socio-technical imaginaries is not only that they change and mold themselves (Tarkkala et al., 2018), but also that the idea and understanding of the nature of a biobank changes when the fulfilment of an imaginary requires ever more participants, openings, projects, policies, regulations, and so on. All of these developments also have implications for the knowledge that can be produced in the first place, and might make it challenging to develop biobanks in the long term. This could have an impact on the sort of passage point it was hoped biobanks would be for foreign investments in Finland, and what the collaborators and investors are actually looking for (see also Aarden 2017). For instance, if Finnish biobanks are increasingly used merely to recontact patients and form populations, which then participate in studies organized by pharmaceutical companies, the expected cycle of data return can hardly become reality.

In the literature on expectations, imaginaries, and futures it is emphasized that the future is enacted in the present. I suggest that the specific present of Finnish biobanks could be understood as "biobanks in-formation". This follows and resembles Reardon's description of genomics as being "in-formation": "Little is known, and much is promised", she writes (Reardon, 2017: 174). By describing the situation of biobanking as one that is in-formation, the uncertainties and openness about what a biobank is are underlined. What "biobanking" truly is in the present seems to be about capacity, potential, and promise, exemplified by high quality samples, research populations, and independent cancer research projects. Thus, biobanks are storing samples and data for the future, prospectively, while remaining ambiguous in the present. There are different interpretations of legislation, especially in relation to clinical care, and different ways of presenting biobanking and biobank research, which, together, generate an unclear overall picture of biobanks and biobanking. Then there are the new institutional and personalized medicine-related initiatives, and it is not easy to know how, whether, or to what degree they overlap with biobanking. Thus, I wish to underline the uncertain status of biobanks.

Borup et al. (2006: 286) have noted that expectations "change over time in response and adaptation to new conditions or emergent problems". This is also the case with

personalized medicine, as it has increasingly become a vision of the transformation of health care and data collection systems. One of the big changes in this field has been the aforementioned focus on data. The efforts to collect, produce, and utilize data ever more efficiently and in public-private collaboration are being supported in clinical environments and encouraged nationally. In a sense our health care system is becoming an exercise in data management and data circulation (Aronson and Rehm, 2015). Indeed, Nimmesgern et al., (2017) argue that for personalized medicine to become reality, health care systems need to be "much better at generating, storing, and processing health-related information, in order to inform appropriate action" (Nimmesgern et al., 2017: 63). Again, what this requires is further standardization and accuracy of health data, enhanced reproducibility, phenotype information with standardized ontologies, better analytical tools able to analyze information "available in a healthcare system organized around personalized medicine", as well as a clinical interface allowing all this to be of benefit to patients (Nimmesgern et al., 2017: 63). When the need to continue research and innovation activities is added to this list (Nimmesgern et al. 201: 63), one can see that business as usual goes on (see also the 2017 report by the International Consortium for Personalized Medicine indicating the leading role taken by data rather than genomics).

The imperative of biobanks and genomic knowledge is to make it easier to circulate knowledge and data in global assemblages. The commodification of the health care system, as a result of its serving as a site for data production and as part of health care ecosystems, adds a new dimension to the collection and utilization of population-based data in the biomedical research enterprise. In this world, individuals are persuaded to take part in biomedical research via the use of their personal data, thereby creating possibilities for new kinds of health care services to emerge, something that is very much an international development. The healthcare system is increasingly instrumentalized "as a machine for innovation and of wealth generation" (Gardner and Webster, 2016) in countries like the UK and Finland, with the difference that in the UK this has created public controversy which has not so far occurred in Finland (e.g. Presser et al., 2015; Tupasela et al., 2015b; Vezyridis and Timmons, 2017).

The public registries and health care system, which are now resources, have in the past served health and the common good, with connections to an ethos of social responsibility. Now social responsibility and public health are bundled together with innovation potential and are even referred as national treasure. Yet is the health care system recognizably the same after these changes? If not, what are the new values (see also König, 2017)? What kind of expectations do people have of the health care system and what kind of values do they relate to it? Does the effort to build, generate, and utilize big data place legitimacy under scrutiny? Moreover, will it mean that people will no longer want to participate, given that the commercial side of biomedicine and biobanks is consistently creating concern (e.g., Snell, 2018; Tupasela and Snell, 2012)? The trusted public health care system, previously based on universality rather than market logic, is being turned into a data production site

and a vital player in health ecosystems. This contrasts with the way people are accustomed to reason about the ethos and value of universal health care in a welfare state (Tupasela and Snell, 2012). This is taking place as increased data collection, its utilization, and data safety questions are becoming more salient in society, often in reference to how companies such as Google, Apple, and Facebook collect, utilize, and sell data (see also Reardon, 2017: 181).

In the new situation the values linked to a universal health care system might not travel easily into the more commercial and complex context of innovations, data-driven medicine, the building of public-private partnerships, and making clinical care part of an innovation ecosystem. Moreover, if it is not clear who gets the benefits and in what form, acceptance by patients of data and sample collecting might become problematic (Raivola et al., 2018). In what kind of landscape will biobanks find themselves? Are they more connected to the health care system or to commercial partnerships in peoples' minds? Is it possible to sustain the values of the common good, national health, or social responsibility? If not, what will be the new values and, what sort of motivations will there be to participate? What kind of expectations will people have of the health care system and biobanks? Prainsack (2007: 98) has suggested that the "failure or success of biobanks are often located in the social and political field more than in the field of science", thereby foregrounding biobanking practices and how they fit with the "social, religious, 'cultural', and political practices of the society they are embedded in". In Finland, we must wait to see how the social and cultural fit of biobanks plays out.

References

Aarden E (2016) Translating genetics beyond bench and bedside: A comparative perspective on health care infrastructures for 'familial' breast cancer. *Applied & Translational Genomics* 11: 48–54. DOI: 10.1016/j.atg.2016.09.001.

Aarden E (2017) Projecting and producing 'usefulness' of biomedical research infrastructures; or why the Singapore Tissue Network closed. *Science and Public Policy* 44(6): 753–762. DOI: 10.1093/scipol/scx010.

Adam B and Groves C (2007) *Future Matters: Action, Knowledge, Ethics*. Leiden and Boston: BRILL.

Adams V, Murphy M and Clarke AE (2009) Anticipation: Technoscience, life, affect, temporality. *Subjectivity* 28(1): 246–265. DOI: 10.1057/sub.2009.18.

Alastalo M (2009) Viranomaistiedosta tilastoksi: rekisteriperusteisen tilastojärjestelmän muodostaminen Suomessa. *Sosiologia* 46(3): 173–189.

Alasuutari P (1995) *Researching Culture: Qualitative Method and Cultural Studies*. London: SAGE.

Altman RB (2012) Translational Bioinformatics: Linking the Molecular World to the Clinical World. *Clinical Pharmacology & Therapeutics* 91(6): 994–1000. DOI: 10.1038/clpt.2012.49.

Anderson B (1991) *Imagined Communities: Reflections on the Origin and Spread of Nationalism*. London and New York: Verso.

Anderson W (2008) *The Collectors of Lost Souls: Turning Kuru Scientists Into Whitemen*. Baltimore: Johns Hopkins University Press.

Ankeny RA and Leonelli S (2015) Valuing Data in Postgenomic Biology: How data Donation and Curation Practices Challenge the Scientific Publication System. In: *Postgenomics. Perspectives on Biology after the Genome*. Durham and London: Duke University Press, pp. 126–149.

Appadurai A (2013) *The Future as Cultural Fact: Essays on the Global Condition*. London and New York: Verso Books.

Aronson SJ and Rehm HL (2015) Building the foundation for genomics in precision medicine. *Nature* 526(7573): 336–342. DOI: 10.1038/nature15816.

Asslaber M and Zatloukal K (2007) Biobanks: transnational, European and global networks. *Briefings in Functional Genomics* 6(3): 193–201. DOI: 10.1093/bfgp/elm023.

Beaudevin C, Peerbaye A and Bourgain C (forthcoming) 'It has to become true genetics' Tumour genetics and the division of diagnostic labour in the clinic. *Sociology of Health & Illness* 0(0). DOI: 10.1111/1467-9566.12844.

Beckert J (2016) *Imagined Futures*. Cambridge, Massachusetts: Harvard University Press.

Begley CG and Ioannidis JPA (2015) Reproducibility in Science: Improving the Standard for Basic and Preclinical Research. *Circulation Research* 116(1): 116–126. DOI: 10.1161/CIRCRESAHA.114.303819.

Bell J (2017) *Life sciences: industrial strategy - A report to the Government from the life sciences sector*. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/650447/LifeSciencesIndustrialStrategy_acc2.pdf (accessed 25 January 2018).

Benjamin R (2009) A Lab of Their Own: Genomic sovereignty as postcolonial science policy. *Policy and Society* 28(4): 341–355. DOI: 10.1016/j.polsoc.2009.09.007.

Bentley AR, Callier S and Rotimi CN (2017) Diversity and inclusion in genomic research: why the uneven progress? *Journal of Community Genetics* 8(4): 255–266. DOI: 10.1007/s12687-017-0316-6.

Biémont C and Vieira C (2006) Junk DNA as an evolutionary force. *Nature* 443(7111): 521–524. DOI: 10.1038/443521a.

Blow N (2009) Biobanking: freezer burn. *Nature Methods* 6(2): 173–178. DOI: 10.1038/nmeth0209-173.

Blumberg RS, Dittel B, Hafler D, et al. (2012) Unraveling the autoimmune translational research process layer by layer. *Nature Medicine* 18(1): 35–41. DOI: 10.1038/nm.2632.

Boeckhout M and Douglas CMW (2015) Governing the research-care divide in clinical biobanking: Dutch perspectives. *Life Sciences, Society and Policy* 11(1): 1–16. DOI: 10.1186/s40504-015-0025-z.

Bornstein SR and Licinio J (2011) Improving the efficacy of translational medicine by optimally integrating health care, academia and industry. *Nature Medicine* 17(12): 1567–1569. DOI: 10.1038/nm.2583.

Borup M, Brown N, Konrad K, et al. (2006) The sociology of expectations in science and technology. *Technology Analysis & Strategic Management*. DOI: 10.1080/09537320600777002.

Bourret P (2005) BRCA Patients and Clinical Collectives: New Configurations of Action in Cancer Genetics Practices. *Social Studies of Science* 35(1): 41–68. DOI: 10.1177/0306312705048716.

Bourret P, Keating P and Cambrosio A (2011) Regulating diagnosis in post-genomic medicine: Re-aligning clinical judgment? *Social Science & Medicine* 73(6): 816–824. DOI: 10.1016/j.socscimed.2011.04.022.

Bowker GC and Star SL (2000a) Invisible Mediators of Action: Classification and the Ubiquity of Standards. *Mind, Culture, and Activity* 7(1–2): 147–163. DOI: 10.1080/10749039.2000.9677652.

Bowker GC and Star SL (2000b) *Sorting Things Out: Classification and Its Consequences*. Cambridge, Massachusetts: MIT Press.

Brown N (2003) Hope Against Hype - Accountability in Biopasts, Presents and Futures. *Science Studies* 16(2): 3–21.

Brown N and Michael M (2003) A Sociology of Expectations: Retrospecting Prospects and Prospecting Retrospects. *Technology Analysis & Strategic Management* 15(1): 3–18. DOI: 10.1080/0953732032000046024.

Brown N and Webster A (2004) *New Medical Technologies and Society: Reordering Life*. Cambridge: Polity.

Brown N, Rappert B and Webster A (2000) Introducing Contested Futures: From Looking into the Future to Looking at the Future. In: Brown N, Rappert B, and Webster A (eds) *Contested Futures: A Sociology of Prospective Techno-Science*. Aldershot: Ashgate, pp. 3–20.

Brown N, Faulkner A, Kent J, et al. (2006) Regulating Hybrids: 'Making a Mess' and 'Cleaning Up' in Tissue Engineering and Transpecies Transplantation. *Social Theory & Health* 4(1): 1–24. DOI: 10.1057/palgrave.sth.8700062.

Burke W, Burton H, Hall AE, et al. (2010) Extending the reach of public health genomics: What should be the agenda for public health in an era of genome-based and "personalized" medicine?: *Genetics in Medicine* 12(12): 785–791. DOI: 10.1097/GIM.0b013e3182011222.

Busby H and Martin P (2006) Biobanks, national identity and imagined communities: The case of UK biobank. *Science as Culture* 15(3): 237–251. DOI: 10.1080/09505430600890693.

Bustin SA (2014) The reproducibility of biomedical research: Sleepers awake! *Biomolecular Detection and Quantification* 2: 35–42. DOI: 10.1016/j.bdq.2015.01.002.

Butler D (2008) Translational research: Crossing the valley of death. *Nature News* 453(7197): 840–842. DOI: 10.1038/453840a.

Calzolari A, Valerio A, Capone F, et al. (2014) The European Research Infrastructures of the ESFRI Roadmap in Biological and Medical Sciences: status and perspectives. *Annali dell'Istituto Superiore di Sanità* 50: 178–185. DOI: 10.4415/ANN_14_02_12.

Cambrosio A, Keating P, Schlich T, et al. (2006) Regulatory objectivity and the generation and management of evidence in medicine. *Social Science & Medicine* 63(1): 189–199. DOI: 10.1016/j.socscimed.2005.12.007.

Cambrosio A, Keating P, Schlich T, et al. (2009) Biomedical Conventions and Regulatory Objectivity A Few Introductory Remarks. *Social Studies of Science* 39(5): 651–664. DOI: 10.1177/0306312709334640.

Cambrosio A, Keating P, Bourret P, et al. (2009) Genomic platforms and hybrid formations. In: Atkinson P, Glasner P, and Lock M (eds) *Handbook of Genetics and Society*. New York: Routledge, pp. 502–520.

Cambrosio A, Bourret P, Rabeharisoa V, et al. (2014) Big Data and the Collective Turn in Biomedicine. How Should We Analyze Post-genomic Practices? *TECNOSCIENZA: Italian Journal of Science & Technology Studies* 5(1): 11–42.

Cambrosio A, Bourret P, Keating P, et al. (2017) Opening the Regulatory Black Box of Clinical Cancer Research: Transnational Expertise Networks and "Disruptive" Technologies. *Minerva* 55(2): 161–185. DOI: 10.1007/s11024-017-9324-2.

Cambrosio A, Keating P, Vignola-Gagné E, et al. (2018) Extending experimentation: oncology's fading boundary between research and care. *New Genetics and Society* 0(0): 1–20. DOI: 10.1080/14636778.2018.1487281.

Carpén O and Helander T (2017) Jokainen potilas tutkimuspotilaaksi: Biopankit ja Kansallinen syöpäkeskus yhdenvertaisuuden asialla. *Duodecim: Lääketieteellinen aikakauskirja* (133): 592–598.

Carter A and Betsou F (2011) Quality Assurance in Cancer Biobanking. *Biopreservation and Biobanking* 9(2): 157–163. DOI: 10.1089/bio.2010.0031.

Caulfield T and Murdoch B (2017) Genes, cells, and biobanks: Yes, there's still a consent problem. *PLOS Biology* 15(7): e2002654. DOI: 10.1371/journal.pbio.2002654.

Chheda H, Palta P, Pirinen M, et al. (2017) Whole-genome view of the consequences of a population bottleneck using 2926 genome sequences from Finland and United Kingdom. *European Journal of Human Genetics* 25(4): 477–484. DOI: 10.1038/ejhg.2016.205.

Coleman S and von Hellermann P (2011) *Multi-Sited Ethnography: Problems and Possibilities in the Translocation of Research Methods*. New York: Routledge.

Collins FS (2010) *The Language of Life: DNA and the Revolution in Personalized Medicine*. New York: Harper Perennial.

Collins FS (2011) Reengineering Translational Science: The Time Is Right. *Science Translational Medicine* 3(90): 90cm17-90cm17. DOI: 10.1126/scitranslmed.3002747.

Collins FS and Varmus H (2015) A New Initiative on Precision Medicine. *New England Journal of Medicine* 372(9): 793–795. DOI: 10.1056/NEJMp1500523.

Contopoulos-Ioannidis DG, Alexiou GA, Gouvias TC, et al. (2008) Life Cycle of Translational Research for Medical Interventions. *Science* 321(5894): 1298–1299. DOI: 10.1126/science.1160622.

Cool A (2016) Detaching data from the state: Biobanking and building Big Data in Sweden. *BioSocieties* 11(3): 277–295. DOI: 10.1057/biosoc.2015.25.

Cooper M (2008) *Life as Surplus: Biotechnology and Capitalism in the Neoliberal Era*. Seattle, WA: University of Washington Press.

Cooper M and Waldby C (2014) *Clinical Labor: Tissue Donors and Research Subjects in the Global Bioeconomy*. Durham and London: Duke University Press.

Coopmans C and Hua MTA (2018) On 'Asian' Distinctiveness and Race as a Variable: The Case of Ophthalmic Epidemiology in Singapore. *Science, Technology and Society* 23(2): 252–270. DOI: 10.1177/0971721818762865.

Cornel MC and Bonham VL (2017) Genomics for all in the 21st century? *Journal of Community Genetics* 8(4): 249–251. DOI: 10.1007/s12687-017-0333-5.

Crabu S (2016) Translational biomedicine in action: Constructing biomarkers across laboratory and benchside. *Social Theory & Health* 14(3): 312–331. DOI: 10.1057/sth.2015.35.

Crabu S (2018) Rethinking biomedicine in the age of translational research: Organisational, professional, and epistemic encounters. *Sociology Compass* 12(10): e12623. DOI: 10.1111/soc4.12623.

Critchley C, Nicol D and Otlowski M (2015) The Impact of Commercialisation and Genetic Data Sharing Arrangements on Public Trust and the Intention to Participate in Biobank Research. *Public Health Genomics* 18(3): 160–172. DOI: 10.1159/000375441.

Cronin A, Alexander VD, Fielding J, et al. (2017) The Analytic Integration of Qualitative Data Sources. In: Alasuutari P, Bickman L, and Brannen J (eds) *The SAGE Handbook of Social Research Methods*. London: SAGE Publications Ltd, pp. 572–584. DOI: 10.4135/9781446212165.

Dabrock P, Taupitz J and Ried J (2012) *Trust in Biobanking: Dealing with Ethical, Legal and Social Issues in an Emerging Field of Biotechnology*. Berlin and Heidelberg: Springer Science & Business Media.

Day S, Coombes RC, McGrath-Lone L, et al. (2017) Stratified, precision or personalised medicine? Cancer services in the 'real world' of a London hospital. *Sociology of Health & Illness* 39(1): 143–158. DOI: 10.1111/1467-9566.12457.

de la Chapelle A (1993) Disease gene mapping in isolated human populations: the example of Finland. *Journal of Medical Genetics* 30(10): 857–865.

Della Porta D and Keating M (2008) How many approaches in the social sciences? An epistemological introduction. In: Della Porta D and Keating M (eds) *Approaches and Methodologies in the Social Sciences: A Pluralist Perspective*. Cambridge: Cambridge University Press, pp. 19–39.

DelVecchio Good M-J (2003) The Medical Imaginary and the Biotechnical Embrace. Subjective Experiences of Clinical Scientists and Patients. Working Paper #210 Russell Sage Foundation.

Douglas CMW (2014) The Role of Bioinformatics in Facilitating Translational Science and Medicine. *TECNOSCIENZA: Italian Journal of Science & Technology Studies* 5(1): 141–164.

Druker BJ, Talpaz M, Resta DJ, et al. (2001) Efficacy and Safety of a Specific Inhibitor of the BCR-ABL Tyrosine Kinase in Chronic Myeloid Leukemia. *New England Journal of Medicine* 344(14): 1031–1037. DOI: 10.1056/NEJM200104053441401.

Elliott P and Peakman TC (2008) The UK Biobank sample handling and storage protocol for the collection, processing and archiving of human blood and urine. *International Journal of Epidemiology* 37(2): 234–244. DOI: 10.1093/ije/dym276.

Ely S (2009) Personalized medicine: individualized care of cancer patients. *Translational Research* 154(6): 303–308. DOI: 10.1016/j.trsl.2009.08.001.

Epstein S (2007) *Inclusion: The Politics of Difference in Medical Research*. Chicago: University of Chicago Press.

Epstein S (2008) The Rise of `Recruitmentology' Clinical Research, Racial Knowledge, and the Politics of Inclusion and Difference. *Social Studies of Science* 38(5): 801–832. DOI: 10.1177/0306312708091930.

Eskola J (2005) *Molekyylibiologiasta ja geenianalyyseistä terveyttä väestölle. Ehdotus Kansanterveyslaitoksen bioteknologiastrategiaksi.* Publications of the National Public Health Institute KTL B5/2005. Helsinki: Kansanterveyslaitos.

European Commission (2009) *Patient Safety and quality of healthcare.* Special Eurobarometer 327. Brussels: TNS Opinion & Social. Available at: http://ec.europa.eu/public_opinion/archives/eb_special_339_320_en.htm#327 (accessed 9 December 2012).

European Commission (2010a) *Biotechnology*. Eurobarometer 341. Brussels: TNS Opinion & Social. Available at: http://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_341_en.pdf (accessed 22 July 2018).

European Commission (2010b) *Europeans and Biotechnology in 2010 - Winds of change?* Luxembourg: Publications Office of the European Union. Available at: http://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_341_winds_en.pdf (accessed 22 July 2018).

European Commission (2014) *Public Perceptions of Science, Research and Innovation.* Special Eurobarometer 419. Available at: http://ec.europa.eu/COMMFrontOffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2047 (accessed 28 June 2018).

European Union (2009) Towards new research infrastructures for Europe the ESFRI "List of Opportunities". Available at: https://publications.europa.eu/en/publication-detail/-/publication/c6dedf1a-13b8-4a73-80d2-ad5099104bfe/language-en (accessed 5 April 2018).

European Union (2011) Towards personalised medicine. Available at: https://publications.europa.eu/fi/publication-detail/-/publication/01e967cb-7296-4815-a371-82165657b66f/language-en/format-PDF (accessed 5 April 2018).

European Union (2015) Council conclusions on personalised medicine for patients (2015/C 421/03). Notices from European Union Institutions, Bodies, Offices and Agencies. *Official Journal of the European Union, C 421, 17 December 2015*.

European Union (2016) Life sciences : networks of Research infrastructures supported by the European Union. Available at: https://publications.europa.eu/fi/publication-detail/-/publication/e1427f5f-c97b-11e5-a4b5-01aa75ed71a1/language-en/format-RDF (accessed 5 April 2018).

European Union (2017a) Carrying the torch for medical innovation. Available at: https://publications.europa.eu/fi/publication-detail/-/publication/aae0a4ba-b541-11e7-837e-01aa75ed71a1/language-en/format-PDF (accessed 5 April 2018).

European Union (2017b) Rare diseases : a major unmet medical need. Available at: https://publications.europa.eu/fi/publication-detail/-/publication/c2ba4fd4-ae31-11e7-837e-01aa75ed71a1/language-en/format-PDF (accessed 5 April 2018).

Falzon M-A (2009a) Introduction: Multi-sited Ethnography: Theory, Praxis and Locality in Contemporary Research. In: Falzon M-A (ed.) *Multi-Sited Ethnography. Theory, Praxis and Locality in Contemporary Research.* Farnham: Ashgate, pp. 1–24.

Falzon M-A (2009b) *Multi-Sited Ethnography: Theory, Praxis and Locality in Contemporary Research*. Farnham: Ashgate.

Fan C-T, Lin J-C and Lee C-H (2008) Taiwan Biobank: a project aiming to aid Taiwan's transition into a biomedical island. *Pharmacogenomics* 9(2): 235–246. DOI: 10.2217/14622416.9.2.235.

Faulkner A (2017) Bioinformatics imaginaries in the engine-room of genomic health policy. *Science & Technology Studies* (3): 35–53. DOI: 10.23987/sts.60909.

Felt U (2015) Keeping Technologies Out: Sociotechnical imaginaries and the formation of Austria's technopolitical identity. In: Jasanoff S and Kim S-H (eds) *Dreamscapes of Modernity. Sociotechnical Imaginaries and the Fabrication of Power.* Chicago: University of Chicago Press, pp. 103–125.

Flannick J, Thorleifsson G, Beer NL, et al. (2014) Loss-of-function mutations in *SLC30A8* protect against type 2 diabetes. *Nature Genetics* 46(4): 357–363. DOI: 10.1038/ng.2915.

Fletcher AL (2004) Field of genes: the politics of science and identity in the Estonian genome project. *New Genetics and Society* 23(1): 3–14.

Fortun K (2009) Scaling and Visualizing Multi-sited Ethngoraphy. In: Falzon M-A (ed.) *Multi-Sited Ethnography: Theory, Praxis and Locality in Contemporary Research.* Farnham: Ashgate, pp. 73–86.

Fortun M (2008) *Promising Genomics: Iceland and DeCODE Genetics in a World of Speculation*. Berkeley: University of California Press.

Foucault M (2005) *The Order of Things*. Routledge.

Fox Keller E (2009) *The Century of the Gene*. Cambridge, Massachusetts: Harvard University Press.

Frank L (2000) When an Entire Country Is a Cohort. *Science* 287(5462): 2398–2399. DOI: 10.1126/science.287.5462.2398.

Franklin S (1997) *Embodied Progress: A Cultural Account of Assisted Conception*. New York & London: Routledge.

Franklin S (2001) Culturing Biology: Cell Lines for the Second Millennium. *Health:* 5(3): 335–354. DOI: 10.1177/136345930100500304.

Franklin S (2007) *Dolly Mixtures: The Remaking of Genealogy*. Durham and London: Duke University Press.

Friese C (2013) Realizing Potential in Translational Medicine: The Uncanny Emergence of Care as Science. *Current Anthropology* 54(S7): S129–S138. DOI: 10.1086/670805.

Fujimura JH (1996) *Crafting Science: A Sociohistory of the Quest for the Genetics of Cancer*. Cambridge, Massachusetts: Harvard University Press.

Fujimura JH (2003) Future Imaginaries: Genome Scientists as Sociocultural Entrepreneurs. In: Goodman AH, Heath D, and Lindee MS (eds) *Genetic Nature/Culture: Anthropology and Science beyond the Two-Culture Divide*. Berkeley: University of California Press, pp. 176–199.

Fujimura JH and Rajagopalan R (2011) Different differences: The use of 'genetic ancestry' versus race in biomedical human genetic research. *Social Studies of Science* 41(1): 5–30. DOI: 10.1177/0306312710379170.

Gaisser S, Vignola-Gagné E, Hüsing B, et al. (2008) EU policies in personalized medicine-related technologies. *Personalized Medicine* 6(1): 93–102. DOI: 10.2217/17410541.6.1.93.

Gannett L (2003) Making Populations: Bounding Genes in Space and in Time. *Philosophy of Science* 70(5): 989–1001. DOI: 10.1086/377383.

Gardner J and Webster A (2016) The social management of biomedical novelty: Facilitating translation in regenerative medicine. *Social Science & Medicine* 156(Supplement C): 90–97. DOI: 10.1016/j.socscimed.2016.03.025.

Gaskell G, Gottweis H, Starkbaum J, et al. (2013) Publics and biobanks: Pan-European diversity and the challenge of responsible innovation. *European Journal of Human Genetics* 21(1): 14–20. DOI: 10.1038/ejhg.2012.104.

Gibbon S (2013) Ancestry, Temporality, and Potentiality. *Current anthropology* 54(Suppl 7): S107–S117. DOI: 10.1086/671400.

Gibbon S (2016) Translating Population Difference: The Use and Re-Use of Genetic Ancestry in Brazilian Cancer Genetics. *Medical Anthropology* 35(1): 58–72. DOI: 10.1080/01459740.2015.1091818.

Goodman AH, Heath D and Lindee MS (2003) *Genetic Nature/Culture: Anthropology and Science Beyond the Two-Culture Divide*. Berkeley: University of California Press.

Gottweis H (2008) Biobanks in Action. New strategies in the governance of life. In: Gottweis, H and Petersen A (eds) *Biobanks. Governance in Comparative Perspective.* New York: Routledge, pp. 22–38.

Gottweis H and Petersen A (2008) *Biobanks: Governance in Comparative Perspective*. London: Routledge.

Gottweis H, Chen H and Starkbaum J (2011) Biobanks and the phantom public. *Human Genetics* 130(3): 433. DOI: 10.1007/s00439-011-1065-y.

Gottweis H, Kaye J, Bignami F, et al. (2012) *Biobanks for Europe. A challenge for governance*. European Union, Luxembourg. Available at: http://bookshop.europa.eu/en/biobanks-for-europe-pbKINA25302/ (accessed 22 February 2016).

Grizzle WE, Gunter EW, Sexton KC, et al. (2015) Quality Management of Biorepositories. *Biopreservation and Biobanking* 13(3): 183–194. DOI: 10.1089/bio.2014.0105.

Guttmacher AE and Collins FS (2005) Realizing the Promise of Genomics in Biomedical Research. *JAMA* 294(11): 1399–1402. DOI: 10.1001/jama.294.11.1399.

Halverson CME and Ross LF (2012a) Attitudes of African-American parents about biobank participation and return of results for themselves and their children. *Journal of Medical Ethics* 38(9): 561–566. DOI: 10.1136/medethics-2012-100600.

Halverson CME and Ross LF (2012b) Incidental findings of therapeutic misconception in biobank-based research. *Genetics in Medicine* 14(6): 611–615. DOI: 10.1038/gim.2011.50.

Hamburg MA and Collins FS (2010) The Path to Personalized Medicine. *New England Journal of Medicine* 363(4): 301–304. DOI: 10.1056/NEJMp1006304.

Hannerz U (2003) Being there... and there... and there!: Reflections on Multi-Site Ethnography. *Ethnography* 4(2): 201–216. DOI: 10.1177/14661381030042003.

Hansson MG (2005) Building on relationships of trust in biobank research. *Journal of Medical Ethics* 31(7): 415–418. DOI: 10.1136/jme.2004.009456.

Haraway DJ (1988) Situated knowledges: The science question in feminism and the privilege of partial perspective. *Feminist studies* 14(3): 575-599.

Haraway DJ (1997) *Modest–Witness@Second–Millennium.FemaleMan–Meets–OncoMouse: Feminism and Technoscience*. New York: Routledge.

Haraway DJ (2004) *The Haraway Reader*. London and New York: Routledge.

Harris JR, Burton P, Knoppers BM, et al. (2012) Toward a roadmap in global biobanking for health. *European Journal of Human Genetics* 20(11): 1105–1111. DOI: 10.1038/ejhg.2012.96.

Hästbacka J, de la Chapelle A, Kaitila I, et al. (1992) Linkage disequilibrium mapping in isolated founder populations: diastrophic dysplasia in Finland. *Nature Genetics* 2(3): 204–211. DOI: 10.1038/ng1192-204.

Hauskeller C, Baur N and Harrington J (2017) Standards, Harmonization and Cultural Differences: Examining the Implementation of a European Stem Cell Clinical Trial. *Science as Culture*: 1–26. DOI: 10.1080/09505431.2017.1347613.

Hautamäki L (2016) *Movements of Moods: Interplay Between Science, Clinical Practice and Patient in Psychiatry*. Doctoral Dissertation. University of Helsinki, Helsinki. Available at: https://helda.helsinki.fi/handle/10138/160245 (accessed 11 August 2017).

Hedgecoe A (2004) *The Politics of Personalised Medicine: Pharmacogenetics in the Clinic*. Cambridge University Press.

Hedgecoe A and Martin P (2003) The Drugs Don't Work: Expectations and the Shaping of Pharmacogenetics. *Social Studies of Science* 33(3): 327–364. DOI: 10.1177/03063127030333002.

Heesen A te and Spary EC (2001) *Sammeln als Wissen: das Sammeln und seine wissenschaftsgeschichtliche Bedeutung*. Göttingen: Wallstein.

Heikkinen A (2013) Biopankki tallettaa ihmisperäisiä materiaaleja. *Tiedetuokio*. Yle Areena. Available at: http://areena.yle.fi/1-2060610 (accessed 10 April 2016).

Helén I (2004) Health in Prospect. High-tech Medicine, Life Enhancement and the Economy of Hope. *Science Studies* 17(1): 3–19.

Helén I (2013) Elämän politiikka biologisen muokattavuuden aikakaudella : ensimmäinen kartoitus. *Sosiologia* 50(4): 327–341.

Helén I (2016) *Elämän Politiikat. Yhteiskuntatutkimus Foucault´n Jälkeen*. Paradeigma-sarja. Helsinki: Tutkijaliitto.

Hemminki E, Tupasela A, Jallinoja P, et al. (2009) Finnish people's attitudes towards biomedical research and its sponsorship. *Genomics, Society and Policy* 5(2): 67. DOI: 10.1186/1746-5354-5-2-67.

Hennink M, Hutter I and Bailey A (2010) *Qualitative Research Methods*. London: SAGE.

Hewitt R and Watson P (2013) Defining Biobank. *Biopreservation and Biobanking* 11(5): 309–315. DOI: 10.1089/bio.2013.0042.

Hewitt RE (2011) Biobanking: the foundation of personalized medicine. *Current Opinion in Oncology* (23): 112–119.

Hinterberger A (2012a) Categorization, Census, and Multiculturalism: Molecular Politics and the Material of Nation. In: Wailoo K, Nelson A, and Lee C (eds) *Genetics and the Unsettld Past. The Collision of DNA, Race, and History*. New Brunswick, New Jersey, and London: Rutgers University Press, pp. 204–224.

Hinterberger A (2012b) Investing in Life, Investing in Difference: Nations, Populations and Genomes. *Theory, Culture & Society* 29(3): 72–93. DOI: 10.1177/0263276411427409.

Hinterberger A (2012c) Publics and Populations: The Politics of Ancestry and Exchange in Genome Science. *Science as Culture* 21(4): 528–549. DOI: 10.1080/09505431.2012.705272.

Hinterberger A and Porter N (2015) Genomic and Viral Sovereignty: Tethering the Materials of Global Biomedicine. *Public Culture* 27(2 76): 361–386. DOI: 10.1215/08992363-2841904.

Hoeyer K (2003) 'Science is really needed—that's all I know": informed consent and the non-verbal practices of collecting blood for genetic research in northern Sweden'. *New Genetics and Society* 22(3): 229–244. DOI: 10.1080/1463677032000147199.

Hoeyer K (2010) Donors Perceptions of Consent to and Feedback from Biobank Research: Time to Acknowledge Diversity? *Public Health Genomics* 13(6): 345–352. DOI: 10.1159/000262329.

Hoeyer K (2016) Denmark at a crossroad? Intensified data sourcing in a research radical country. In: Mittelstadt BD and Floridi L (eds) *The Ethics of Biomedical Big Data*. Cham: Springer, pp. 73–93.

Hoeyer K and Hogle LF (2014) Informed Consent: The Politics of Intent and Practice in Medical Research Ethics. *Annual Review of Anthropology* 43(1): 347–362. DOI: 10.1146/annurev-anthro-102313-030413.

Hoeyer K, Olofsson B-O, Mjörndal T, et al. (2004) Informed consent and biobanks: a population-based study of attitudes towards tissue donation for genetic research. *Scandinavian Journal of Public Health* 32(3): 224–229. DOI: 10.1080/14034940310019506.

Hogle LF (2009) Pragmatic Objectivity and the Standardization of Engineered Tissues. *Social Studies of Science* 39(5): 717–742. DOI: 10.1177/0306312709103478.

Hogle LF (2016) Data-intensive resourcing in healthcare. *BioSocieties* 11(3): 372–393. DOI: 10.1057/s41292-016-0004-5.

Hood L and Friend SH (2011) Predictive, personalized, preventive, participatory (P4) cancer medicine. *Nature Reviews Clinical Oncology* 8(3): 184–187. DOI: 10.1038/nrclinonc.2010.227.

Horgan D, Romao M and Hastings R (2017) Pulling the Strands Together: MEGA Steps to Drive European Genomics and Personalised Medicine. *Biomedicine Hub* 2(Suppl. 1): 28–28. DOI: 10.1159/000481300.

Huber PW (2013) *The Cure in the Code. How 20th Century Law Is Undermining 21st Century Medicine*. New York: Basic Books.

Huppertz B and Holzinger A (2014) *Biobanks – A Source of Large Biological Data Sets: Open Problems and Future Challenges*. Berlin and Heidelberg: Springer.

HUS (2016) *Helsingin biopankille annettu jo 10 000 suostumusta*. Announcement, 6 October. HUS - The Hospital District of Helsinki and Uusimaa. Available at: http://www.hus.fi/hus-tietoa/uutishuone/Sivut/Helsingin-Biopankille-annettu-jo-10-000-suostumusta-.aspx (accessed 14 March 2017).

International Consortium for Personalized Medicine (2017) *Action Plan. Actionable Research and Support Activities Identified by the International Consortium for Personalised Medicine*. Available at: http://www.icpermed.eu/media/content/ICPerMed_Actionplan_2017_web.pdf (accessed 29 January 2018).

Ioannidis JPA (2005) Why Most Published Research Findings Are False. *PLOS Med* 2(8): e124. DOI: 10.1371/journal.pmed.0020124.

Ioannidis JPA (2014) How to Make More Published Research True. *PLOS Medicine* 11(10): e1001747. DOI: 10.1371/journal.pmed.1001747.

Jacob F (1982) *The Possible and the Actual*. Seattle, WA: University of Washington Press.

Jakkula E, Rehnström K, Varilo T, et al. (2008) The Genome-wide Patterns of Variation Expose Significant Substructure in a Founder Population. *The American Journal of Human Genetics* 83(6): 787–794. DOI: 10.1016/j.ajhg.2008.11.005.

Jasanoff S (2004) *States of Knowledge: The Co-Production of Science and the Social Order*. London and New York: Routledge.

Jasanoff S (2015a) Future Imperfect. In: Jasanoff S and Kim S-H (eds) *Dreamscapes of Modernity. Sociotechnical Imaginaries and the Fabrication of Power.* Chicago: University of Chicago Press, pp. 1–33.

Jasanoff S (2015b) Imagined and Invented Worlds. In: Jasanoff S and Kim S-H (eds) *Dreamscapes of Modernity. Sociotechnical Imaginaries and the Fabrication of Power.* Chicago: University of Chicago Press, pp. 321–341.

Jasanoff S and Kim S-H (2009) Containing the Atom: Sociotechnical Imaginaries and Nuclear Power in the United States and South Korea. *Minerva* 47(2): 119–146. DOI: 10.1007/s11024-009-9124-4.

Jasanoff S and Kim S-H (2013) Sociotechnical Imaginaries and National Energy Policies. *Science as Culture* 22(2): 189–196. DOI: 10.1080/09505431.2013.786990.

Jasanoff S and Kim S-H (2015) *Dreamscapes of Modernity: Sociotechnical Imaginaries and the Fabrication of Power*. Chicago: University of Chicago Press.

Jimenez-Sanchez G (2003) Developing a Platform for Genomic Medicine in Mexico. *Science* 300(5617): 295–296. DOI: 10.1126/science.1084059.

Johnsson L, Hansson MG, Eriksson S, et al. (2008) Patients' refusal to consent to storage and use of samples in Swedish biobanks: cross sectional study. *The BMJ* 337. DOI: 10.1136/bmj.a345.

Johnsson L, Helgesson G, Rafnar T, et al. (2010) Hypothetical and factual willingness to participate in biobank research. *European Journal of Human Genetics* 18(11): 1261–1264. DOI: 10.1038/ejhg.2010.106.

Kääriäinen H, Muilu J, Perola M, et al. (2017) Genetics in an isolated population like Finland: a different basis for genomic medicine? *Journal of Community Genetics* 8(4): 319–326. DOI: 10.1007/s12687-017-0318-4.

Kallio SP, Jakkula E, Purcell S, et al. (2009) Use of a genetic isolate to identify rare disease variants: C7 on 5p associated with MS. *Human Molecular Genetics* 18(9): 1670–1683. DOI: 10.1093/hmg/ddp073.

Kant I (2004) *Kritik der reinen Vernunft Zweite hin und wieder verbesserte Auflage (1787)*. Available at: http://www.gutenberg.org/ebooks/6343 (accessed 8 February 2019).

Käpyaho K, Peltonen-Palotie L, Perola M, et al. (2004) Suomalaiset geenit hyötykäyttöön. *Tieteessä tapahtuu* (8): 5–11.

Keating P and Cambrosio A (2003) *Biomedical Platforms: Realigning the Normal and the Pathological in Late-Twentieth-Century Medicine*. Cambridge, Massachusetts: MIT Press.

Keating P and Cambrosio A (2012) *Cancer on Trial*. Chicago and London: The University of Chicago Press.

Keating P, Cambrosio A and Nelson NC (2016) "Triple negative breast cancer": Translational research and the (re)assembling of diseases in post-genomic medicine. *Studies in History and Philosophy of Science Part C: Studies in History and Philosophy of Biological and Biomedical Sciences* 59: 20–34. DOI: 10.1016/j.shpsc.2016.05.003.

Kent M, García-Deister V, López-Beltrán C, et al. (2015) Building the genomic nation: 'Homo Brasilis' and the 'Genoma Mexicano' in comparative cultural perspective. *Social Studies of Science* 45(6): 839–861. DOI: 10.1177/0306312715611262.

Kere J (2001) Human Population Genetics: Lessons from Finland. *Annual Review of Genomics and Human Genetics* 2(1): 103–128. DOI: 10.1146/annurev.genom.2.1.103.

Kere J (2007) Miten Suomessa kerättyjä DNA- ja kudosnäytteitä voidaan hyödyntää? *Duodecim: Lääketieteellinen aikakauskirja* 123(8): 864–866.

Kerr A, Swallow J, Chekar CK, et al. (2019) Genomic research and the cancer clinic: uncertainty and expectations in professional accounts. *New Genetics and Society* 0(0): 1–18. DOI: 10.1080/14636778.2019.1586525.

Kettis-Lindblad Å, Ring L, Viberth E, et al. (2006) Genetic research and donation of tissue samples to biobanks. What do potential sample donors in the Swedish general public think? *European Journal of Public Health* 16(4): 433–440. DOI: 10.1093/eurpub/cki198.

Khoury MJ, Gwinn M, Yoon PW, et al. (2007) The continuum of translation research in genomic medicine: how can we accelerate the appropriate integration of human genome discoveries into health care and disease prevention? *Genetics in Medicine* 9(10): 665–674. DOI: 10.1097/GIM.0b013e31815699d0.

Kitzinger J (2008) Questioning Hype, Rescuing Hope? The Hwang Stem Cell Scandal and the Reassertion of Hopeful Horizons. *Science as Culture* 17(4): 417–434. DOI: 10.1080/09505430802515114.

Knoppers BM and Kharaboyan L (2009) Deconstructing Biobank Communication of Results. *SCRIPTed: A Journal of Law, Technology and Society* 6: 677.

Knorr Cetina K (2001) Objectual practice. In: Schatzki TR, Knorr Cetina K, and von Savigny E (eds) *The Practice Turn in Contemporary Theory*. New York: Routledge.

Knorr-Cetina K (1999) *Epistemic Cultures: How the Sciences Make Knowledge*. Cambridge, Massachusetts: Harvard University Press.

Kohler RE (1994) *Lords of the Fly: Drosophila Genetics and the Experimental Life*. Chicago and London: University of Chicago Press.

Kohli-Laven N (2012) French Families, Paper Facts: Genetics, Nation, and Explanation. In: Wailoo K, Nelson A, and Lee C (eds) *Genetics and the Unsettled Past. The Collision of DNA, Race, and History*. New Brunswick, New Jersey, and London: Rutgers University Press, pp. 183–203.

Kohli-Laven N, Bourret P, Keating P, et al. (2011) Cancer clinical trials in the era of genomic signatures: Biomedical innovation, clinical utility, and regulatory-scientific hybrids. *Social Studies of Science* 41(4): 487–513. DOI: 10.1177/0306312711398741.

König PD (2017) The place of conditionality and individual responsibility in a "data-driven economy". *Big Data & Society* 4(2): 2053951717742419. DOI: 10.1177/2053951717742419.

Kousta S, Ferguson C and Ganley E (2016) Editorial: Meta-Research: Broadening the Scope of PLOS Biology. *PLOS Biology* 14(1). DOI: 0.1371/journal.pbio.1002334.

Kraft A (2013) New Light Through an Old Window? The 'Translational Turn' in Biomedical Research - A Historical Perspective. In: Mittra J and Milne C-P (eds) *Translational Medicine: The Future of Therapy?* Singapore: Pan Stanford Publishing, pp. 19–54.

Lahermo P, Sajantila A, Sistonen P, et al. (1996) The genetic relationship between the Finns and the Finnish Saami (Lapps): analysis of nuclear DNA and mtDNA. *American Journal of Human Genetics* 58(6): 1309–1322.

Laitinen T, Carpén O, Mannermaa A, et al. (2018) Biopankkinäytteillä on tärkeä rooli täsmähoidoissa. *Helsingin Sanomat*, 9 June. Helsinki.

Lakoff A (2012) Diagnostic Liquidity: Mental Illness and the Global Trade in DNA. In: Sunder Rajan K (ed.) *Lively Capital: Biotechnologies, Ethics, and Governance in Global Markets*. Durham and London: Duke University Press, pp. 251–279.

Lampland M and Star SL (2009) *Standards and Their Stories: How Quantifying, Classifying, and Formalizing Practices Shape Everyday Life*. Ithaca and London: Cornell University Press.

Landecker H (2009) *Culturing Life: How Cells Became Technologies*. Cambridge, Massachusetts: Harvard University Press.

Lander B and Atkinson-Grosjean J (2011) Translational science and the hidden research system in universities and academic hospitals: A case study. *Social Science & Medicine* 72(4): 537–544. DOI: 10.1016/j.socscimed.2010.11.019.

Lander E (2011) Initial impact of the sequencing of the human genome. *Nature* 470(7333): 187–189.

Lappalainen T, Koivumäki S, Salmela E, et al. (2006) Regional differences among the Finns: A Y-chromosomal perspective. *Gene* 376(2): 207–215. DOI: 10.1016/j.gene.2006.03.004.

Latour B (1999) *Pandora's Hope: Essays on the Reality of Science Studies*. Cambridge, Massachusetts: Harvard University Press.

Latour B and Woolgar S (1979) *Laboratory Life: The Construction of Scientific Facts*. Princeton: Princeton University Press.

Lauss G, Snell K, Bialobrzeski A, et al. (2011) Embracing complexity and uncertainty: An analysis of three orders of ELSA research on biobanks. *Genomics, Society and Policy* 7(1): 47. DOI: 10.1186/1746-5354-7-1-47.

Law J (2004) *After Method. Mess in Social Science Research.* New York: Routledge.

Lee F (2015) Purity and interest. On relational work and epistemic value in the biomedical sciences. In: Dussauge I, Helgesson C-F, and Lee F (eds) *Value Practices in the Life Sciences & Medicine*. Oxford: Oxford University Press, pp. 207–223.

Lee SS-J (2012) Waiting on the Promise of Prescribing Precision: Race in the Era of Pharmacogenomics. In: Wailoo K, Nelson A, and Lee C (eds) *Genetics and the Unsettled Past. The Collision of DNA, Race, and History*. New Brunswick, New Jersey, and London: Rutgers University Press, pp. 164–180.

Lehtinen PM (2013) Tarkemmin leukemian kimppuun. *Focus -Syöpätutkimus nyt.*: 5–12.

Lehto M and Neittaanmäki P (2017) *Suomen terveysdataympäristö*. No. 35/2017, Informaatioteknologian tiedekunnan julkaisuja. Jyväskylä: Jyväskylän yliopisto.

Lek M, Karczewski KJ, Minikel EV, et al. (2016) Analysis of protein-coding genetic variation in 60,706 humans. *Nature* 536(7616): 285–291. DOI: 10.1038/nature19057.

Lenfant C (2003) Clinical Research to Clinical Practice — Lost in Translation? *New England Journal of Medicine* 349(9): 868–874. DOI: 10.1056/NEJMsa035507.

Lenoir T (2010) Foreword: Epistemology Historicized. Making Epistemic Things. In: *Epistemology of the Concrete*. Durham & London: Duke University Press, pp. xi–xix.

Leonelli S (2016) *Data-Centric Biology: A Philosophical Study*. Chicago: University of Chicago Press.

Levin N (2014) What's Being Translated in Translational Research? Making and Making Sense of Data between the Laboratory and the Clinic. *TECNOSCIENZA: Italian Journal of Science & Technology Studies* 5(1): 91–114.

Lewis J, Hughes J and Atkinson P (2014) Relocation, realignment and standardisation: Circuits of translation in Huntington's disease. *Social Theory & Health; London* 12(4): 396–415. DOI: http://dx.doi.org.ezproxy.uef.fi:2048/10.1057/sth.2014.13.

Lim ET, Würtz P, Havulinna AS, et al. (2014) Distribution and Medical Impact of Loss-of-Function Variants in the Finnish Founder Population. *PLOS Genetics* 10(7): e1004494. DOI: 10.1371/journal.pgen.1004494.

Lindee MS, Goodman AH and Heath D (2003) Anthropology in an Age of Genetics. Practice, Discourse, and Critique. In: Goodman AH, Heath D, and Lindee MS (eds) *Genetic Nature/Culture. Anthropology and Science beyond the Two-Culture Divide*. Berkeley: University of California Press, pp. 1–19.

Lipworth W, Forsyth R and Kerridge I (2011) Tissue donation to biobanks: a review of sociological studies. *Sociology of Health & Illness* 33(5): 792–811. DOI: 10.1111/j.1467-9566.2011.01342.x.

Lock M and Nguyen V-K (2011) *An Anthropology of Biomedicine*. Oxford: Wiley-Blackwell.

Mackenzie A, Waterton C, Ellis R, et al. (2013) Classifying, Constructing, and Identifying Life: Standards as Transformations of "The Biological". *Science, Technology, & Human Values* 38(5): 701–722. DOI: 10.1177/0162243912474324.

Madden R (2010) *Being Ethnographic: A Guide to the Theory and Practice of Ethnography*. London: SAGE.

Majewski IJ and Bernards R (2011) Taming the dragon: genomic biomarkers to individualize the treatment of cancer. *Nature Medicine*: 304–312. DOI: 10.1038/nm.2311.

Majumder MM, Silvennoinen R, Anttila P, et al. (2017) Identification of precision treatment strategies for relapsed/ refractory multiple myeloma by functional drug sensitivity testing. *Oncotarget* 8(34): 56338–56350. DOI: 10.18632/oncotarget.17630.

Malm J, Fehniger TE, Danmyr P, et al. (2013) Developments in biobanking workflow standardization providing sample integrity and stability. *Journal of Proteomics* 95. Special Issue: Standardization and Quality Control in Proteomics: 38–45. DOI: 10.1016/j.jprot.2013.06.035.

Marcon AR, Bieber M and Caulfield T (2018) Representing a "revolution": how the popular press has portrayed personalized medicine. *Genetics in Medicine*. DOI: 10.1038/gim.2017.217.

Marcus GE (1995) Ethnography in/of the World System: The Emergence of Multi-Sited Ethnography. *Annual Review of Anthropology* 24: 95–117.

Marcus GE (2011) Multi-sited Ethnography: Five or Six Things I Know About It Now. In: Coleman S and von Hellermann P (eds) *Multi-Sited Ethnography. Problems and Possibilities in the Translocation of Research Methods.* Routledge Advances in Research Methods. New York: Routledge, pp. 16–32.

Marko-Varga G (2013) BioBanking as the central tool for translational medicine CTM issue 2013. *Clinical and Translational Medicine* 2: 4. DOI: 10.1186/2001-1326-2-4.

Martin P, Brown N and Turner A (2008) Capitalizing hope: the commercial development of umbilical cord blood stem cell banking. *New Genetics and Society* 27(2): 127–143. DOI: 10.1080/14636770802077074.

Martin P, Brown N and Kraft A (2008) From Bedside to Bench? Communities of Promise, Translational Research and the Making of Blood Stem Cells. *Science as Culture* 17(1): 29–41. DOI: 10.1080/09505430701872921.

Mattila L (2015) Mitä tapahtuu biopankeissa ja konservatiivin ja liberaalin aivoissa? *Tiedeykkönen*. YLE ykkönen. Available at: http://areena.yle.fi/1-2690326 (accessed 11 May 2015).

Maughan T (2017) The Promise and the Hype of 'Personalised Medicine'. *The New Bioethics* 23(1): 13–20. DOI: 10.1080/20502877.2017.1314886.

McCormack P, Kole A, Gainotti S, et al. (2016) 'You should at least ask'. The expectations, hopes and fears of rare disease patients on large-scale data and biomaterial sharing for genomics research. *European Journal of Human Genetics*: 1403–1408. DOI: 10.1038/ejhg.2016.30.

M'charek A (2005) *The Human Genome Diversity Project: An Ethnography of Scientific Practice*. Cambridge: Cambridge University Press.

M'charek A (2013) Beyond Fact or Fiction: On the Materiality of Race in Practice. *Cultural Anthropology* 28(3): 420–442. DOI: 10.1111/cuan.12012.

Meijer I, Molas-Gallart J and Mattsson P (2012) Networked research infrastructures and their governance: The case of biobanking. *Science and Public Policy* 39(4): 491–499. DOI: 10.1093/scipol/scs033.

Meloni M (2017) Race in an epigenetic time: thinking biology in the plural. *The British Journal of Sociology* 68(3): 389–409. DOI: 10.1111/1468-4446.12248.

Meskus M (2009) *Elämän Tiede. Tutkimus Lääketieteellisestä Teknologiasta, Vanhemmuudesta Ja Perimän Hallinnasta.* Tampere: Vastapaino.

Meskus M (2018) *Craft in Biomedical Research: The IPS Cell Technology and the Future of Stem Cell Science*. London and New York: Palgrave Macmillan.

Meslin EM, Blasimme A and Cambon-Thomsen A (2013) Mapping the translational science policy 'valley of death'. *Clinical and Translational Medicine* 2: 14. DOI: 10.1186/2001-1326-2-14.

Meulenkamp TM, Gevers SJ, Bovenberg JA, et al. (2012) Researchers' opinions towards the communication of results of biobank research: a survey study. *European Journal of Human Genetics* 20(3): 258–262. DOI: 10.1038/ejhg.2011.216.

Mills IG and Sykes RB (2010) Taking Risks with Translational Research. *Science Translational Medicine* 2(24): 24cm10-24cm10. DOI: 10.1126/scitranslmed.3000667.

Ministry of Employment and the Economy (2014) *Health Sector Growth Strategy for Research and Innovation Activities*. 16/2014, MEE reports. Enterprise and innovation department. Available at: https://www.tem.fi/en/current_issues/publications/health_sector_growth_strategy_for_research_and_innovation_activities.98158.xhtml (accessed 11 November 2015).

Ministry of Employment and the Economy (2016) *Innovating Together: Growth Strategy for Health Sector Research and Innovation Activities: The Roadmap for 2016-2018*. työ- ja elinkeinoministeriö. Available at: http://urn.fi/URN:ISBN:978-952-327-142-5 (accessed 16 May 2017).

Ministry of Health and Danish Regions (2016) *Personalised Medicine for the Benefit of Patients. Clear Diagnosis Targeted Treatment Strengthened Research. Summary. National Strategy for Personalized Medicine*. Denmark: The Ministry of Health. Available at: http://www.sum.dk/~/media/Filer%20-%20Publikationer_i_pdf/2017/Personalised-Medicine-Summary/SUM_klar_diagnose_summary_UK_web.ashx (accessed 27 April 2017).

Ministry of Social Affairs and Health (2015) *Improving Health through the Use of Genomic Data. Finland´s Genome Strategy. Working Group Proposal*. STM. Available at: http://www.julkari.fi/handle/10024/126940 (accessed 11 November 2015).

Ministry of Social Affairs and Health (2016) *Report of the Expert Group Appointed to Evaluate the Integration of Finnish Biobanks*. 15 June. Helsinki. Available at: http://stm.fi/documents/1271139/3226819/FBB-EG-Report1_woannex.pdf/b36e3f31-8d43-4e64-973c-0f8c5426672b (accessed 19 June 2017).

Mirtti T and Rannikko A (2012) Eturauhassyövän yksilöllinen hoitovalinta - apuna molekyylipatologiset merkkiaineet ja biopankki. *Duodecim: Lääketieteellinen aikakauskirja* 128(24): 2497–2499.

Mittra J (2015) *The New Health Bioeconomy: R&D Policy and Innovation for the Twenty-First Century*. London and New York: Palgrave Macmillan.

Mittra J and Milne C-P (2013a) Introduction to Translational Medicine. In: Mittra J and Milne C-P (eds) *Translational Medicine: The Future of Therapy?* Singapore: Pan Stanford Publishing, pp. 3–16.

Mittra J and Milne C-P (2013b) *Translational Medicine: The Future of Therapy?* Singapore: Pan Stanford Publishing.

Mol A (2002) *The Body Multiple: Ontology in Medical Practice*. Durham and London: Duke University Press.

Montoya M (2011) *Making the Mexican Diabetic: Race, Science, and the Genetics of Inequality*. Berkeley, Los Angeles and London: University of California Press.

Moodley K and Singh S (2016) "It's all about trust": reflections of researchers on the complexity and controversy surrounding biobanking in South Africa. *BMC Medical Ethics* 17(1): 57. DOI: 10.1186/s12910-016-0140-2.

Moreira T and Palladino P (2005) Between truth and hope: on Parkinson's disease, neurotransplantation and the production of the 'self'. *History of the Human Sciences* 18(3): 55–82. DOI: 10.1177/0952695105059306.

Moreira T, May C and Bond J (2009) Regulatory Objectivity in Action: Mild Cognitive Impairment and the Collective Production of Uncertainty. *Social Studies of Science* 39(5): 665–690. DOI: 10.1177/0306312709103481.

Morrison M (2017) Infrastructural expectations: exploring the promise of international large-scale induced pluripotent stem cell banks. *New Genetics and Society* 36(1): 66–83. DOI: 10.1080/14636778.2017.1289470.

Müller-Wille S (2001) Carl von Linnés Herbarschrank. Zur epistemischen Funktion eines Sammlungmöbels. In: Heesen A te and Spary EC (eds) *Sammeln Als Wissen. Das Sammeln Und Seine Wissenschaftsgeschichtliche Bedeutung.* Göttingen: Wallstein, pp. 22–38.

Müller-Wille S and Charmantier I (2012) Natural history and information overload: The case of Linnaeus. *Studies in History and Philosophy of Science Part C: Studies in History and Philosophy of Biological and Biomedical Sciences* 43(1): 4–15. DOI: 10.1016/j.shpsc.2011.10.021.

Munafò MR, Nosek BA, Bishop DVM, et al. (2017) A manifesto for reproducible science. *Nature Human Behaviour* 1(1): s41562-016-0021–016. DOI: 10.1038/s41562-016-0021.

Murphy J, Scott J, Kaufman D, et al. (2008) Public Expectations for Return of Results from Large-Cohort Genetic Research. *The American Journal of Bioethics* 8(11): 36–43. DOI: 10.1080/15265160802513093.

Nadai E and Maeder C (2005) Fuzzy Fields. Multi-Sited Ethnography in Sociological Research. *Forum Qualitative Sozialforschung / Forum: Qualitative Social Research* 6(3). Available at: http://www.qualitative-research.net/index.php/fqs/article/view/22 (accessed 14 November 2017).

Nadai E and Maeder C (2009) Contour of the Field(s): Multi-sited Ethnography as a Theory-driven Research Strategy for Sociology. In: Falzon M-A (ed.) *Multi-Sited Ethnography. Theory, Praxis and Locality in Contemporary Research.* Farnham: Ashgate, pp. 233–250.

National Research Council (2011) *Committee on A Framework for Developing a New Taxonomy of Disease. 'Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease'*. The National Academies Collection: Reports funded by National Institutes of Health. Washington (DC): National Academies Press (US). Available at: http://www.ncbi.nlm.nih.gov/books/NBK91503/ (accessed 1 February 2018).

Nature (1998) Mining a rich seam of genetic diversity. 396: 304.

Nature Methods (2013) Enhancing reproducibility. 10(5): 367–367. DOI: 10.1038/nmeth.2471.

Nelson NC, Keating P and Cambrosio A (2013) On being "actionable": clinical sequencing and the emerging contours of a regime of genomic medicine in oncology. *New Genetics and Society* 32(4): 405–428. DOI: 10.1080/14636778.2013.852010.

Nelson NC, Keating P, Cambrosio A, et al. (2014) Testing devices or experimental systems? Cancer clinical trials take the genomic turn. *Social Science & Medicine* 111: 74–83. DOI: 10.1016/j.socscimed.2014.04.008.

Niederhuber JE (2010) Translating Discovery to Patient Care. *JAMA* 303(11): 1088–1089. DOI: 10.1001/jama.2010.281.

Nimmesgern E, Benediktsson I and Norstedt I (2017) Personalized Medicine in Europe. *Clinical and Translational Science* 10(2): 61–63. DOI: 10.1111/cts.12446.

Nobile H, Vermeulen E, Thys K, et al. (2013) Why do participants enroll in population biobank studies? A systematic literature review. *Expert Review of Molecular Diagnostics* 13(1): 35–47. DOI: 10.1586/erm.12.116.

Nobile H, Borry P, Pischon T, et al. (2017) Participants' decision to enroll in cohort studies with biobanks: quantitative insights from two German studies. *Personalized Medicine* 14(6): 477–485. DOI: 10.2217/pme-2017-0049.

Nordforsk (2014) *Joint Nordic Registers and Biobanks - A goldmine for health and welfare research*. Policy Paper 5. Oslo: Nordforsk. Available at: https://www.nordforsk.org/no/publikasjoner/publications_container/joint-nordic-registers-and-biobanks-a-goldmine-for-health-and-welfare-research (accessed 14 June 2017).

Nordforsk (2017) *Nordic biobanks and registers - A basis for innovative research on health and welfare — NordForsk*. Policy Paper 2/2017. Oslo: Nordforsk. Available at: https://www.nordforsk.org/en/publications/publications_container/nordic-biobanks-and-registers-a-basis-for-innovative-research-on-health-and-welfare (accessed 14 June 2017).

Norio R (2000) *Suomi-neidon geenit: tautiperinnön takana juurillemme johtamassa*. Helsinki: Otava.

Norio R (2003a) Finnish Disease Heritage I: *Human Genetics* 112(5–6): 441–456. DOI: 10.1007/s00439-002-0875-3.

Norio R (2003b) Finnish Disease Heritage II: population prehistory and genetic roots of Finns. *Human Genetics* 112(5–6): 457–469. DOI: 10.1007/s00439-002-0876-2.

Norio R (2003c) The Finnish disease heritage III: the individual diseases. *Human Genetics* 112(5–6): 470–526. DOI: 10.1007/s00439-002-0877-1.

Norio R and Löytönen M (2002) The Finnish disease heritage. *Fennia - International Journal of Geography* 180(1–2): 177–182.

Norio R, Perheentupa J and Nevanlinna RH (1973) Hereditary diseases in Finland; rare flora in rare soil. *Annals of clinical research* 5(3): 109–141.

Novas C (2006) The Political Economy of Hope: Patients' Organizations, Science and Biovalue. *BioSocieties* 1(03): 289–305. DOI: 10.1017/S1745855206003024.

Nowotny H and Testa G (2010) *Naked Genes: Reinventing the Human in the Molecular Age*. Cambridge, Massachusetts: MIT Press.

OECD (2007) *OECD best practice guidelines for biological resource centres*. Paris: Organisation for eonomic co-operation and development. Available at: http://www.oecd.org/sti/biotech/38777417.pdf (accessed 4 May 2018).

OECD (2009) *OECD Guidelines on Human Biobanks and Genetic Research Databases*. OECD. Available at: http://www.oecd.org/sti/biotech/44054609.pdf (accessed 4 May 2018).

Oikkonen V (2018) *Population Genetics and Belonging: A Cultural Analysis of Genetic Ancestry*. London: Palgrave Macmillan.

Ommen G-JB van, Törnwall O, Bréchot C, et al. (2015) BBMRI-ERIC as a resource for pharmaceutical and life science industries: the development of biobank-based Expert Centres. *European Journal of Human Genetics* 23(7): 893–900. DOI: 10.1038/ejhg.2014.235.

Ong A (2013) A Milieu of Mutations: The Pluripotency and Fungibility of Life in Asia. *East Asian Science, Technology and Society*: 2075241. DOI: 10.1215/18752160-2075241.

Ong A (2016) *Fungible Life: Experiment in the Asian City of Life*. Durham and London: Duke University Press.

Paavola A-L (2007) It's in the genes. *Universitas Helsingiensis*. Available at: http://www.helsinki.fi/uh/1-2007/juttu5.html (accessed 21 September 2016).

Palo JU, Ulmanen I, Lukka M, et al. (2009) Genetic markers and population history: Finland revisited. *European Journal of Human Genetics* 17(10): 1336–1346. DOI: 10.1038/ejhg.2009.53.

Palotie A and Peltonen-Palotie L (2004) Pitäisikö perustaa suomalainen biopankki? *Duodecim: Lääketieteellinen aikakauskirja* 120(14): 1710–1712.

Palotie A, Widén E and Ripatti S (2013) From genetic discovery to future personalized health research. *New Biotechnology* 30(3): 291–295. DOI: 10.1016/j.nbt.2012.11.013.

Pálsson G (2007) *Anthropology and the New Genetics*. Cambridge: Cambridge University Press.

Pálsson G (2008) The rise and fall of a biobank. In: Gottweis H and Petersen A (eds) *Biobanks. Governance in Comparative Perspective.* New York: Routledge, pp. 41–55.

Pálsson G and Prainsack B (2011) Genomic stuff: Governing the (im)matter of life. *International Journal of the Commons* 5(2): 259. DOI: 10.18352/ijc.247.

Paltiel L, Aarem J, Bækken S, et al. (2012) Biospecimen quality program in the biobank of the Norwegian Institute of Public Health. *Norsk Epidemiologi* 21(2). Available at: https://www.ntnu.no/ojs/index.php/norepid/article/view/1498 (accessed 14 December 2015).

Parry B (2004) *Trading the Genome: Investigating the Commodification of Bio-Information*. New York: Columbia University Press.

Peakman TC and Elliott P (2008) The UK Biobank sample handling and storage validation studies. *International Journal of Epidemiology* 37(suppl_1): i2–i6. DOI: 10.1093/ije/dyn019.

Pekkinen J (2015) Minkälaista työtä tehdään biopankissa? *Puheen Aamu*. YLE puhe. Available at: http://arenan.yle.fi/1-2629744 (accessed 5 November 2015).

Peltonen L (1997) Molecular Background of the Finnish Disease Heritage. *Annals of Medicine* 29(6): 553–556. DOI: 10.3109/07853899709007481.

Peltonen L (2000) Positional Cloning of Disease Genes: Advantages of Genetic Isolates. *Human Heredity* 50(1): 66–75. DOI: 10.1159/000022892.

Peltonen L, Jalanko A and Varilo T (1999) Molecular genetics of the Finnish disease heritage. *Human Molecular Genetics* 8(10): 1913–1923.

Peltonen L, Palotie A and Lange K (2000) Use of population isolates for mapping complex traits. *Nature Reviews Genetics* 1(3): 182–190. DOI: 10.1038/35042049.

Pemovska T, Kontro M, Yadav B, et al. (2013) Individualized Systems Medicine Strategy to Tailor Treatments for Patients with Chemorefractory Acute Myeloid Leukemia. *Cancer Discovery* 3(12): 1416–1429. DOI: 10.1158/2159-8290.CD-13-0350.

Petersen A (2005) Securing our genetic health: engendering trust in UK Biobank. *Sociology of Health & Illness* 27(2): 271–292. DOI: 10.1111/j.1467-9566.2005.00442.x.

Petersen A (2009) The ethics of expectations: biobanks and the promise of personalised medicine. *Monash Bioethics Review* 28(1): 05.

Petersen A (2015) *Hope in Health: The Socio-Politics of Optimism*. London and New York: Palgrave Macmillan.

Petryna A (2009a) Kokeilullisuus : maanlaajuiset kliiniset kokeet ja lääketieteen tulevaisuus. *Tiede & edistys* (2): 114–129.

Petryna A (2009b) *When Experiments Travel: Clinical Trials and the Global Search for Human Subjects*. Princeton: Princeton University Press.

Pitkänen K and Porkka K (2012) Biopankki - osa potilailden hyvää hoitoa 2012. *Duodecim: Lääketieteellinen aikakauskirja* (128): 1628–1629.

Prainsack B (2007) Research populations: biobanks in Israel. *New Genetics and Society* 26(1): 85–103. DOI: 10.1080/14636770701218183.

Prainsack B (2017) *Personalized Medicine: Empowered Patients in the 21st Century?* New York: NYU Press.

Presser L, Hruskova M, Rowbottom H, et al. (2015) Care.data and access to UK health records: patient privacy and public trust. *Technology Science*. Available at: https://techscience.org/a/2015081103/ (accessed 16 July 2018).

Rabinow P (2002) *French DNA: Trouble in Purgatory*. Chicago and London: University of Chicago Press.

Rabinow P and Dan-Cohen T (2005) *A Machine to Make a Future: Biotech Chronicles*. Princeton: Princeton University Press.

Raivola V, Snell K, Pastila S, et al. (2018) Blood donors' preferences for blood donation for biomedical research. *Transfusion* 58(7): 1640–1646. DOI: 10.1111/trf.14596.

Reardon J (2009) *Race to the Finish: Identity and Governance in an Age of Genomics*. Princeton, New Jersey: Princeton University Press.

Reardon J (2017) *The Postgenomic Condition: Ethics, Justice, and Knowledge After the Genome*. Chicago and London: University of Chicago Press.

Reichel J, Lind A-S, Hansson MG, et al. (2014) ERIC: a new governance tool for Biobanking. *European Journal of Human Genetics* 22(9): 1055–1057. DOI: 10.1038/ejhg.2014.6.

Repo P (2011) Biopankki aloittaa ensi viikolla. *Helsingin Sanomat*, 12 January. Helsinki. Available at: https://www.hs.fi/kotimaa/art-2000004843520.html (accessed 22 July 2018).

Repo P (2016) Uudet hoidot tehoavat hankaliinkin syöpiin – "Tiedän tosiasiat mutta luotan, ettei tämä ole vielä tässä". *Helsingin Sanomat*, 11 November. Helsinki. Available at: https://www.hs.fi/kotimaa/art-2000002929667.html (accessed 22 July 2018).

Rheinberger H-J (1997) *Toward a History of Epistemic Things: Synthesizing Proteins in the Test Tube*. Stanford, CA: Stanford University Press.

Richardson SS and Stevens H (2015) *Postgenomics: Perspectives on Biology after the Genome*. Durham and London: Duke University Press.

Rose H (2003) The Commodification of Virtual Reality: The Icelandic Health Sector Database. In: Goodman AH, Heath D, and Lindee MS (eds) *Genetic Nature/Culture: Anthropology and Science beyond the Two-Culture Divide*. Berkeley: University of California Press, pp. 77–94.

Rose H (2006) From Hype to Mothballs in Four Years: Troubles in the Development of Large-Scale DNA Biobanks in Europe. *Public Health Genomics* 9(3): 184–189. DOI: 10.1159/000092655.

Rose N (2009) *The Politics of Life Itself: Biomedicine, Power, and Subjectivity in the Twenty-First Century*. Princeton: Princeton University Press.

Salmela E (2012) *Genetic structure in Finland and Sweden : aspects of population history and gene mapping*. Doctoral Dissertation. University of Helsinki, Helsinki. Available at: https://dspace3.hulib.helsinki.fi/handle/10138/36772 (accessed 11 August 2017).

Salmén K (2017) Oi maamme luonto! *Aspekti*. YLE puhe. Available at: https://areena.yle.fi/1-4291752 (accessed 9 December 2017).

Schatz MC (2015) Biological data sciences in genome research. *Genome Research* 25(10): 1417–1422. DOI: 10.1101/gr.191684.115.

Scott CT, Caulfield T, Borgelt E, et al. (2012) Personal medicine—the new banking crisis. *Nature Biotechnology* 30(2): 141–147. DOI: 10.1038/nbt.2116.

Selin C (2008) The Sociology of the Future: Tracing Stories of Technology and Time. *Sociology Compass* 2(6): 1878–1895. DOI: 10.1111/j.1751-9020.2008.00147.x.

Shabihkhani M, Lucey GM, Wei B, et al. (2014) The procurement, storage, and quality assurance of frozen blood and tissue biospecimens in pathology, biorepository, and biobank settings. *Clinical Biochemistry* 47(4): 258–266. DOI: 10.1016/j.clinbiochem.2014.01.002.

Shim JK, Darling KW, Lappe MD, et al. (2014) Homogeneity and heterogeneity as situational properties: Producing – and moving beyond? – race in post-genomic science. *Social Studies of Science* 44(4): 579–599. DOI: 10.1177/0306312714531522.

Silverman D (2001) *Interpreting Qualitative Data: Methods for Analysing Talk, Text and Interaction*. London: SAGE.

Simeon-Dubach D and Watson P (2014) Biobanking 3.0: Evidence based and customer focused biobanking. *Clinical Biochemistry* 47(4–5). Biorepositories and Biobanks: 300–308. DOI: 10.1016/j.clinbiochem.2013.12.018.

Simeon-Dubach D, Zeisberger SM and Hoerstrup SP (2016) Quality Assurance in Biobanking for Pre-Clinical Research. *Transfusion Medicine and Hemotherapy* 43(5): 353–357. DOI: 10.1159/000448254.

Simpson B (2000) Imagined Genetic Communities: Ethnicity and Essentialism in the Twenty-First Century. *Anthropology Today* 16(3): 3–6.

Sitra (2015) Finland your testbed for next generation research & innovation. A presentation to be uploaded from the homepage, for the purposes of advertising Finland. Helsinki. Available at: http://www.sitra.fi/uutiset/perima-ja-terveys/varasta-tama-uusi-esitys-vie-suomen-genomiosaamisen-maailmalle (accessed 15 June 2016).

Snell K (2018) *Focus group discussions about genomic data. Report for the use of the Genome Centre working group.* Helsinki: Ministry of Social Affairs and Health.

Snell K and Tupasela A (2012) Miten suomalaiset suhtautuvat biopankkeihin? *Duodecim: Lääketieteellinen aikakauskirja* 128(16): 1685–90.

Snell K, Starkbaum J, Lauß G, et al. (2012) From Protection of Privacy to Control of Data Streams: A Focus Group Study on Biobanks in the Information Society. *Public Health Genomics* 15(5): 293–302. DOI: 10.1159/000336541.

Soini S (2016) Biobanks as a Central Part of the Finnish Growth and Genomic Strategies: How to Balance Privacy in an Innovation Ecosystem? *Journal of Law, Medicine & Ethics* 44(1): 24–34. DOI: 10.1177/1073110516644187.

Solberg B and Steinsbekk KS (2012) Managing incidental findings in population based biobank research. *Norsk Epidemiologi* 21(2): 195–201. DOI: 10.5324/nje.v21i2.1494.

Sosiaali- ja terveysministeriö (2007) *Biopankit, yhteinen etu. Ihmisperäisten näytekokoelmien hyödyntämistä selvittäneen työryhmän loppuraportti*. Reports of the Ministry of Social Affairs and Health 52. Helsinki: Sosiaali- ja terveysministeriö. Available at: http://www.julkari.fi/handle/10024/111274 (accessed 23 February 2016).

Sosiaali- ja terveysministeriö (2015) Biopankkilainsäädännön ohjausryhmän väliraportti 2015. Raportteja ja muistioita (STM): 2015:26. Available at: http://julkaisut.valtioneuvosto.fi/handle/10024/74513 (accessed 16 April 2018).

Star SL (1990) Power, technology and the phenomenology of conventions: on being allergic to onions. *Sociological Review* 38: 26–56. DOI: 10.1111/j.1467-954X.1990.tb03347.x.

Star SL (1999) The Ethnography of Infrastructure. *American Behavioral Scientist* 43(3): 377–391. DOI: 10.1177/00027649921955326.

Star SL (2016) Living Grounded Theory: Cognitive and Emotional Forms of Pragmatism. In: Bowker GC, Timmermans S, Clarke AE, et al. (eds) *Boundary Objects and Beyond: Working with Leigh Star*. Cambridge, Massachusetts: The MIT Press, pp. 121–142.

Star SL and Griesemer JR (1989) Institutional Ecology, 'Translations' and Boundary Objects: Amateurs and Professionals in Berkeley's Museum of Vertebrate Zoology, 1907-39. *Social Studies of Science* 19(3): 387–420.

Star SL and Lampland M (2009) Reckoning with Standards. In: Lampland M and Star SL (eds) *Standards and Their Stories. How Quantifying, Classifying, and Formalizing Practices Shape Everyday Life*. Ithaca and London: Cornell University Press.

Steinsbekk KS, Ursin LØ, Skolbekken J-A, et al. (2013) We're not in it for the money—lay people's moral intuitions on commercial use of 'their' biobank. *Medicine, Health Care and Philosophy* 16(2): 151–162. DOI: 10.1007/s11019-011-9353-9.

Stephens N, Atkinson P and Glasner P (2011) Documenting the doable and doing the documented: Bridging strategies at the UK Stem Cell Bank. *Social Studies of Science* 41(6): 791–813. DOI: 10.1177/0306312711423306.

Stephens N, Lewis J and Atkinson P (2013) Closing the regulatory regress: GMP accreditation in stem cell laboratories. *Sociology of Health & Illness* 35(3): 345–360. DOI: 10.1111/j.1467-9566.2012.01482.x.

Stevens H and Richardson SS (2015) Beyond the Genome. In: *Postgenomics. Perspectives on Biology after the Genome*. Durham and London: Duke University Press, pp. 1–8.

Strasser BJ (2008) GenBank--Natural History in the 21st Century? *Science* 322(5901): 537–538. DOI: 10.1126/science.1163399.

Strasser BJ (2009) Response to the letter 'Specimens Versus Sequences' by Guanyang Zhang. *Science* 323(27 March): 1672.

Strasser BJ (2011) The Experimenter's Museum: GenBank, Natural History, and the Moral Economies of Biomedicine. *Isis. A Journal of the History of Science Society.* 102(1): 60–96.

Strasser BJ (2012a) Collecting Nature: Practices, Styles, and Narratives. *Osiris* 27(1): 303–340. DOI: 10.1086/667832.

Strasser BJ (2012b) Data-driven sciences: From wonder cabinets to electronic databases. *Studies in History and Philosophy of Science Part C: Studies in History and Philosophy of Biological and Biomedical Sciences* 43(1): 85–87. DOI: 10.1016/j.shpsc.2011.10.009.

Strathern M (2003) *Audit Cultures: Anthropological Studies in Accountability, Ethics and the Academy*. London: Routledge.

Strathern M (2004) *Partial Connections*. Walnut Creek, CA: Rowman Altamira.

Strathern M (2014) Innovation or replication? Crossing and criss-crossing in social science. *Arts and Humanities in Higher Education* 13(1–2): 62–76. DOI: 10.1177/1474022212467603.

Sturdy S (2017) Personalised Medicine and the Economy of Biotechnological Promise. *The New Bioethics* 23(1): 30–37. DOI: 10.1080/20502877.2017.1314892.

Subramaniam B (2014) *Ghost Stories for Darwin: The Science of Variation and the Politics of Diversity*. Urbana, IL: University of Illinois Press.

Sunder Rajan K (2006) *Biocapital: The Constitution of Postgenomic Life*. Durham and London: Duke University Press.

Sunder Rajan K (2012) *Lively Capital: Biotechnologies, Ethics, and Governance in Global Markets*. Durham and London: Duke University Press.

Sunder Rajan K and Leonelli S (2013) Introduction: Biomedical Trans-actions, Postgenomics, and Knowledge/Value. *Public Culture* 25(3 71): 463–475. DOI: 10.1215/08992363-2144607.

Suzuki W (2015) The Care of the Cell. Onomatopoeia and Embodiment in a Stem Cell Laboratory. *NatureCulture*: 87–105.

Swan M (2012) Health 2050: The Realization of Personalized Medicine through Crowdsourcing, the Quantified Self, and the Participatory Biocitizen. *Journal of Personalized Medicine* 2(3): 93–118. DOI: 10.3390/jpm2030093.

TallBear K (2013) *Native American DNA: Tribal Belonging and the False Promise of Genetic Science*. Minneapolis and London: University of Minnesota Press.

Tambets K, Yunusbayev B, Hudjashov G, et al. (2018) Genes reveal traces of common recent demographic history for most of the Uralic-speaking populations. *Genome Biology* 19(1): 139. DOI: 10.1186/s13059-018-1522-1.

Tamminen S (2010) *Calculating Life. Nation, Nature, and the Nativisation of Nonhuman Genetics*. Social Psychological Studies 24. Helsinki: Faculty of Social Sciences, University of Helsinki.

Tamminen S, Webster PA and Vermeulen PN (2013) *Bio-Objects: Life in the 21st Century*. Farnham: Ashgate Publishing, Ltd.

Tarkkala H and Tupasela A (2018) Shortcut to Success? Negotiating Uniqueness in Global Biomedicine. *Social Studies of Science* 48(5): 740–761.

Tarkkala H, Helén I and Snell K (2018) From Health to Wealth: The Future of Personalized Medicine in the Making. *Futures*. DOI: 10.1016/j.futures.2018.06.004.

Taussig K-S, Hoeyer K and Helmreich S (2013) The Anthropology of Potentiality in Biomedicine: An Introduction to Supplement 7. *Current Anthropology* 54(S7): S3–S14. DOI: 10.1086/671401.

Taylor C (2004) *Modern Social Imaginaries*. Durham and London: Duke University Press.

Thacker E (2006) *The Global Genome: Biotechnology, Politics, and Culture*. Cambridge, Massachusetts: MIT Press.

Thévenot L (2009) Postscript to the Special Issue: Governing Life by Standards: A View from Engagements. *Social Studies of Science* 39(5): 793–813. DOI: 10.1177/0306312709338767.

Thompson C (2013) *Good Science: The Ethical Choreography of Stem Cell Research*. Cambridge, Massachusetts: MIT Press.

Thompson EE, Sun Y, Nicolae D, et al. (2010) Shades of gray: A comparison of linkage disequilibrium between Hutterites and Europeans. *Genetic epidemiology* 34(2): 133–139. DOI: 10.1002/gepi.20442.

Thornton H (2009) The UK Biobank project: Trust and altruism are alive and well: A model for achieving public support for research using personal data. *International Journal of Surgery* 7(6): 501–502. DOI: 10.1016/j.ijsu.2009.09.001.

Timmermans S (2015) Trust in standards: Transitioning clinical exome sequencing from bench to bedside. *Social Studies of Science* 45(1): 77–99. DOI: 10.1177/0306312714559323.

Timmermans S and Almeling R (2009) Objectification, standardization, and commodification in health care: A conceptual readjustment. *Social Science & Medicine* 69(1): 21–27. DOI: 10.1016/j.socscimed.2009.04.020.

Timmermans S and Berg M (2003) *The Gold Standard: The Challenge of Evidence-Based Medicine and Standardization in Health Care*. Philadelphia, PA: Temple University Press.

Timmons S and Vezyridis P (2017) Market-driven production of biospecimens and the role of NHS hospital-led biobanks. *Sociology of Health & Illness* 39(7): 1242–1257. DOI: 10.1111/1467-9566.12584.

Toivio T (2016) Biopankkitoiminta ottaa harppauksia eteenpäin. Available at: http://www.aka.fi/fi/akatemia/media/Ajankohtaiset-uutiset/2016/biopankkitoiminta-ottaa-harppauksia-eteenpain/ (accessed 16 June 2017).

Tsai Y (2010) Geneticizing Ethnicity: A study on the "Taiwan Bio-Bank". *East Asian Science, Technology and Society: an International Journal* 4(3): 433–455. DOI: 10.1007/s12280-010-9146-x.

Tsing AL (2015) *The Mushroom at the End of the World. On the Possibility of Life in Capitalist Ruins.* Princeton and Oxford: Princeton University Press.

Tupasela A (2006a) Kudostalous ja kaupalliset mallit biolääketieteellisen tutkimuksen muuttuvat ehdot. *Tiede & edistys* 31(2): 105–118.

Tupasela A (2006b) Locating tissue collections in tissue economies—deriving value from biomedical research. *New Genetics and Society* 25(1): 33–49. DOI: 10.1080/14636770600603469.

Tupasela A (2007) Re-examining medical modernization: framing the public in Finnish biomedical research policy. *Public Understanding of Science* 16(1): 63–78. DOI: 10.1177/0963662506070182.

Tupasela A (2008) *Consent Practices and Biomedical Knowledge Production in Tissue Economies*. Research Reports No. 256. Helsinki: University of Helsinki, Department of Sociology. Available at: https://helda.helsinki.fi/handle/10138/23533 (accessed 28 October 2015).

Tupasela A (2011) From gift to waste: changing policies in biobanking practices. *Science and Public Policy* 38(7): 510–520. DOI: 10.3152/030234211X12960315268056.

Tupasela A (2016a) Genetic Romanticism—Constructing the Corpus in Finnish Folklore and Rare Diseases. *Configurations* 24(2): 121–143. DOI: 10.1353/con.2016.0011.

Tupasela A (2016b) Populations as brands in medical research: placing genes on the global genetic atlas. *BioSocieties* 12(1): 47–65.

Tupasela A and Liede S (2016) State Responsibility and Accountability in Managing Big Data in Biobank Research: Tensions and Challenges in the Right of Access to Data. *SpringerLink*: 257–275. DOI: 10.1007/978-3-319-33525-4_12.

Tupasela A and Snell K (2012) National interests and international collaboration: tensions and ambiguity among Finns towards usages of tissue samples. *New Genetics and Society* 31(4): 424–441. DOI: 10.1080/14636778.2012.692548.

Tupasela A and Tamminen S (2015) Authentic, Original, and Valuable: Stabilizing the Genetic Identity in Non-human and Human Populations in Finland. *Studies in Ethnicity and Nationalism* 15(3): 411–431. DOI: 10.1111/sena.12163.

Tupasela A, Snell K and Cañada JA (2015a) Constructing populations in biobanking. *Life Sciences, Society and Policy* 11(1): 1–18. DOI: 10.1186/s40504-015-0024-0.

Tupasela A, Snell K and Cañada JA (2015b) *Patients, business and the state – Translating health information into sustainable benefits*. Tekes Review 322/2015. Helsinki: Tekes - the Finnish Funding Agency for Innovation.

Turrini M (2014) The Controversial Molecular Turn in Prenatal Diagnosis. CGH-array Clinical Approaches and Biomedical Platforms. *TECNOSCIENZA: Italian Journal of Science & Technology Studies* 5(1): 115–140.

Tutton R (2007) Constructing Participation in Genetic Databases: Citizenship, Governance, and Ambivalence. *Science, Technology, & Human Values* 32(2): 172–195. DOI: 10.1177/0162243906296853.

Tutton R (2009) Biobanks and the Inclusion of Racial/Ethnic Minorities. *Race/Ethnicity: Multidisciplinary Global Contexts* 3(1): 75–95.

Tutton R (2012) Personalizing medicine: Futures present and past. *Social Science & Medicine* 75(10): 1721–1728. DOI: 10.1016/j.socscimed.2012.07.031.

Tutton R (2014) *Genomics and the Reimagining of Personalized Medicine*. Farnham: Ashgate Publishing, Ltd.

Tutton R, Kaye J and Hoeyer K (2004) Governing UK Biobank: the importance of ensuring public trust. *Trends in Biotechnology* 22(6): 284–285. DOI: 10.1016/j.tibtech.2004.04.007.

Valvira and Tietosuojavaltuutetun toimisto (2015) Valviran ja tietosuojavaltuutetun toimiston yhteinen ohjaus koskien näytteeseen ja siihen liittyvän tiedon siirtämistä biopankkiin, tutkimusnäytteiden jatkokäytön turvaamista ja tunnisteellisten näytteiden sekä niihin liittyvien tietojen luovuttamista biopankista. Directional letter. Available at: http://www.tietosuoja.fi/material/attachments/tietosuojavaltuutettu/tietosuojavaltuutetuntoimisto/tiedotteet/puAfi7h0p/Valvira__TSV_ohjaus.pdf (accessed 9 April 2018).

van der Laan AL and Boenink M (2015) Beyond Bench and Bedside: Disentangling the Concept of Translational Research. *Health Care Analysis* 23(1): 32–49. DOI: 10.1007/s10728-012-0236-x.

van Lente H (2012) Navigating foresight in a sea of expectations: lessons from the sociology of expectations. *Technology Analysis & Strategic Management* 24(8): 769–782. DOI: 10.1080/09537325.2012.715478.

Varilo T, Laan M, Hovatta I, et al. (2000) Linkage disequilibrium in isolated populations: Finland and a young sub-population of Kuusamo. *European journal of human genetics: EJHG* 8(8): 604–612. DOI: 10.1038/sj.ejhg.5200482.

Varmus H (2006) The New Era in Cancer Research. *Science* 312(5777): 1162–1165. DOI: 10.1126/science.1126758.

Vezyridis P and Timmons S (2017) Understanding the care.data conundrum: New information flows for economic growth. *Big Data & Society* 4(1): 2053951716688490. DOI: 10.1177/2053951716688490.

Vierula H (2011) Vanhat pakastimet vaihtuvat nestetyppisäiliöihin. *Suomen lääkärilehti* 66(2): 18–19.

Vignola-Gagné E and Biegelbauer DPS (2013) Translational Research. In: Carayannis EG (ed.) *Encyclopedia of Creativity, Invention, Innovation and Entrepreneurship*. New York: Springer, pp. 1834–1843. Available at: http://link.springer.com/referenceworkentry/10.1007/978-1-4614-3858-8_338 (accessed 11 November 2015).

Vignola-Gagné E, Keating P and Cambrosio A (2017) Informing materials: drugs as tools for exploring cancer mechanisms and pathways. *History and Philosophy of the Life Sciences* 39(2). DOI: 10.1007/s40656-017-0135-4.

Virtaranta-Knowles K, Sistonen P and Nevanlinna HR (1991) A Population Genetic Study in Finland: Comparison of the Finnish- and Swedish-Speaking Populations. *Human Heredity* 41(4): 248–264. DOI: 10.1159/000154009.

Visscher PM, Brown MA, McCarthy MI, et al. (2012) Five Years of GWAS Discovery. *The American Journal of Human Genetics* 90(1): 7–24. DOI: 10.1016/j.ajhg.2011.11.029.

Wade P (2014) Race, Ethnicity, and Technologies of Belonging. *Science, Technology, & Human Values* 39(4): 587–596. DOI: 10.1177/0162243913516807.

Wade P (2017) *Degrees of Mixture, Degrees of Freedom: Genomics, Multiculturalism, and Race in Latin America*. Durham and London: Duke University Press.

Wade P, Beltrán CLL, Restrepo E, et al. (2014) *Mestizo Genomics: Race Mixture, Nation, and Science in Latin America*. Durham and London: Duke University Press.

Wahlberg A (2015) Making CAM auditable - technologies of assurance. In: Gale NK and McHale JV (eds) *Routledge Handbook of Complementary and Alternative Medicine: Perspectives from Social Science and Law*. London and New York: Routledge, pp. 129–143.

Wahlberg A (2018) *Good Quality: The Routinization of Sperm Banking in China*. Oakland, CA: University of California Press.

Wailoo K, Nelson A and Lee C (2012) *Genetics and the Unsettled Past: The Collision of DNA, Race, and History*. New Brunswick, New Jersey, and London: Rutgers University Press.

Wainwright SP, Williams C, Michael M, et al. (2006) From bench to bedside? Biomedical scientists' expectations of stem cell science as a future therapy for diabetes. *Social Science & Medicine* 63(8): 2052–2064. DOI: 10.1016/j.socscimed.2006.05.003.

Wainwright SP, Williams C, Michael M, et al. (2013) Stem cells, translational research and the sociology of science. In: Atkinson P, Glasner P, and Lock M (eds) *Handbook of Genetics and Society.* London: Routledge, pp. 41–58.

Waldby C (2000) *The Visible Human Project: Informatic Bodies and Posthuman Medicine*. Hove: Psychology Press.

Waldby C (2009) Biobanking in Singapore: post-developmental state, experimental population. *New Genetics and Society* 28(3): 253–265. DOI: 10.1080/14636770903151943.

Waldby C and Mitchell R (2006) *Tissue Economies: Blood, Organs, and Cell Lines in Late Capitalism*. Durham and London: Duke University Press.

Wang SR, Agarwala V, Flannick J, et al. (2014) Simulation of Finnish Population History, Guided by Empirical Genetic Data, to Assess Power of Rare-Variant Tests in Finland. *The American Journal of Human Genetics* 94(5): 710–720. DOI: 10.1016/j.ajhg.2014.03.019.

Webster A and Eriksson L (2008) Governance-by-standards in the field of stem cells: managing uncertainty in the world of "basic innovation". *New Genetics and Society* 27(2): 99–111. DOI: 10.1080/14636770802077009.

Wehling M (2008) Translational medicine: science or wishful thinking? *Journal of Translational Medicine* 6: 31. DOI: 10.1186/1479-5876-6-31.

Wheelwright J (2005) Finland's Fascinating Genes. *Discover*, April. Vol. 26 No. 4. Available at: http://science.jburroughs.org/mbahe/BioEthics/Articles/Findland2.pdf (accessed 28 June 2017).

Williams R (2017) Bloody infrastructures!: Exploring challenges in cord blood collection maintenance. *Technology Analysis & Strategic Management*: 1–11. DOI: 10.1080/09537325.2017.1337888.

Williams R (2018) Enactments of Race in the UK's Blood Stem Cell Inventory. *Science as Culture* 27(1): 24–43. DOI: 10.1080/09505431.2017.1322054.

Winickoff DE (2006) Genome and Nation: Iceland's Health Sector Database and its Legacy. *Innovations: Technology, Governance, Globalization* (1.2): 80–105.

Woolf SH (2008) The Meaning of Translational Research and Why It Matters. *JAMA* 299(2): 211–213. DOI: 10.1001/jama.2007.26.

Woolgar S and Lezaun J (2013) The wrong bin bag: A turn to ontology in science and technology studies? *Social Studies of Science* 43(3): 321–340. DOI: 10.1177/0306312713488820.

Wyatt D, Cook J and McKevitt C (2019) Participation in the BioResource. Biobanking and Value in the Changing NHS. *TECNOSCIENZA: Italian Journal of Science & Technology Studies* 9(2): 89-108–108.

Yadav B, Pemovska T, Szwajda A, et al. (2014) Quantitative scoring of differential drug sensitivity for individually optimized anticancer therapies. *Scientific Reports* 4(5193): 1–10. DOI: 10.1038/srep05193.

Yuille M, Ommen G-J van, Bréchot C, et al. (2008) Biobanking for Europe. *Briefings in Bioinformatics* 9(1): 14–24. DOI: 10.1093/bib/bbm050.

Zara I (2015) Population Isolates. In: Zeggini E and Morris A (eds) *Assessing Rare Variation in Complex Traits. Design and Analysis of Genetic Studies.* New York: Springer, pp. 107–122.

Zeggini E (2014) Using genetically isolated populations to understand the genomic basis of disease. *Genome Medicine* 6: 83. DOI: 10.1186/s13073-014-0083-5.

Zerhouni EA (2005a) Translational and Clinical Science — Time for a New Vision. *New England Journal of Medicine* 353(15): 1621–1623. DOI: 10.1056/NEJMsb053723.

Zerhouni EA (2005b) US Biomedical Research: Basic, Translational, and Clinical Sciences. *JAMA* 294(11): 1352–1358. DOI: 10.1001/jama.294.11.1352.

Zika E, Paci D, Schulte in den Bäumen T, et al. (2010) *Biobanks in Europe: Prospects for Harmonisation and Networking*. Publications Office of the European Union 24361 EN 5/2010, JRC Scientific and Technical Reports. Luxembourg: European Commission Joint Research Centre Institute for Prospective Technological Studies. Available at: http://ftp.jrc.es/EURdoc/JRC57831.pdf (accessed 4 May 2018).

Internet sources

Auria Biobank: Auria biobank homepage. Available at: http://www.auriabiopankki.fi/en (accessed 6.5.2013).

BBMRI-ERIC: BBMRI-ERIC homepage. Available at: http://www.bbmri-eric.eu/ (accessed 9.4.2018).

BBMRI.fi: BBMRI.FI homepage. Available at: http://www.bbmri.fi (accessed: 28.2.2015 & 10.2.2016).

Biobank Act: Biopankkilaki 688/2012. Available at: http://www.finlex.fi/fi/laki/alkup/2012/20120688#Lid2180503 (accessed 9.1.2014). Unofficial translation of Biobank Act is available at: https://www.finlex.fi/fi/laki/kaannokset/2012/en20120688.pdf, (accessed 29.4.2018).

Bioshare: Homepage of "BioSHaRE: Biobank Standardization and Harmonization for Research Excellence in the European Union" –project. Available at: www.bioshare.eu, (accessed 19.3.2018).

Borealis Biobank: Homepage of Borealis Biobank. Available at: http://www.oulu.fi/university/node/38474 (accessed 26.3.2018).

European Alliance for Personalized Medicine: Homepage of European Alliance for Personalized Medicine. Available at: www.eapm.eu (accessed 29.1.2018).

European Research Infrastructures: European Research Infrastructures - European Strategy Forum on Research Infrastructures (ESFRI) – homepage. Available at: http://ec.europa.eu/research/infrastructures/index.cfm?pg=esfri (accessed 19.3.2018).

Finnish biobanks: Homepage of Finnish Biobanks. Available at: www.biopankki.fi (accessed 9.1.2014)

Finnish disease heritage: http://www.findis.org/heritage.html, (accessed: 8.1.2018).

Finngen: Finngen-study homepage. Available at: www.finngen.fi/en, (accessed 8.1.2018).

Finnish hematology register and biobank: FHRB Sample Status - webpage. Available at: http://www.hematology.fi/en/shy/fhrb/fhrb-sample-status, (accessed 9.4.2018).

Fimea: "Terveysteknologian valvonta siirtyy Valvirasta Fimeaan" – Announcement on a webpage, 12.3.2018. Available at: http://www.fimea.fi/-/terveysteknologian-valvonta-siirtyy-valvirasta-fimeaan (accessed 9.4.2018)

Fimm: "Helsinki Urological Biobank has collected tens of thousands of high quality samples" – Announcement on the Institute for Molecular Medicine Finland –homepage. Available at: https://www.fimm.fi/en/news/1448266459 (accessed 4.3.2016).

Global Alliance for Genomics and Health: "About Us – Enabling genomic data sharing for the benefit of human health". Webpage. Available at: https://www.ga4gh.org/aboutus/, (accessed 19.3.2018).

Helsinki Biobank: "Helsingin Biopankin selvitys näytteenantajalle suostumuksen antamista varten. Versio 15.12.2016". Available at: https://www.terveyskyla.fi/helsinginbiopankki/SiteAssets/Documents/fi/15122016_selvitys%20n%C3%A4ytteenantajalle_Z13109.pdf (accessed: 15.2.2018).

HUS: Sample Collections of Helsinki Biobanks. Webpage. Available at: http://www.hus.fi/en/about-hus/helsinkibiobank/Sample_Collections/Pages/default.aspx, (accessed 18.4.2018).

International Organization for Standardization: "ISO/TC 276 Biotechnology". Webpage. Available at: https://www.iso.org/committee/4514241.html (accessed 9.3.2018).

Ministry of Social Affairs and Health: Individualized medicine initiative homepage. Available at: http://stm.fi/yksilollistetty-laaketiede, (accessed 8.6.2018).

Teknologianteollisuus: Homepage of Technology Industries of Finland. Available at: www.teknologiateollisuus.fi, (accessed: 23.4.2018)

Terveyskylä: Information for researchers –webpage of Helsinki Biobank. Available at: https://www.terveyskyla.fi/helsinginbiopankki/en/for-researchers , (accessed 28.3.2018).

Terveyskylä: Sample Collections –webpage of Helsinki Biobank. Available at: https://www.terveyskyla.fi/helsinginbiopankki/en/sample-collections, (accessed 26.3.2018).

APPENDIXES

Appendix 1.

Type of data	N	Description	Timespan
Interviews	47	47 interviews with 42 informants. 47/47 recorded, 45/47 transcribed. 2 interviews conducted alongside sample processing and, thus, part of participant observation, were not transcribed.	15.3.2012-28.4.2016
Observation in laboratories	4	Fieldnotes, photos (interviews conducted during observation are counted in interviews).	16.1.2013-6.6.2013
Observation in events and seminars	38	Fieldnotes, photos, leaflets	5.10.2011-1.6.2018
Written and published materials	over 150	Strategy papers, reports, newspaper articles, articles in journals, leaflets, other written materials such as information sheets provided at conferences and seminars, informed consent sheets, videos and radio interviews.	Covers a wider perspective of the development of the Finnish biomedical research field in the 2000s, public presentations about biobanks and health data, as well as miscellaneous materials collected during participant observations. Sources: e.g., Finnish Government, YLE, Suomen lääkärilehti, Duodecim, Helsingin Sanomat, TEKES, Academy of Finland, Nordforsk, Ministry of Social Affairs and Health. Plus scientific articles on Finnish genetic homogeneity and sample quality.

Appendix 2.

The informants. Informants have overlapping positions and may be counted in more than one category.

The positions/roles of the informants	N
Worked in a biobank or was involved in founding one	16
Researcher, professor	16
Pathologist	3
Medical doctor, clinician	11
Expert (pharma, patient organization, ombudsman, health data)	14
Laboratory personnel	4

Appendix 3.

Events attended.

1. Seminar: Tulevaisuus biopankkiirina – tekniset ja eettiset haasteet, 5.10-6.10.2011, Helsinki. [Future as a biobanker – technical and ethical challenges]
2. Press Conference: Kansallinen veritautien biopankki aloittaa toimintansa, 30.11.2011, Helsinki. [National biobank for hematological diseases starts to operate]
3. Event: Tiedekulma: Terveys ja hyvinvointi, 14.2.2012, Helsinki. [Science Corner: Health and Well-being]
4. Event: TUTKAS: Genomitieto kertoo - mistä tulemme, mihin menemme 12.6.2012 Helsinki. [Genome data reveals – where we come from, where we are going]
5. Seminar: Lääketieteellisen tutkimusetiikan seminaari, 29.10.2012, Helsinki. [Seminar on the ethics of medical research]
6. Lecture: "Personalized medicine 2020", inaugural lecture 18.1.2013, Helsinki.
7. Expo: Chembio 2013, Helsinki 21.3.2013. Seminar: Genomitieto yksilöidyssä hoidossa. [Genome data in personalized care]
8. Seminar: Biopankkiseminaari 23.5.2013, Kuopio. [Biobank seminar]
9. Press conference and discussion: Biopankkilain toimeenpanosta, 19.8.2013, Helsinki. [The implementation of the Biobank Act]
10. Public event: Voidaanko syöpä voittaa? - syöpäsäätiön 65-vuotisjuhlan yleisötilaisuus 26.9.2013, Helsinki. [Can we conquer cancer?]
11. Seminar: Monien mahdollisuuksien biopankkilaki, 2.10.2013, Helsinki. [The many possibilities of biobank legislation]
12. Seminar: Genomiikka muuttaa terveydenhuoltoa 2.10.2013, Helsinki. [Genomics transforms health care]
13. Lecture: Studia Medicina: Kantasolut saapuvat klinikkaan, 2.10.2013, Helsinki [Stem cells arrive at the clinic]
14. Conference: Laboratoriolääketiede ja näyttely 2013, 10.10-11.10.2013, Helsinki. Symposium 5 Biopankit ja geenitieto, Symposium 13 Histologia ja sytologia: Urologinen biopankki tutkimuksen tukena. [Symposiums on biobanks and genetic data, and histology and cytology: Urological Biobank supporting research]
15. Seminar: Building Bridges Autumn 2013: Biobanking in Clinical and Translational Research, 28.10.2013, Helsinki.
16. Seminar: Lääketieteellisen tutkimusetiikan seminaari, 29.10.2013, Helsinki. [Seminar on the ethics of medical research]

17. Conference: HandsOn Biobanks: From Biobanks to medical innovations, BBMRI, BBMRI-ERIC, P3G 24-25.9.2014, Helsinki.
18. Seminar: Kansallinen Genomistrategia - missä mennään? 12.1.2015, Espoo. [National Genome Strategy – Where are we now?]
19. Expo: ChemBio Finland 2015, 18-19.3.2015, Helsinki. Yksilöllistetty diagnostiikka ja hoito -GET IT DONE -seminaari, Suomalaiset biopankkitalletukset edistävät tutkimusta ja terveyttä –seminaari & New Cancer Treatments - syövän uudet hoitomahdollisuudet –seminaari. [Seminars on: Personalized diagnostics and care, Get it done seminar, Finnish biobank deposits advance research and health, New Cancer Treatments – new possibilities for treating cancer]
20. Conference: Nordic Trial Alliance Conference, 23.4.2015, Helsinki. Seminar on: Health registries and Biobanks – Excellent opportunities for clinical research and real-life evaluation.
21. Event: Upgraded Life Festival, Health Spa 19.5.2015, Helsinki.
22. Event: Get Personalized! – Summit by Sitra 25.5.2015, Ruoholahti.
23. Congress/Conference: HandsOn Biobanks: The EXPOnential relevance of biobanking. Clinical biobanks for personalized medicine. 29.7-30.7.2015, Milan, Italy.
24. Conference: Open bridges for life science data, 17.11-18.11.2015, Hinxton,UK.
25. THL Tietoaineistot tehokäyttöön – THL:n datapolitiikan julkistaminen, 26.1.2016, Helsinki.[Data sources for efficient use – publication of the data policy of the THL (National Institute of Health)]
26. Lecture: "Biopankit yksilöllistetyn lääketieteen vauhdittajina" 25.5.2016, Helsinki. [Speeding up personalized medicine with biobanks]
27. Event: Upgraded Life Festival, 31.5.2016, Helsinki
28. Lecture: Studia generalia: Ole osana tiedettä, 29.9.2016, Helsinki [Be part of science]
29. Expo: ChembioFinland 2017, 30.3.2017, Helsinki. Seminar: "Biopankit lääketieteen etulinjassa". [Biobanks in the front line of medicine]
30. Event: Upgraded Life Festival, 25-26.4.2017, Helsinki
31. Event: Dday, reboot Finland, 11.5.2017, Espoo.
32. Seminar: Biopankkiseminaari of BC Platforms, 19.5.2017, Helsinki. [Biobank seminar]
33. Seminar: Terveysalan kasvu: tutkimus- ja innovaatiopanostukset, 15.6.2017, Helsinki. [Health Sector Growth: Research and innovation investments]
34. Seminar: ISAACUS-väliseminaari, 13.11.2017, Helsinki.
35. Seminar: TUTKAS: Biopankkipäivä eduskunnassa, 5.4.2018, Helsinki. [Biobank-day in the Parliament]

36. Seminar: Tiedon vallankumous ja yksilöllinen terveydenhuolto, 19.4.2018, Helsinki. [Data revolution and individualized health care]
37. Seminar: Biobanking for Future Research and Health 28-29.5.2018, Helsinki.
38. Event: Upgraded Life Festival, 31.5-1.6.2018, Helsinki.

Appendix 4.

Table on "Biobanking Value Proposition: PPP: public-private partnership; FFPE: formalin fixed paraffin embedded; TMA: tissue microarray; EHR: electronic health record." Reproduced from the *Report of the Expert Group Appointed to Evaluate the Integration of Finnish Biobanks* published by Ministry of Social Affairs and Health (2016: 10).

	Sample category	Academic / Public Health value	PPP/commercial value	Strength	Weakness	Challenge
Existing today	Retrospective diagnostic pathology samples, partly in biobanks (FFPE)	tissue-based biomarkers (restricted genotyping, transcriptomics)	Modest: similar samples available from many sources; value only if phenotypic annotation (EHR, IHC etc.)	large numbers available (≈2 M), low cost, limited structured information (SNOMED); TMAs increase value	limited use; labor intensive	pathology expertise; lab techs
	Retrospective research samples from registries in biobanks (THL) (blood, DNA)	Genotyping, sequencing, blood-based biomarkers	Significant: value from annotation with disease-specific registry data	Currently available ≈200,000; utilized in research; deep phenotype in disease studied	no general EHR§ data annotation	Legacy IC may be narrow
	Retrospective research samples in various academic archives, not in organized biobanks (blood, DNA)	Genotyping, sequencing, blood-based biomarkers	Significant: value from annotation with disease-specific registry data	Currently available ≈10-100,000; utilized in research; deep phenotype in disease studied	no general EHR§ data annotation	Legacy IC may be narrow, access/ transfer process
	Specialized registries with longitudinal samples (HUB, FHRB) (fresh-frozen tissue, blood, DNA, body fluids, living cells, iPSCs etc.)	All omics tissue and blood biomarkers; translational research	Very high: but niche market	needed for high-end application; only option for translational research; ≈3000 available	sample number small; expensive; requires special infrastructure (by acad. researchers) cost/benefit may be low	funding, sample collection
New effort	Prospective consented samples, hospital/clinic or population-based (blood, DNA, etc.)	Genotyping, sequencing, blood-based biomarkers	Very high: if quantity is high (preferably 100,000s) and extensive EHR data annotation	Low cost per sample, prospective phenotype/EHR annotation can be planned, re-contacting possible;	current sample number small, high cost to collect sufficient number	IC, sample collection; funding; coordination