HELLENIC REPUBLIC

National and Kapodistrian University of Athens

EST. 1837

Department of History and Philosophy of Science &

Department of Informatics and Telecommunications

Interdepartmental Graduate Program:
Science, Technology, Society—Science and Technology Studies

MSc Thesis

"Health Data Sharing under the Imaginary of a European Health Data Space: *A comparative study of the performative role of imaginaries on health data sharing within the Greek and Norwegian BBMRI-ERIC research-network*"

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Athens, 2023

Abstract

In the last decade, digital health and health research has been omnipresent in policy agendas in the EU context, determining a discourse about progress that is based on the beneficial impact of science, technology, and biomedicine in data-driven healthcare. With these policy agendas, data-driven healthcare launches itself as a means for public authorities to respond to wider sets of problems related to not only health research and health care but also to budget restraints and demographic challenges. Subsequently, expectations and promises of a prosperous future for health and biomedicine in Europe, along with the handling of present and future risks, become key arguments in favour of sharing health data. These expectations are explicitly communicated in the latest European Commission mission letters, as well as in the proposal for a regulation of the European Health Data Space (EHDS). As a regulation, the EHDS will, through its performative power, create new kinds of responsibilities, both for the visioners – as their visions have tangible impacts on how potential futures might look – as well as for the researchers and the people on the ground who facilitate and handle the prospected data that is aimed to be shared. Consequently, the European Commission is prominently involved in creating, institutionalizing, and extending sociotechnical imaginaries. However, the process of creating, nourishing, and stabilizing a sociotechnical imaginary runs through several stages, especially in the EHDS, as it is an overreaching policy initiative involving a multitude of actors from a multitude of different national and regional contexts and organisational levels.

Within this framework, biobanks and biobank networks, like the BBMRI-ERIC, have often been endorsed as key infrastructures with the expectation that they would help to generate benefits and values through biomedicine, made possible by the discovery, storing, and sharing of samples and data. Nevertheless, reconceptualizing biobanks and stakeholders to fit under the EHDS expectations and visions of health data sharing is translated into tension with old practices and arrangements. Being attentive to expectations, visions, and imaginaries in data practices and research infrastructures is imperative in order to understand how data flows and do not flow. Thus, sharing of health data is very much about sociotechnical rearrangements being made and actions being taken that, arguably, are necessary for it to be realized.

By following a sociotechnical imaginary approach, this thesis offers insight into the performative dimension of European policy-making as well as into how the expectations and

visions of such policy initiatives are mediated among heterogeneous and competing expectations and visions. Drawing on approaches from the interdisciplinary field of study known as ‘Science, Technology, Society’ or ‘Science and Technology Studies’ (STS), this thesis sets out to analyse the currently predominant frames for reasoning for promoting EHDS. Additionally, through the use of a comparative case study, the thesis aims to understand how the expectations and visions of EHDS materialize within the biobank network of BBMRI-ERIC in Greece and Norway, especially on how it affects expectations regarding sharing of health data. By comparing the two cases, both distinct characteristics of Greece and Norway have been outlined and highlighted, and more generic insights have emerged.

Keywords: EHDS, HEALTH DATA, BIOBANKS, BBMRI-ERIC, SOCIOTECHNICAL IMAGINARY

Acknowledgments

I am truly grateful for the opportunity to be able to write this thesis as well as for the immense support I have received in the process of doing so. Moving more or less directly from an education in humanities and history of ideas into writing an STS thesis on sociotechnical outlooks regarding cross-country sharing of health data has been challenging, to say the least; yet it was a challenge that made it even more educational and fulfilling. There are many to thank for helping me through this educational and challenging process. First and foremost, I wish to thank my Thesis Advisory Committee, with a special thanks to Katerina Vlantoni who can only be described as having been an exemplary advisor in leading me through this work and keeping me grounded in the process. Another important figure to thank is Professor Aristotle Tympas, who has not only been unbelievably welcoming and generous throughout my first year of study in a new country, but who also introduced me to the exciting field of Science and Technology Studies (STS) in a way that has made me more motivated than ever to pursue a further academic career.

Finally, to my family, thank you for always supporting me throughout my life and education, encouraging me to travel abroad, and letting me choose my own paths in life. A special thank you to my father who has been acting as a constructive conversation partner throughout my writing process, and who has always been intellectually and emotionally engaged in my education.

August 2023, Athens

Abbreviations

BBMRI - the Biobanking and BioMolecular Resources Research Infrastructure

BBMRI-ERIC - the Biobanking and BioMolecular Resources Research Infrastructure-European Research Infrastructure Consortium

EHDS – European Health Data Space

EC – European Commission

EU – European Union

FAIR - Findable, Accessible, Interoperable, and Reusable

GDPR – General Data Protection Regulation

MS – Member States

RCN - The Research Council of Norway

TEHDAS – Towards a European Health Data Space

QM – Quality Management

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1 Introduction

In her State of the Union address on 16 September 2020 before the European Parliament, European Commission President Ursula von der Leyen announced a new legislative proposal to create a common European health data space (EHDS) - directly following up on her mission letter to Health Commissioner Stella Kyriakides, in which she stated: "I want you to work on the creation of a European Health Data Space to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes." (European Commission. Stella Kyriakides, COM/1, 2019). This policy agenda can be seen as an extension of the European data strategy adopted in February 2020, in which the European Commission (the EU's executive branch) stressed the importance of creating European data spaces, where the EHDS would be the first proposal for a domain-specific common European data space (European Commission. Directorate-General for Health and Food Safety [COM/DG SANTE/197/2], 2022). The key aim is to tap into the imagined potential of European health data so as to turn the wealth of health data across Europe into knowledge at the service of citizens:

> Health data can help achieve more efficient, higher-quality, safer and more personalised care, and help improve healthcare delivery. Health data and data science could dramatically transform public health and revolutionise healthcare systems, enabling life- saving healthcare improvements. Health data can also play a crucial role in speeding up the development of new medical products and treatments for patients who need them most (European Commission. Directorate-General for Health and Food Safety [COM/DG SANTE/196 final], 2022, p. 1).

European countries' health systems already generate, process, and store a vast amount of health data, and a successful governance of the use of these data and metadata implies significant socio-economic benefits. However, the complexity and divergence of rules, structures, and processes within and across Member States (MS) and other associated European countries makes it difficult to easily access and share health data. Accordingly, the legislative proposal to create the EHDS aims at enabling the European Union (EU) to make full use of the potential offered by a safe and secure exchange, use and re-use of health data (COM/DG SANTE/197/2, 2022). Building on legislation such as the proposed Data Governance Act[1], draft Data Act[2], the NIS Directive[3], and the General Data Protection

[1] EUR-Lex - 52020PC0767 - EN - EUR-Lex (europa.eu) .
[2] EUR-Lex - 52022PC0068 - EN - EUR-Lex (europa.eu).
[3] http://data.europa.eu/eli/dir/2016/1148/oj.

Regulation (GDPR)[4], the EHDS aims at addressing the complexity of present European rules on data sharing in the health sector. A policy agenda that gained particular urgency in the aftermath of the COVID-19 pandemic[5], which, according to EU officials, clearly demonstrated the importance of digital services in the health domain: "it has shown that up-to-date, reliable and FAIR health data is key in providing an efficient public health response to crisis and in developing effective treatments and vaccines. It has also significantly accelerated […] the sharing of research data" (COM/DG SANTE/196 final, 2022, p. 2). The pandemic made it clear that the public government and the EU as a whole needed to handle some important data, and to work in order to make them findable, accessible, interoperable and re-usable. Subsequently, both the European parliament and the Council of the EU pushed that the EHDS should be the priority for the health policies and data policies in general in Europe. Then, in May 2022, a final proposal for regulation of the European parliament and of the Council on the European Health Data Space was put forward, with the promise to help unleash the full potential of health data within Europe (COM/DG SANTE/197/2, 2022).

The promises and expectations of data-driven health care and health research, along with the recent pandemic and the risk of new ones, brought together new ideas of the scale of risks and manageable problems with a new political vision of how to govern the EU, now facing a form of second-generation digitization, where data sharing for ever more purposes is imagined to be made possible through data use and data centralization. The proliferation of health research and health care digital innovation strategies, roadmaps, and plans that have emerged offer a vision of a world transformed by data, together with prescriptions for pathways to this future. In the support and implementation of such policy agendas, the EC can be said to be engaged in technological foresight (Hilgartner 2007, p. 382), in which future-oriented expectations and imaginaries of technoscience are central. However, it seeks not only to anticipate the future but also to shape and/or transform it, by linking particular hopes and visions to practical political and policy activities (Martin, 2018, p. 80). Hopes and expectations that are embedded within policy approaches and strategies are not simply rhetorical, they have a material impact

[4]The GDPR provides the rights to access, to portability and to accessibility/transmission to a new controller of data. It also designates data related to health as a "special category of data", affording it special protection through the establishment of additional safeguards for its processing, like informed consent (http://data.europa.eu/eli/reg/2016/679/2016-05-04).

[5] The COVID-19 pandemic is a global outbreak of coronavirus, an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
The first cases of novel coronavirus (nCoV) were first detected in China in December 2019, with the virus spreading rapidly to other countries across the world. This led WHO to declare a Public Health Emergency of International Concern (PHEIC) on 30 January 2020, and to characterize the outbreak as a pandemic on 11 March 2020. (Coronavirus disease (COVID-19) pandemic (who.int)).

on what areas of science get funded and what kind of research is valued (Tarkalla et al, 2019). In practice, the EHDS (when regulated) will shape how healthcare delivery, research and innovation activities across the EU are implemented, thus making its impact transformative (Marelli et al., 2023). Hence, the EC explicitly aims to play a central role in creating forward-looking policy frameworks for the sharing of health data and, subsequently, also for the development of biotechnology and biomedicine over the coming decades.

Within this EU framework context, biobanks and biobank networks have often been endorsed as central infrastructures with the expectation that they would help to generate benefits and values, such as new insights, better health, innovation, and economic growth in the future through biomedicine made possible by the discovery, storing, and sharing of samples and data (Aarden, 2021; Beltrame & Hauskeller, 2018; Gibbon et al., 2018; Hoeyer, 2016; 2017; Litton, 2018; Mitchell & Waldby, 2010; Tarkkala & Tupasela, 2018). Biobanks are very diverse and exist within a variety of organizational settings that differ in size and operational practices, while the size of biobanks in terms of the number of samples they store, ranges from several hundreds to millions (Meijer et al, 2012). Biobanks can broadly be defined as: "…collections, repositories and distribution centres of all types of human biological samples, such as blood, tissues, cells or DNA and/or related data such as associated clinical and research data, as well as biomolecular resources, including model- and micro-organisms that might contribute to the understanding of the physiology and diseases of humans" (BBMRI-ERIC, January 25, 2023). As such, biobanks and biobank networks are envisioned as mediators for biomedical research through the sharing of data.

The Biobanking and BioMolecular Resources Research Infrastructure-European Research Infrastructure Consortium (BBMRI-ERIC) is of particular interest as it is developed almost exclusively under the auspices of European formalized procedures for establishing transnational European research infrastructures (Aarden, 2023). The BBMRI-ERIC was first set up in 2012 as a distributed research infrastructure, and today it consists of 23 member states and one international organisation, making it one of the largest research infrastructures for health research in Europe.[6] Throughout its course, the BBMRI-ERIC has developed several performance indicators to monitor the operation of the research infrastructure accordingly; most importantly, by actively contributing to the process of international standards development through the International Organisation for Standardization (ISO) and its general requirements for biobanking, which specify various aspects related to the quality

[6] More information: https://www.bbmri-eric.eu/about/.

management system of biobanks (Akyüz et al., 2023). From the outset, one of the main goals of BBMRI-ERIC has been to promote sample and data-sharing practices among its members. The network, as such, has become a vehicle for sample and data sharing, fitting into the data-driven expectations and visions of the EU (Tupasela, 2021). Hence, the BBMRI-ERIC has come to be viewed as a critical infrastructure for health, giving Europe a striking advantage "due to biobanks'" potential for a substantial impact on the economic growth and improvement of healthcare (Litton, 2018, p. 240).

Subsequently, biobanks and biobank networks, like the BBMRI-ERIC, are also expected to make scientific knowledge productive in new ways, leading to a shift in the focus of biobanking from mere sample storage to sharing, whereby the maintaining, sharing, accessing, and the re-use of data become an imperative task for biobanks and the researcher connected to biobanks (Aarden, 2023; Hoeyer, 2019; Ortega & Tupasela, 2019; Tarkkala et al, 2019). Henceforth, biobanks and biobank research networks are placed in an environment characterized by uncertainty that incessantly requires flexibility in regard to the very idea of what biobanks are and what is expected from them. Most evidently, biobanks and their users have to adapt to not only new technologies but also study designs and research strategies, and finally to preferred policy approaches to ensure that data can be combined and shared across different sites and countries. As such, they are deeply interrelated with the social arrangements that inspire them and sustain them along their developmental trajectory.

Going forward, the EU will provide major investments through the EHDS policy agenda, and these massive investments will undoubtedly influence health care and health research, as well as biobanks and biobank networks, but we do not know how.

This short introduction is not meant to question that health-related data are essential for advancing medical research, treatment, and care, or to say that an increasing amount of health data should not be made available for research purposes. Rather it should draw our attention to two things. First, it makes visible how the coexistence of available digital data, the capacity for easily handling ever bigger amounts of data, and the dominant framing of the promises and expectations of its timely and proficient use, have changed our perception of the legitimate use of health data. Second, it opens up the question of what health-related data is in the first place, and how it is to be collected, by whom, and for what purposes. While these aspects became highly visible and relevant during the COVID-19 pandemic, the observations are valid well beyond this, and they should lead to further reflection on how health data sharing is imagined and how the future of digital health infrastructures and research networks

connected to its facilitation and implementation is imagined. This proliferation of sharing of health data should turn analytic attention to less obvious spaces, where new imaginaries shape how health data sharing takes place. Data sharing among participants and researchers does not just happen; it is made to happen. Practices of sharing and the conditions for enabling health data sharing are always performed by someone, and maybe, more importantly, for someone. By taking into consideration the "facts on the ground" (Moen, 2022), through seeking input from stakeholders personally affected by the performative expectations and visions of policies, one might bring performance back into the landscape of political theory and help reposition science and technology as key sites for the constitution of modern social imaginaries (Jasanoff, 2015).

Therefore, in this thesis, I will not focus on the actual policy impact of the proposal for regulation on the European health data space - as this is hardly possible in such a complex all-encompassing overarching policy agenda involving many heterogeneous actors. Rather, my study sets out to analyse the current predominant frames for reasoning for promoting EHDS and whether it can be approached as a sociotechnical imaginary; and to follow how the expectations and visions of health data sharing are contested and/or stabilized in different organizational levels and in different contexts, focusing on the biobank network and stakeholders who actively work with, collect, and share the promissory health data.

The train of thought for my study goes as follows: Surely, imaginaries deriving from the proposal for regulation of the EHDS will shape practices and expectations regarding the sharing of health data. The EC, through the policy initiative for the implementation of a European health data space, is engaging in technological foresight in which future-oriented expectations and imaginaries of technoscience are central. As such, they have the power to modify how present resources are reconfigured and reorganized, to point toward a particular future, and even to mobilize that future today. However, the power of imaginaries is not purely performative. Promissory discourses promoting sociotechnical future imaginaries tend to be largely based on the visions of experts coming from the top, such as policymakers, but they are not always made meaningful for the people on "the ground" (Jasanoff, 2015). If the expectations of sharing of health data does not transfer to the visions of biobank professionals and researchers, then the data work needed for facilitation of sharing might not be meaningful for them. Additionally, disregarding cultural specificities and the particularities of different contexts can jeopardize the implementation of the practices that are envisioned. So, to be effective, policy agendas for the sharing of health data also need to be articulated and

embedded in practical measures for facilitating health data sharing in concrete ways and in actual political, economic, biomedical research and health care settings. Therefore, while these visions of future digital health solutions are rather promising, we should not overlook the potential challenges encountered in their realization. The EHDS creates new kinds of responsibilities, both for the visioners – as their visions have tangible impacts on how potential futures might look – and for the researchers and the people on the ground who facilitate and handle the prospected data that is aimed to be shared. Hence, the EHDS could be understood not only as a development project but also as a sociotechnical imaginary. Understanding the EHDS as a sociotechnical imaginary can help underline how the sharing of health data is not merely about health care or health research but also very much about sociotechnical rearrangements being made and actions being taken that, arguably, are necessary for it to be realized.

This study's research questions are therefore: How are imaginaries of a common European health data space:

i) made visible in the predominant frames for reasoning in the proposal for regulation of the EHDS policy document?

ii) constructing promissory expectations and visions of health data sharing?

iii) contested and/or stabilized by actors within national BBMRI nodes and how do they themselves envision health data sharing going forward?

To answer the research questions, I have analysed the EHDS proposal for regulation document so as to draw out the imaginaries, expectations, and visions within it. In addition, I have conducted five qualitative interviews with various actors in different organisational levels and contexts. I have also participated in a stakeholder forum conference on the EHDS.

In order to understand more about how imaginaries of the EHDS are contested and/or stabilised at different organizational levels and in different contexts, I will be comparing responses from central actors connected with the research network of BBMRI-ERIC in Greece and Norway. Both countries have longstanding collaborations with the BBMRI-ERIC infrastructure; Greece being a founder member state while Norway being an official observer state from the beginning. By comparing the two contexts, the peculiarities and similarities of

each case are elucidated. Moreover, a comparative case study can also produce more generic insights about challenges for the future implementation of the EHDS.

I have chosen to elaborate on some main strains within STS research on biomedicine and biobanking in order to discuss the predominant frames for reasoning for promoting EHDS and whether or not stakeholders within the BBMRI-ERIC network of and by expectations work and configure in pursuits to sustain and promote promissory features of data-driven health research and data sharing. Through an abductive approach, going back and forth between empirical data and theory, I have compiled some main concepts from STS that can help to explain and fruitfully discuss the empirical findings. The main STS concepts are based on the salience of expectations, visions, and imaginaries in health data and biobanking within the promissory bioeconomy.

The analysis of the data based on these concepts show that there are both differences and similarities between the two national cases. In addition, the two cases can tell us something about how the EHDS and its imaginaries are contested and/or stabilized in different national contexts. A focus on how imaginaries travel and how European policy visions are perceived in different contexts and at different organisational levels can bring up new questions concerning implementations of such policies.

1.1 Outline

The outlining of the thesis goes as follows. First, STS scholarly work will be presented and discussed in relation to the main concepts listed over, ending with the study's contribution to the literature being reviewed. The purpose of this is to ground the empirical study in theory and to make explicit where the analysis fits into the existing literature.

Next, the methodology used in data collection and analysis is outlined and defended. The methodology chapter gives a description of the data collection process and of the abductive approach to data analysis. Further, the quality of the study, in terms of reliability and validity, is reviewed.

In what follows, chapters 4 and 5, the findings and the analysis are presented in a four-fold structure. Firstly, there is a document analysis of the proposal for regulation, outlining and discussing the predominant frames behind the reasoning for promoting EHDS. Secondly, I approach the framing of the EHDS as a sociotechnical imaginary, by analysing the imaginaries, expectations and visions deriving from the document, based on some main

concepts from STS studies on imaginaries, expectations, and visions as presented in chapter 2. This is complemented with an analysis of the interview conducted with the TEHDAS representative as well as drawing on ethnography from my participation in the conference of the TEHDAS Stakeholders forum 2023. Next, the study outlines the BBMRI-ERIC research network official statements regarding the EHDS, before investigating the two cases of Greece and Norway and the organization of the BBMRI network within the respective countries. The second and the third part of the research question is answered, namely on how the stakeholders connected with national BBMRI nodes relates to imaginaries of the EHDS, and how they themselves envision health data sharing going forward. The analysis is built on semi-constructed qualitative interviews conducted with BBMRI-ERIC national node officials and researchers in each country. Finally, the foregoing analysis will be discussed in relation to the STS studies and to make explicit where the analysis fits into the existing literature and how the data and the analysis contributes and builds on previous STS scholarly work. The implications of the findings for the literature will be discussed: I juxtapose readings of the policy document with interviews to attend to the imaginaries, expectations, and visions, and how these are contested and/or stabilized.

In the conclusion, the analysis and discussions are summarised, combined with a discussion of the overarching research questions, my contributions, theoretical implications, and practical implications of the study. In addition, suggestions for future research are presented, commenting on the ways in which STS can fruitfully contribute and intervene in future work related to the EHDS, and on ways in which STS scholars have successfully done this previously in connecting fields of research.

2 The theoretical framework

Over the years, the relation of technological innovation to wider social developments has been addressed by numerous analysts in science and technology studies (STS), predominantly by pointing to the fact that technological innovations are shaped by the values of those developing and designing them, and that when designing technologies in specific ways, values and designs are inscribed into them (e.g., Winner 1986). Furthermore, by giving attention to the large-scale sociotechnical systems and to the response of modern societies to certain technological imperatives, it has been shown that some technologies require their social environments to be structured in particular ways (e.g., Winner, 1980). In addition, it has

been pointed out that it often falls to institutions of power to elevate some imagined futures above others, ascribing to them a dominant position for policy purposes (Kim & Jasanoff, 2015). In the pursuit of new sociotechnical pathways, the production and use of anticipatory knowledge (such as predictions, scenarios, forecasts, and narratives about possible futures), has become a salient feature of the action at the interface of the life sciences and society. Many forms of anticipatory knowledge have played a role in the process through which futures of the life sciences are envisioned and monitored, supported and opposed, bought and sold, nurtured and regulated, revised and reimagined. As such, anticipatory knowledge has been shown to articulate feasible futures and specific types of technopolitical order through the projection of visions of what is good and desirable, and worth attaining for a political community, making them both instrumental and futuristic (Hilgartner, 2007, p. 382).

Within STS, the performative force of sociotechnical pathways and the use of anticipatory knowledge and promises has been thoroughly studied (Jasanoff & Kim 2015; Felt et al., 2017). A key concern of STS research has been to investigate the performativity of future representations, showcasing how future-oriented discourses, practices and materialities shape the way society makes sense of science and technology, adjust how actors create strategy, and contribute to the shaping of technology, as well as to the development of entire sociotechnical fields (Konrad et al, 2017).This has been taking place most notably through the performative role of imaginaries, expectations, and visions.

According to *The Handbook of Science and Technology Studies* (Felt et al., 2017), the use of imaginaries offers new ways to investigate the relationships among science, technology and society. STS researchers' emphasizes that imaginaries are held collectively and draw attention to embedded visions of the social in operation, in particular technological and scientific developments, or regimes (McNeil et al, 2017). Imaginaries are instrumental and futuristic: "they project visions of what is good and desirable, and worth attaining for a political community; they articulate feasible futures" (Jasanoff & Kim, 2013). In addition to imaginaries, terms such as expectations and visions have been used for denoting future-oriented statements and representations in the STS literature (Konrad et al, 2017). Expectations can be linked with statements about future conditions or developments that imply assumptions about how likely these are supposed to be and how they travel in a community or public space. They emerge as the result of strategic voicing and dedicated promotional efforts of actors, and as the aggregated effects of discursive dynamics or the outcome of collective anticipatory practices, such as foresight, road mapping, or other forms

of joint, systematic exploration of future possibilities and developments, connecting it to the production and use of anticipatory knowledge. Moreover, expectations are rarely presented as neutral, value-free statements, but instead can be read as promises sketching the potential and assumed benefits which may follow from a technology. However, expectations are typically heterogeneous in that they refer both implicitly and explicitly to technical, economic or cultural developments and are not the exclusive domain of straight technical trajectories (Konrad et al., 2017, p. 467). Visions are tightly interwoven with the concept of expectations, but whereas expectations may be confined to particular technological developments or future states, the concept of visions often refers to more or less coherent packages of potential future states. More often, visions rely on a fuller portrait of an alternative world; one that includes revised social orders, governance structures, and societal values. Further, visions usually imply normative connotations, often being statements of desirable or preferable futures, while not necessarily including assessments of likelihood or plausibility (Konrad et al, 2017, p. 468).

An increasing number of STS scholars have embarked on investigations of imaginaries, expectations and visions associated with science and technologies, and in particular, the concept of sociotechnical imaginaries as collectively imagined forms of social life and social order reflected in the design and fulfilment of scientific or technological projects, has informed a growing body of work (Felt, 2015; Jasanoff & Kim, 2013; 2015). The work on sociotechnical imaginaries has largely focused on the ways in which broad future-oriented narratives anticipate and legitimate certain pathways (Konrad et al., 2017).

For instance, STS has greatly contributed to understanding the performative role of future-oriented expectations, visions, and imaginaries within the field of biomedicine, connected to the promissory and performative expectations and visions of “Bioeconomy”, “Big Data” and “Personal Medicine”. Concepts such as the Bioeconomy, Big Data, and Personal Medicine are all filled with expectations and visions to improve and take up innovative health technologies (such as digital ones) based on estimations of future potential gains, value generation, support of national competitiveness as well as solving global challenges. In particular, the emergence of a strong policy discourse on the Bioeconomy, as well as policies for data sharing and open-access, have garnered a great deal of attention within the STS field of research (Dozema & Hurlbut, 2017; Gibbon et al., 2018; Goven & Pavone, 2017; Hilgartner, 2007; Hoeyer, 2019; Tarkkala et al., 2019). STS scholars have also emphasised that multiple kinds of values are entangled in promissory policy discourses, including scientific or epistemic values,

biomedical or (public) health values, as well as commercial and financial ones (Mitchell & Waldy, 2010; Tarkkala & Tupasela, 2018; Tamminen, 2015).

As already underlined in the introduction, in contemporary biomedicine, biobanks exemplify a discourse about progress that is based on the beneficial impact of science, technology, and medicine on healthcare that they are imagined to enable in the future. Innovation in biomedicine about future therapies becomes associated with the future values generated form biobanks and biobanking networks that enable data collection and sharing (Beltrame & Hauskeller, 2018; Ortega & Tupasela, 2019; Tarkkala et al, 2019). Further, it has been pointed towards how expectations and visions regarding future biomedical and economic values facilitate investments from funding agencies and policymakers into biobanking infrastructures as the likes of BBMRI-ERIC (Aarden, 2017; Tarkkala & Tupasela, 2018; Tupasela et al., 2020). Promissory policy agendas in population health sciences have created extensive infrastructures of biobanks through which new sets of ideas about both populations and the individual emerge (Tarkkala & Tupasela, 2018; Tupasela et al., 2020). In addition, studies have drawn attention to expectations and promissory values that failed to materialise (Aarden 2017), or biobanks that were closed down (Larsson, 2019). Furthermore, financial sustainability has been identified as a major problem that many biobanks seem to meet in the face of promissory claims and expectations (Tupasela 2017; Meijer et al., 2012). Lastly, STS literature has paid close attention to what allows for data and samples to move and not move between different actors (Hoeyer et al., 2017; Metzler et al., 2023; Tupasela, 2021).

While this scholarly literature is too large and diverse to review here, and as this is by now a rather complex field of research, I point only to those aspects that promise to be helpful for my empirical research. In what follows, I review the relevant work in STS that connects with my empirical case, thematically, and deals with my case study, theoretically. I will present scholarly work on the salience of expectations, visions, and imaginaries in health data and biobanking within the promissory bioeconomy. This review of related work and relevant conceptual approaches in STS outlines a theoretical framework that provides a general lens to be used in the following empirical chapters and analysis.

2.1 The salience of expectations, visions, and imaginaries in health data and biobanking within the promissory bioeconomy

The emergence of a strong policy discourse on the knowledge-based bioeconomy and of policies for data sharing and open access has garnered a great deal of attention in the STS community on questions regarding what the bioeconomy entails. For instance, James Mittra and Giorgos Zoukas (2020) made it their effort to try to unpack the concept of bioeconomy by highlighting its promissory qualities. Their key point is that the expectations and visions that the bioeconomy brings with it is promissory, in that they are envisioned to generate value, support national competitiveness as well as responding to global challenges (Mittra & Zoukas, 2020, p. 16). For example, in the last decades digital health and datafication has been omnipresent in policy making in the EU context, promising to become the solution for many of the challenges that Europe's health care systems were facing, making the EU into a key region for the promoting of the bioeconomy. Given this, initiatives for developing the bioeconomy featured prominently in Horizon 2020 (the past EU Framework Program for Research and Innovation[7]). Promises of health and wealth turned the bioeconomy concept into a pervasive organizing principle within the European context (Tupasela, 2017). Hence, Mittra and Zoukas (2020, p.12) understand the bioeconomy as a primarily political project, in that political institutions, rights, and responsibilities within the bioeconomy are subordinated to the "needs" of a particular innovation regime. The bioeconomy subsequently brings with it promises of future health and wealth that generate an amalgam of policies, regulations, institutions, infrastructures, and technologies promoting advances in the life sciences.

For instance, Ulrike Felt, Ingrid Metzler and Lisa-Maria Ferent (2020, p.9) placed the GDPR policy agenda into a specific kind of bioeconomy: "a system built around the sharing of health data that aims at creating added value and innovation, and how this creation of value and innovation is funded in a sociotechnical imaginary". As such, the GDPR policy agenda can be conceptualized as a political innovation regime, in that it is envisioned to make it easier to harmonize data, envisioned to be a catalyst for adoptive harmonization of biobanks regulation within the European framework and to lead to a common regulatory framework throughout

[7] Horizon 2020 was the EU's research and innovation funding programme from 2014-2020 with a budget of nearly €80 billion. More information: https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-2020_en.

the EU so that shared definitions and standards may emerge. A harmonisation that is seen as being needed due to the constant flow of data and samples between MS.

Amongst STS scholars there is a shared agreement that the GDPR matters for biobanks. For example, Johannes Starkbaum and Ulrike Felt (2019), analysed how interventions by actors from data-dependent fields of science to the GDPR negotiations shifted the discourse from its key topic 'data protection', to a paradigmatic focus on 'protecting the health' of individuals and societies at large. This paradigm shift was labelled as a 'communitarian turn', emphasizing more strongly ideals such as equity and solidarity within the biobanking community. An effort that can be seen as part of an epistemic transition, where Big Data approaches were increasingly framed as necessary innovative modes for knowledge generation to serve the public good (Starkbaum & Felt, 2019, p.2). According to Starkbaum and Felt (2019), the promissory aspects of GDPR and EU policy agendas on health data sharing found a threshold in the biobanking community, as the expected and envisioned field of 'data-driven innovation' within the bioeconomy became increasingly dependent on access to abundant biological samples and related information that accompany and describe data (metadata), framed not only as valuable but as key elements of biomedical knowledge generation. Additionally, the GDPR regulation directly affected the sociotechnical assemblage of biobanks in that it shifted understandings of the role of biological materials and related data when it came to questions of ownership, use in research, and obligations towards those providing these samples/data. (Felt, Metzler and Ferent, 2020).

Consequently, the expectations and promises of the bioeconomy and the GDPR policy agenda, mobilised, justified, and legitimated the activities of scientists, biomedical professionals, biobankers, policy makers, and regulators around the making of biobanks. In this context, it transformed practices of biobanking, the use and sharing of material and data, and the practice of providing material for research (Felt, Metzler, and Ferent, 2020, p. 11). Thus, the biobank community became deeply intertwined with the bioeconomy. This development aligns with Mittra & Zoukas' (2020, p. 12) attention to how particular conceptualization of bioeconomy becomes attached to innovation policy and strategy, and how this shapes behaviour in the communities that are responsible for developing and applying biotechnology research. Biobank communities became subordinated to the "needs" of the European bioeconomy innovation regime, which brought with it an impact on research strategy and organizational practices, where biobanks were imagined as an important tool for making new types of research possible - and as a result, they were also expected to make

scientific knowledge productive in new ways (Tupasela, 2017, p. 188). Biobanks came to be described as a 'public good' in the sense of benefiting (future) society, pointing to the collective benefit flowing from giving broader access to data (Starkbaum & Felt, 2019).

Within the EU context, biobanks and the growing emphasis on data-driven medicine and genomics consequently all became part of the same promissory landscape – that of the bioeconomy (Tarkkala & Snell, 2022). Biobanks and the European biobank infrastructure BBMRI-ERIC can be considered to be a manifestation of the growing emphasis on data-driven medicine and genomes pushing for the use of Big Data to open up new fields of research and to enable ground-breaking health innovation (Starkbaum & Felt, 2019, p.9). In relation to the GDPR regulation, BBMRI-ERIC communicated that biomedical research has a 'substantive public interest' because it furthers knowledge about health and helps to develop new treatments and therapies (BBMRI-ERIC, 2015b, p.3, in Starkbaum & Felt, 2019). They thereby underlined the importance of access to high-quality samples and Big Data that could be shared across Europe. Connecting biobanks across Europe then supposedly ensures the ability to harvest benefits for European citizens in the future (Aarden, 2023, p. 5). Consequently, biobanks also came to reflect a new promissory discourse related to bioeconomies where much of the value of biobanking laid in its future use (Starkbaum & Felt, 2019, p. 3). By approaching biobanks as *promissory entities*, Aaro Tupasela (2017, p. 188) points to how financial and personal investment in biobanks is driven by expectations of future benefits of genetic science and technology.

The increasing possibilities and promissory policies of data-driven medicine to create and make use of Big Data, not only opened up new fields of research but were also expected to enable ground-breaking analytical possibilities in fields such as disease prediction or personalized health (Starkbaum & Felt, 2019, p.9). Both 'personalized medicine' and 'precision medicine' are two of several names for various streams of overlapping and related ideas also known as genomic, targeted, stratified or differentiated medicine, facilitated through the combination of data-related skills and technologies and the ability to aggregate, analyse, visualize, and make available high-quality data, larger or linked, in close to real time, depending on a view that social and natural phenomena can be counted and stored in previously unimaginable quantities and on ever larger scales (Hoeyer, 2016).

Many of the expected benefits of Personalized Medicine (PM) depends on reliable and valid biomarkers for diagnostics and treatment. However, the use of omics is also expected to predict diseases and, ultimately, to prevent it. In addition, issues of ageing societies, health

workforce shortages, and more generally rising expenditures on health and long-term care, are all imagined to be addressable through PM (Hoeyer, 2019). In this sense, PM and the necessary data intensification for its facilitation is envisioned as a way for public authorities to respond to a wider set of problems related to not only health research and health care but also to budget restraints and demographic challenges (Hoeyer, 2019, p. 542). As such, the expectations and visions of PM carries with it more or less coherent packages of potential future states (Konrad et al., 2017). Secondary use and re-use of data becomes a central precondition for medical progress and public benefits with links to economic aspects of society (Starkbaum & Felt, 2019, p 7).This makes visible how health data, by means of a very expansive and inclusive definition, have been used to make claims about an array of practices, activities, and economic sectors that, together, are expected to generate value, support national competitiveness, and deal with grand global challenges (Mittra & Zoukas, 2020, p. 15).

Nevertheless, Mittra & Zoukas (2020, p. 16) also point towards the realisation that the supposed biotechnology revolution is perhaps not as revolutionary and profitable as it has been assumed to be. Instead, they suggest that, more often than not, it has been based on unfulfilled expectations driven by the promissory discourses found in the bioeconomy's policy regimes, highlighting that promissory also entails that much of its value is speculative.

Klaus Hoeyer (2019) brings an interesting insight into the discussion of the promissory aspect of data and data intensification within the bioeconomy by proclaiming that data can deliver legitimate postponement of action. As an alternative to doing something today, Hoeyer claims that authorities sometimes postpone action until more data has been accumulated, making data serve as promises of future action (2019, p. 549). The promise of data, or what Hoeyer (2019) coins 'promissory data', becomes a more powerful resource – politically speaking – than data as evidence. This highlights that the value of data can be speculative and based on estimations of future potential rather than current reality (Mittra & Zoukas, 2020). As such, researchers and politicians seek to mobilize commitments, not so much through the use of data, but by dint of promissory expectations and visions (Hoeyer, 2019, p. 539). Thus, the visions of the bioeconomy imply normative connotations, with statements of desirable or preferable futures, while not necessarily including assessments of likelihood or plausibility (Konrad et al, 2017).

In mobilizing commitments, the advocating of urgency and unity has been described by several STS scholars as being a tool for promoting promissory policy agendas (Dozema & Hurlbut, 2017; Starkbaum & Felt, 2019). Heta Tarkkala and Karoliina Snell (2022),

emphasise that metaphors can be used to frame current and urgent needs so as to foster innovation and research-friendly policies, building on urgency in the general sense that time is running out. An important characteristic of such metaphors is that they simultaneously imply a larger narrative story and a prescription for action. According to Tarkkala and Snell, the sense of urgency might serve in creating pressure, and to an extent it might even be a condition of possibility for rapid developments and even innovations (2022, p. 7). They express a concern over the potential hasty regulations that such efforts may lead to and the way this is prone to silencing wider societal discussions on the topics (Tarkkala & Snell, 2022).

Another aspect of biomedical realisation not living up to its promised potential may have to do with how samples and data are shared and sometimes not shared. Although recognition for sharing data is becoming more of a merit in some contexts, STS has shown that there are still several concerns that hinder the sharing of samples and data. While policies of "open science" are shown to tend to imagine that material and information will flow if only an infrastructure is provided and a demand of sharing is installed (Hoeyer et al., 2017), and that the overarching importance of data curation practices is often overlooked by policymakers (Parmiggiani & Grisot, 2019), Aaro Tupasela (2021) introduces the concept of 'Data Hugging' as a way to show how value creation in biobanking can be far more complex and multifaceted than imagined in policy discourses within the knowledge-based bioeconomy. "Hugging" comes from an interest to care for the samples and data, as well as the ways in which they are used. "Hugging" also has structural factors related to it, shown in cases where biobanks are simply not able to find the funds needed to share samples and data (Tupasela, 2021, p. 527).

For instance, the sharing of samples and data within the European context has been related to inequality among member states in relation to how biobanking activities are nationally funded, where in some cases biobanks and biobank networks are not guaranteed adequate funding at the national level (Aarden; 2023; Tupasela, 2021). Such structural inequalities related to sharing have temporal dimensions to it in relation to the long-term sustainability of biobanking.

As a means to counter and/or understand the many complexities of sharing, Ingrid Metzler, Lisa-Maria Ferent, and Ulrike Felt (2023) give their attention to the biomedical professionals "on the ground", who plan, build, and maintain biobank collections, through exploring how values, visions and hopes makes the practice of curating samples and data meaningful for

those pursuing them. They emphasize how, in order for samples to become amenable and datafied in the future, they need to be collected, transported, handled, and stored in specific ways (Metzler et al., 2023, p. 3). This way, STS fosters awareness about the fact that data sharing does not just happen but it is made to happen, and that emphasizing the importance of social ties, emotions and affects, as well as expectations, visions and imaginaries in data practices and research infrastructures, is imperative in order to understand how data flows and not flow.

In the end, the concept of bioeconomy makes it visible how expectations emerge as the result of strategic voicing and dedicated promotional efforts of actors, connecting it to the production and use of anticipatory knowledge for promissory purposes either through expectations and visions for PM, Big Data, and the promissory role of biobanks and biobank networks (Konrad et al., 2017). As Felt, Metzler and Ferent assert, "expectations are never value-free statements about potential options; they are always already a step to guide developments into a specific direction; they can be seen as governing sociotechnical developments" (2020, p. 24). In this regard, 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 and creating research policy priorities. As such, promissory agendas also have a coordinating effect: they bring actors, institutions, and networks together and organize practices and communities; they also reconfigure and reorganize resources to highlight particular futures and shape practices, thus mobilizing futures today. In other words, they are sociotechnical performative political agendas.

The investigation and tracing of such imaginaries can offer some insight into how policy expectations and visions travel within the European Union, and into how they are sustained or disputed in the face of different actors at different levels, as well as reveal potential encounters and bottlenecks that government agencies possibly would face in the regulation of new ones, like that of the EHDS.

2.2 Contribution to the literature

These different STS perspectives have discussed the many aspects of what health data and sharing of health data necessitates, how it is perceived, its promissory attributes, and its future-oriented performativity on biobanks and biobank research. Much of what the promissory bioeconomy entails seems to be built around the expectations and visions of health data and the availability of said data. Health data sharing can therefore be said to be

merged in sociotechnical imaginaries - dependent on promissory technological advances as well as on the many social relations needed for its facilitation.

Conceptualising biobanks and biobanking networks as infrastructures is important as it highlights how the imaginaries of EHDS and the expectations and visions for health data sharing within biobanks and biobank networks is translated into tension with old practices and sociotechnical configurations, how they exist as forms separate from their purely technical functioning, an investigation of the futures of health research and care that get imagined through them (Argudo-Portal & Domènech, 2020; Felt, Metzler, and Ferent, 2020).

However, looking more closely into the infrastructure assemblage and the sustainability of biobanks and biobank networks following implementations of new policy regulations requires a lot of work. Therefore, I have chosen to focus more on the aspect of imaginaries regarding sharing of health data and whether the EHDS and its promissory statements regarding health data sharing is contested and/or stabilised by members and users of the BBMRI-ERIC research network and how they themselves envision health data sharing going forward within such an imagined health data space infrastructure.

As many of those using the term within STS indicate, all imaginaries are necessarily social in some ways (McNeil, 2017, p. 38). Since imaginaries are never solely tied to individuals, it is important to pay specific attention to the more collective character of imaginations, which can be rooted in a political and/or scientific community, in my case the BBMRI-ERIC research infrastructure.

To assist my analysis of the predominant frames for reasoning of the EHDS and the performativity of future-oriented expectations and visions of sharing of health data, I specifically find Jasanoff's (2015) definition of "sociotechnical imaginaries" aptly capturing the many strands and aspects of expectations, visions, and imaginaries in STS. She defines sociotechnical imaginaries as "collectively held, institutionally stabilized, and publicly performed visions of desirable futures, animated by shared understandings of forms of social life and social order attainable through, and supportive of, advances in science and technology" (Jasanoff, 2015, p. 6). Her definition privileges the word "desirable" because efforts to build new sociotechnical futures are typically grounded in positive visions of social progress. By this account, imaginaries have a powerful prescriptive character supporting specific futures that ought to be attained in specific contexts, implicitly prescribing the horizons of actions to be taken, thus making them performative. This performative dimension

of sociotechnical imaginaries also links this term to concepts more closely affiliated with instrumental political action—in other words, with policy as well as politics (Jasanoff, 2015, p. 28). As such, policy discourses and processes of issue framing and agenda-setting as a starting point can help ask how actors with the authority to shape imaginations construct stories of progress in their programmatic statements, and how they blend into these their expectations of science and technology. Those questions, in turn, can be turned toward specific types of technopolitical order (Jasanoff, 2015, p. 37). One may ask, for instance, as in my case, how imaginaries define European health care and health research with respect to sharing of health data.

Jasanoff (2015) further asserts that international organizations are prominently involved in creating, institutionalizing, and extending sociotechnical imaginaries. Nevertheless, imaginaries often come with specific local characteristics, be it legal, national political goal, expectations of value, etc. Therefore, the process of creating, nourishing, and stabilizing such a sociotechnical imaginary run through several stages, especially in the EHDS, as it is an overreaching policy initiative involving a multitude of actors from a multitude of different national and regional contexts and organisational levels.

By inquiring into imaginations as sociotechnical practices, I follow the embedding of the imaginary of a common European health data space and the expectations and visions of health data sharing into the institutions and infrastructure of biobanks in the biobank network of the BBMRI-ERIC. More specifically, how do the omnipresent agents, instruments, and processes of science and technology—in my case the national BBMRI-ERIC officials and researchers creating, collecting and sharing health data—help mediate among competing expectations; and to what extent are institutions of power (the EU) equipped to detect and correct for their own unexamined presuppositions when pursuing or implementing grand visions of progress?

My aim is not to dispute the visions and expectations and the imagined potential gains from an implementation of the EHDS. Rather it is to analyse the predominant framings for it by way of the notion of sociotechnical imaginary, and to see how these imaginaries, expectations and visions are contested, and/or stabilized within the BBMRI national network of Greece and Norway, and how they themselves imagine health data sharing going forward.

By following a sociotechnical imaginary approach, I can offer insight into the performative dimension of European policy-making as well as into how the expectations and visions of such policy initiatives are mediated among heterogeneous and competing expectations and

visions. Seemingly, this is one of the first STS studies on the sociotechnical imaginaries and the performative role of the EHDS on the BBMRI-ERIC network and its stakeholders. Further, looking at how such imaginaries are contested and/or stabilized adds to the literature on the salience of expectations, visions, and imaginaries within the promissory bioeconomy.

3 Methodology

The aim of this study is to develop an understanding of the ways in which the sociotechnical imaginary of the EHDS transforms the practices and future expectations of sharing of health data, if it does so at all. To do this, I have chosen to compare the experiences of biobanking professionals and researchers within the BBMRI-ERIC national networks of Greece and Norway. Understanding the sociotechnical imaginaries of the EHDS and the expectations and vision for cross-border sharing of health data, grasping the perspective of a variety of relevant actors, demands an approach which allows actors to express how they perceive and make sense of sharing of health data. This entails sharing their experiences, practices, assessments, justifications and visions related to biobanking and the sharing of health data. To collect this information, I have conducted interviews with different actors on different organizational levels in the two national contexts. The main empirical data for this thesis, therefore, consists of the EHDS proposal for regulation document and the data collected from five qualitative interviews, as well as data collected from participation in a stakeholders' forum conference.

In this chapter the methods of the study will be outlined. I start by explaining why I have chosen the research network of BBMRI-ERIC and Greece and Norway as a comparative case. Subsequently, I summarize how the data was collected, and provide a run-down of the different documents that have been reviewed, and how the qualitative interviews were conducted, and with whom. I then explain the data analysis process and what it entails to use an abductive approach. Lastly, I will evaluate the reliability and validity of the study. The ethical considerations that have been made will also be discussed.

3.1 Comparative case study

In order to gain more insight into how imaginaries of a common European health data space are contested and/or stabilized by stakeholders, and into how they envision health data sharing going forward, I chose to make use of the method of a comparative case study.

Jasanoff (2015) suggests that perhaps the most indispensable method for studying sociotechnical imaginaries is comparison. Likewise, *The Handbook of Science and*

Technology Studies (Felt et al., 2017) addresses questions regarding the epistemic and institutional geographies of science and technology and the importance of comparative work in order to generate insight on these issues. According to Felt et al. (2017), a comparative lens allows for questioning taken-for-granted practices, institutions, and structures and for asking how, despite making reference to ostensibly the same scientific and technological rationality and to shared values, different nation states or regions sometimes draw fundamentally different conclusions. In other words, comparison can raise awareness of technoscientific divides, of the diverse technopolitical cultures that develop within different places. Moreover, it can highlight the hierarchical knowledge orders at work, which create different impacts in different places (Felt et al., 2017, p. 254).

According to Jasanoff, the challenge for analysts is to conduct their own comparisons with epistemic charity and due respect for difference; not to apply universal yardsticks for measuring advances toward, or deviance from, allegedly transcendental ideals (2015, p. 36). In this regard, comparing across social and political structures therefore not only helps to identify the content and contours of sociotechnical imaginaries but also avoids the intellectual trap of taking as universal epistemic and ethical assumptions that turn out, on investigation, to be situated and particular.

3.1.1 BBMRI-ERIC research network in Greece and Norway

As outlined in the previous chapter, biobanks and the BBMRI-ERIC research infrastructure has garnered a lot of attention by STS scholars. The biobanking infrastructure BBMRI–ERIC is one of the earliest and allegedly largest infrastructures governed according to the European Research Infrastructure Consortium (ERIC) legal framework.[8] Hence, the BBMRI-ERIC is an already well-established critical infrastructure for health and health research in the EU (Litton, 2018, p. 8). From the outset, BBMRI-ERIC has had the scope to facilitate access to samples and data collections across Europe to advance biomedical research for the benefit of the European citizens, while also aiming to promote sample- and data-sharing practices among its members. As such, the network positions itself as a vehicle for sample and data sharing (Tupasela, 2021, p.514). Moreover, BBMRI-ERIC is official partners with the EHDS pilot project (HealthData@EU), described as work package leaders.[9]

[8] The ERIC is a specific legal form that facilitates the establishment and operation of Research Infrastructures with European interest. For more information: https://research-and-innovation.ec.europa.eu/strategy/strategy-2020-2024/our-digital-future/european-research-infrastructures/eric_en.
[9] Partners - EHDS2 Pilot - Official website.

In addition, biobanking in Europe has been characterized by asymmetrical relations (Aarden, 2023, p. 17). Biobanks' governance, organizational features, and funding actors vary across European countries (Meijer et al. 2012). And many biobanks and biobankers find themselves in situations that they did not originally envision for themselves regarding sharing, situations in which institutional goals may differ greatly from individual goals and interests (Tupasela, 2017, 2021). Therefore, it is interesting to research whether their members express expectations and visions regarding the sharing of health data and of the EHDS differently. This is done by using the Greek and Norwegian BBMRI-ERIC networks national nodes as a comparative case. By looking at two different nation-states, in my case with a very different point of departure (which I will elaborate on later on), the heterogeneous visions and expectations can be brought into light and scrutinised (Jasanoff, 2015).

I have chosen these two countries for several reasons. Mainly, because I easily gained access to information and informants in both countries. Another important factor was that both countries are official participants of the BBMRI-ERIC network and has been so since the starting face - Greece being stated as a founding member state while Norway as an official observer, before becoming a full member in 2018 (Litton, 2018). In addition, both countries are part of the TEHDAS project[10]. Moreover, the Norwegian Directorate of eHealth[11] is described as a work package leader in the HealthData@EU pilot projects[12]. And in Greece, the EHDS is explicitly mentions as a means of support for national digitisation strategies (OECD/European Observatory on Health Systems and Policies, 2021a).

Furthermore, Greece/Norway makes for an interesting case for comparative studies because the two countries have a somewhat different health care profile, where the technical maturity and efficiency of health care can be said to differ substantially.

Despite progress over the last 10 years, including the implementation of a nationwide ePrescription system, health information and digitalisation of health services in Greece rank among the least developed among EU countries. Per capita health expenditure in Greece

[10] More information: Partners - Tehdas.
[11] Established on January 1st, 2016, the Directorate of e-health is a sub-ordinate institution of the Norwegian Ministry of Health and Care Services. The Directorate of e-health is responsible for steering and coordination of e-health through close cooperation with regional health authorities, local authorities, technical organisations, and other interested parties.Main responsibilities include developing and implementing the national policy on e-health, establishing the requisite standards, and administrating the use of e-health methodology nationwide. (English - ehelse).
[12] The HealthData@EU Pilot project brings together 17 partners including health data access bodies, health data sharing infrastructures and European agencies. It will build a pilot version of the European Health Data Space (EHDS) infrastructure for the secondary use of health data which will serve research, innovation, policy making and regulatory purposes (Home - EHDS2 Pilot - Official website).

continues to be well below the EU average, spending 7.8 % of GDP, compared to 9.9 % in the EU in 2019. Despite declines since 2016, Greece recorded the second highest level of unmet needs for medical care before the COVID-19 pandemic (OECD/European Observatory on Health Systems and Policies, 2021a).

Norway on the other hand is characterized as having a very elaborate IT infrastructure, digitalized health services and very elaborate national registries for collecting structured data on all citizens from birth to death. Everyone in Norway is allocated a personal identification number at birth or immigration, which is used in all interactions with public authorities (and for many private services). Per capita spending on health in Norway has remained among the highest in Europe for a decade. The share of public spending is also the highest in Europe, at 86% in 2019. Access to health care is generally good in Norway, where in 2019, fewer than 1% of adults reported forgoing needed medical care, which is about half the EU average (OECD/European Observatory on Health Systems and Policies, 2021b).

Norway further makes for a very interesting case because, like other Nordic countries, extensive population registers and digital health records that are collected as part of the universal healthcare system are identified as particular strengths through which economic gain, new jobs and international competitiveness and attractiveness can be gained, to such an extent that these kinds of data have been termed the ‘new oil’ (Tupasela et al., 2020; Hoeyer, 2020; NordForsk, 2019).

In respect to biobanks and biobank networks, the Biobank of Norway represents one of the world’s largest existing resources within biobanking, while Greece seems to still be in the starting phase.

In conclusion, Greece and Norway make for an interesting case for comparative study because these countries are dissimilar in several ways. Moreover, there are things each case can learn from each other, and other cases can learn from them. Especially within European policy-making and implementation, such comparative analysis can be useful for understanding possible bottle necks and challenges that might translate to different situations and cases. Transferring knowledge and practices into different contexts is a difficult task, made evident by the many policy programs over the last decades, failed developmentalism, different approaches to the COVID-19 pandemic, and challenges with getting people to take the vaccines. These issues can be ascribed to the fact made clear by STS: that the interplay between technology and politics is embedded in the culture, history and society, which is

often specific to a nation state, and by disregarding the cultural specificities one can risk an unsuccessful implementation of said practices, which in several instances could turn out to have fateful consequences not only for the political process and the success of new policy initiatives, but also for the actual lived life of people, the users - the people on the ground (Jasanoff, 2015).

Therefore, a comparative analysis on Greece and Norway within the BBMRI research network and their visions and expectations regarding sharing of health data within the context of the EHDS could disclose possible differential capacities and requisites for the sharing of health data and its means of organization, while at the same time perhaps elude to the degree of Greece's and Norway's enabling environments and maturity to join the EHDS.

It is important to note that Norway is not a full MS of the EU. However, Norway is closely linked with the EU through membership in the Agreement on the European Economic Area (EEA), which brings together all the 27 EU Member States and three of the European Free Trade Association (EFTA) countries, Iceland, Norway and Liechtenstein in a Single Market. [13] Norway is furthermore a member of the Schengen Area, which gives its citizens the right to travel passport-free within the Schengen Area.[14]Additionally, Norway is stated as participating on an equal footing with EU countries in numerous EU framework programs, such as Horizon Europe.[15] Moreover, the proposal for regulation document of the EHDS is explicitly stated to be a text with EEA relevance (COM/DG SANTE, 2022). Subsequently, Norway can be viewed as an equal partner also within the policy agenda of the EHDS. As such, throughout the thesis, the case of Norway can be framed on equal footing with MS in the discussions and analysis of the EHDS.

3.2 Data collection

According to Jasanoff (2015), policy documents can be mined for insights into the framing of desirable futures, as well as for specific verbal tropes and analogies that help identify elements of the imaginary. Documents and other verbal texts related to science, technology,

[13] The EEA Agreement guarantees equal rights and obligations within the Internal Market for individuals and economic operators in the EEA. It provides for the inclusion of EU legislation covering the four freedoms — the free movement of goods, services, persons and capital — throughout the 30 EEA States. In addition, the Agreement covers cooperation in other important areas such as research and development, education, social policy, the environment, consumer protection, tourism and culture, collectively known as "flanking and horizontal" policies. The Agreement guarantees equal rights and obligations within the Internal Market for citizens and economic operators in the EEA. More information: EEA Agreement | European Free Trade Association (efta.int).
[14]More information: https://home-affairs.ec.europa.eu/policies/schengen-borders-and-visa/schengen-area_en.
[15] More information: https://www.eeas.europa.eu/norway/european-union-and-norway_en?s=174.

and power provide some of the most accessible and ubiquitous resources for analysing sociotechnical imaginaries (Jasanoff, 2015, p. 41).

In my analysis, the proposal for regulation document and other relevant documents can tell us something about how efforts to build and implement the EHDS are grounded in positive visions of social progress. It allows me to explore the prescriptive character supporting specific futures that ought to be attained, implicitly prescribing the horizons of actions to be taken.

I have limited the scope and range of documents to those explicitly referring to the EHDS. As such, the documents can be described as quite recent documents, meaning from the past two to five years. My chosen topic, the EHDS, is a very contemporary subject, especially considering that the proposal for regulation is under review at the moment of time of writing. The creation of European data spaces can be traced back to the policy initiative of the European data strategy adopted in February 2020 (European Commission. Directorate-General for Health and Food Safety [COM/DG SANTE/197/2], 2022). Documents and literature explicitly referring to the EHDS document has naturally only occurred after the publication of said document. Therefore, there is a limited number of public documents available that touches upon my chosen topic. However, as made clear in the introduction and in the theoretical framework chapter, initiatives for health data sharing are not new, and the EHDS builds on previously policies (GDPR), and as such, some relevant documents and literature can also be traced back in time.

The main empirical data is the Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space (COM/DG SANTE/197/2). The additional documents that I have collected and analysed are:

> European Commission. Directorate-General for Health and Food Safety. (2022). COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL A European Health Data Space: harnessing the power of health data for people, patients and innovation (COM/DG SANTE/196 final) EUR-Lex - 52022DC0196 - EN - EUR-Lex (europa.eu).
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> European Commission. Stella Kyriakides. (2019). President von der Leyen's mission letter to Stella Kyriakides. (COM/ 1 DECEMBER 2019) mission-letter-stella-kyriakides_en.pdf (europa.eu).

3.3 Qualitative interviews

To supplement the documents and to extract both explicit and implicit expectations and visions connected to the imaginaries of the EHDS, I have conducted five qualitative semi-structured interviews with key individuals, all connected to the BBMRI-ERIC research network, either as officials, biobank professionals or researchers working with and/or creating data. I tried to interview similar types of actors in each case. The people I interviewed were found with the help of my thesis' advisors through their contacts from an ongoing research project[16], or through me contacting potential participants directly.

One interview subject is involved in the TEHDAS project, having been central in conducting TEHDAS country visits[17], as well as having written and co-authored several TEHDAS reports, and as such working directly with the implementation and configuration of the EHDS on a policy level; two interviews were conducted with actors related to the BBMRI network in Greece, one of them the deputy representative of BBMRI.gr, the other one a clinical researcher, who is in the process of starting up a new biobank; the last two interviews were conducted with actors connected with the BBMRI network in Norway, one of them the director of Biobank Norway, the other one a researcher and a data user. All these different actors have been informants about the various and heterogeneous understandings of the expectations and values of cross-country health data sharing embedded in and realised through biobanks.

The interview with the representative from TEHDAS is meant to help gain more insight and perspectives into the discussion surrounding the EHDS as a sociotechnical imaginary. The purpose of the interview with the representatives from the different national BBMRI-ERIC research networks of Greece and Norway has been to gain more insight into how high-standing BBMRI officials in two different European national contexts express their expectations and visions regarding the sharing of health data and the regulation of the EHDS, and whether it aligns with the imaginaries of the EHDS. Additionally, the two researchers provided the perspective from the data collector, handler, and user perspectives – the perspectives and "facts on the ground" (Moen, 2022).

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[16] The research project "Contextualizing biobanking in Greece: histories, practices, discourses–BIO-CONTEXT" (2021-2024), led by Dr. Katerina Vlantoni (PI), is hosted in the Department of History and Philosophy of Science, National and Kapodistrian University of Athens, and was supported by the Hellenic Foundation for Research and Innovation (H.F.R.I.) under the "2nd Call for H.F.R.I. Research Projects to support Post-Doctoral Researchers" (Project Number: 00089).

[17] More information: https://tehdas.eu/packages/package-4-outreach-engagement-and-sustainability/tehdas-country-visits/.

As I have had little knowledge on the topic beforehand and being more interested in the expectations and visions expressed by the interviewees, not necessarily in the facts or the technological specificities of biobanking and sharing of health data practices, the implicit views and perceptions are more central for my inquiry than the explicit ones. Therefore, a less structured interview provides me with the leeway and the atmosphere needed to seek the information that I want. The aim of such qualitative semi-structured interviews is to both cover predetermined topics, as well as being open to tangents and new topics (Yin, 2016). Listening to people's spoken words, as opposed to dominating conversations with your own words, can produce helpful insights into people's thoughts about what is going on (Yin, 2016, p. 28). As such, semi-structured qualitative interviews can tell us something about the world seen from the interviewee's point of view.

Consequently, it is important to have a semi-structured interview guide and sufficient time to allow for deeper responses and relevant digressions. When used properly, an interview guide in effect serves as a conversational guide, producing a "guided conversation" (Yin, 2016, p. 147). The interview guide usually contains a small subset of key words tailored to the topics considered to be directly relevant to a given interview, followed by some brief probes and words reflecting follow-up queries, but the interview guide should in no sense be considered a questionnaire. A more structured interview, for example as in the form of a survey, would make it possible to interview more people and get more data points, but it would come at the expense of depth (Yin, 2016, p. 147). And since imaginaries in many cases are communicated implicitly, it would be difficult to derive and analyse the interviewees response only based on surveys.

The interview guide that I made was to some degree adapted to fit the informants' profile, background, knowledge, and position. It also reflected my knowledge of the case at that time. Still, the guide followed a general structure of five main sections: introduction of role and task and project/institution/organisation; on the BBMRI-ERIC national network; funding and sustainability of biobanks; standards and interoperability; and question related more directly to the EHDS. The first and the last section were always in that order, whereas the middle sections sometimes changed depending on the flow of the conversation. I made sure not to bring up the EHDS before the end of the interview as I wanted to expose possible implicit expectations and visions on cross-country sharing of health data throughout the conversation before explicitly referring to the EHDS. This is important because when examining visions and expectations of the future and how an emerging sociotechnical imaginary is perceived,

there are implicit assumptions and beliefs that lie behind the perceptions (Jasanoff, 2015, p. 35). Since the interview participants had different roles and professions some of the questions were altered to fit their respective situation better . For example, I asked the BBMRI national node director and deputy representative more about their national node, while I asked the researchers more questions related to the biobanking practices and collection and sharing of data. Lastly, the interview with the representative from TEHDAS was structured more towards the EHDS, aiming at adding to the analysing of the visions and expectations of the official EHDS proposal for regulation document.

More specifically, the purpose of the first section was to get a clear image of their work and position. The interviewees were asked about their backgrounds and the project or institution they were part of. This created a baseline for understanding the rest of the information that was provided throughout the interview, as well as being a point of interest in its own right.

The second talking point was about how the national node is organised and supported in the country. This was to gain more insight into how the research infrastructure of BBMRI operates, how it is integrated in the country related to policy and politics and the expectations deriving from that, and to gauge the perceived importance of the different actors in the different contexts.

The third and fourth sections focused on the sustainability of biobanks and the capabilities for sharing of health data. The purpose of these sections was to get a sense of the enabling environment for data sharing and the maturity of biobanks to do so, and the interviewees expectations and needs for the future.

In the last section, I asked about their relationship towards the EHDS and cross-country data sharing. This was mainly to get more insight into the actors' visions and expectations regarding a future common European health data space and to map out the degree to which the imaginaries of the EHDS are contested, and/or stabilized.

Overall, I intended to grasp the participants' reflections on recent developments towards health data sharing, and to get a more detailed understanding of the future-oriented expectations and vision regarding health data sharing and the potential performativity of the sociotechnical imaginary of the EHDS.

3.3.1 Transcription

Interviews were conducted online, with one exception (face-to-face), lasting approximately one hour, and fully transcribed. All interviews were conducted in English. This was a deliberate choice since through exploring how sociotechnical imaginaries are contested, and/or stabilized it is important to analyse the language, listening to people's spoken words (Yin, 2016). Moreover, translation is always problematic, and would be affected by the translator's subjectivity. Therefore, by conducting all interviews in English mistranslations were not a topic to consider, as the risk of altering what was expressed by the interviewees was minimal. Also, the proposal for a regulation document has been read and analysed in English, and BBMRI-ERIC's official language is English. Therefore, it made sense to stick to the same language. For the TEHDAS Stakeholder Forum conference, the presentation slides used in the conference and events were collected from the Internet, or notes were made from them along with participants' observations.

3.4 Data analysis

Arriving at my specific research questions, theory selection and analysis of data, is the result of an abductive approach. According to Alvesson (2018), an abductive approach alternates between theoretical concepts and empirical findings. In abduction, a single case is interpreted from a hypothetic overarching pattern, which, if it were true, would explain the case in question. The interpretation should then be strengthened by new observations, and during the process the empirical area of application is successively developed, and the theory (the proposed overarching pattern) is also adjusted and refined (Alvesson, 2018, p. 5). What is needed is a repeated process of alternating between (empirically-laden) theory and (theory-laden) empirical 'facts'. This means a hermeneutic process during which the researcher, as it were, eats into the empirical matter with the help of theoretical preconceptions, and also keeps developing and elaborating the theory (Alvesson, 2018, p. 7).

The data was analysed in multiple iterations. Firstly, I was particularly interested in the predominant frames of reasoning for the EHDS proposed regulation, based on the concept of sociotechnical imaginary; I looked at recurring themes in the data, and connected it with previous STS scholarly work on sociotechnical imaginaries and expectations and visions.

Secondly, this generated questions regarding biobanks and biobanking, which were both data holder and data creators, as well as being perceived as a fundamental part of realising the envisioned future of European health care and health research through facilitating the

necessary pooling of data. I then turned back to the literature to try to explain how sharing proceeded within biobanks and the biobank networks, and how expectations and visions regarding sharing are perceived. This led me to take into consideration STS scholarly work on research networks, infrastructures, and the sociotechnical assemblages of biobanks.

Moving back and forth between data selection and theories, I realised that looking specifically at expectations and visions of health data sharing within the BBMRI-ERIC research network in the two countries would allow me to study the performative nature of imaginaries and how the expectations and visions of the future are constructed, contested, and/or stabilized.

In the analysis of the EHDS document, I focus on the sections regarding secondary use of data. The policy document is distinctly divided into sections that concern primary and secondary use of data (COM/DG SANTE, 2022). Given that there is no common definition of secondary use of health data and that the term is not defined in the GDPR (Council of the European Union. European Parliament [EU/ 2016/679], 2016), my interpretation has taken its stance from what is commonly understood within the data protection community and TEHDAS framework, explaining secondary use as data used for a purpose different from the purpose for which the data was initially collected for (Hendolin & Pirttivaara, 2021). Secondary use explicitly impacts research and, accordingly, also biobankers. Thus, for the study at hand, the main object of analysis is the sections and proposed regulations regarding secondary use. Hence, when mentioning health data throughout the study, I am referring to secondary purposes, unless something else is explicitly stated.

In relation to the task at hand, “grey” literature also needs careful study. Analytic methods applicable to such materials go beyond formal techniques of discourse analysis to more interpretive means of identifying linguistic and symbolic elements that are crucial to the production and uptake of sociotechnical imaginaries (Jasanoff, 2015). The “grey” literature includes TEHDAS reports and official statements from the BBMRI-ERIC on the EHDS policy agenda. As well as EU or national reports of Greece and Norway.

While conducting interviews and attending the Stakeholder Forum conference, it became apparent that the policies and strategies to support and develop sample and data sharing were being met with different responses. From the interview material, as well as from the TEHDAS stakeholder forum conference, I identified common themes and concepts. The material was analysed by paying attention to what factors gave rise to sharing as a practice and its

relationship to EHDS. Of interest became issues surrounding the aftermath of the COVID-19 pandemic, the financial sustainability of biobanks, and data QM.

3.5 Reliability

The reliability of the study depends on the replicability and transparency of the research. As Donna Haraway (1989) argues, when doing research, researchers have a certain situated knowledge that needs to be disclosed, like researchers' predispositions that can influence the research or analysis process in some way. It is therefore suggested that researchers should be aware of their predispositions and make explicit how these might affect the research. Mainly, the fact that I am Norwegian makes me more knowledgeable of the Norwegian context than the Greek context. However, throughout the study I have tried to approach the cases symmetrically, for example by interviewing similar actors in each country and using the same interview guide.

In addition, I have limited knowledge of biobanking, medical technology and the technology and data QM processes used in the process of sharing of data. I have tried to educate myself on the key aspects of health data, what it is and what it sets out to do, and which are the important facets of it. Health data sharing is both difficult to define and difficult to understand completely, taking into consideration the many laws and regulations and how health data are treated differently from other data sources. This coupled with a lack of medical and digital data knowledge means that there might be aspects that I have inadvertently misinterpreted or dismissed. Additionally, I share many experts' concerns with regard to future expectations on intensified data sourcing and promises of efficiency thanks to big data and new smart solutions, especially within the public sector. This could affect my ability to analyse the data impartially.

Therefore, in order to counteract these possible predispositions, I have tried to be open and transparent about the research process and data analysis method.

3.6 Ethical considerations

As a researcher, I have the responsibility to collect and analyse data ethically. This entails getting consent, keeping participants informed, and assuring their anonymity. When contacting potential respondents, I would always make sure to enclose a brief description of the study, and if they agreed to proceed with interviews, I would send them an informed consent form including all necessary information to be signed by them as well as myself

before the interviews were conducted. In the beginning of each interview, I repeated some of the information displayed in the consent form and I asked them to confirm that they had read and understood the form and that both of us had signed it. Only after this confirmation did I proceed with the questions. Additionally, I have the responsibility to delete the transcriptions and recordings after they are no longer of use, and to make sure that no one else are getting access to them while I am storing the data. Respondents' names are not included but characterized according to professions.

The interview objects will be referred to throughout the analysis with the following descriptive epithets, identifying the interviewees according to their role:

- TEHDAS Representative (June 20, 2023).
- BBMRI Norway Director (June 16, 2023).
- BBMRI Greece Deputy Representative (June 20, 2023).
- Norwegian Researcher (July 4, 2023).
- Greek Researcher (June 26, 2023).

Regarding the Stakeholders Forum conference, as it was over 600 participants online and around 200 in person, it made it impossible to get an informed consent from everyone. However, as the conference was open for all by registration beforehand, and recording was published online for the public (on their website and on YouTube), as well as all speakers representing organisations or institutions, it should be unproblematic and entail no ethical issues stating their names and positions and citing their statements.

4 Main analysis

In this chapter, I present the findings of my research. The findings are based on the analysis of the EHDS proposed regulation document (COM/DG SANTE/197/2,2022), the semi-constructed qualitative interviews with the various actors, and the participation in the TEHDAS Stakeholders Forum conference. The following presentation of the findings has a four-fold structure. First comes an overview of the mission and goal of the proposed regulation of the EHDS. I then go on to analyse and describe how the EHDS can be conceptualised as a sociotechnical imaginary following the abductive approach moving between my own empirical findings and earlier STS scholarly work. This entails drawing out the imaginaries, expectations and visions form the EHDS document, discussing how its

perceived importance and justifications are depicted, as well as its performative and promissory aspects. Moving on, I will discuss the BBMRI-ERIC research network in the context of the EHDS, before continuing on to discuss whether the imaginaries are contested and/or stabilized by the different actors in the different contexts and how they themselves see health data sharing going forward.

4.1 Towards a European Health Data Space

Since 2019, the European Commission has identified the creation of a European Health Data Space as one of the top priorities for European health policy. The aim of the EHDS is to facilitate discoverability and access to different types of data available in European countries to develop innovative tools in the service of citizens' health, while also addressing the complexity of present European rules on data sharing in the health sector and to foster digital health services across Europe (COM/DG SANTE, 2022).

As a European regulation, the EHDS will (when accepted) come into force in all member states. Unlike directives, which need to be translated into national laws of member states, regulations are immediately effective.[18] This proposal for regulation defines the rules, rights and obligations for the functioning of the European Health Data Space, as well as the rollout of the necessary infrastructures, certification/labelling schemes and governance frameworks (COM/DG SANTE/197/2, 2022). The EHDS has strong ties with several other actions of the EU in the areas of health and social care, digitisation, research, innovation and fundamental rights.

Numerous prefiguration instruments have already been set up by the European Commission (COM/DG SANTE/196 final, 2022). Most recently, the HealthData@EU Pilot project (also referred to as EHDS2), which brings together 17 partners including health data access bodies, health data sharing infrastructures and European agencies in building a pilot version of the EHDS infrastructure for the secondary use of health data.[19]

One concrete tool to develop the EHDS and the access to health data for secondary purposes is the Joint Action[20] Towards European Health Data Space (TEHDAS), established by the

[18]A "directive" is a legislative act that sets out a goal that EU countries must achieve. However, it is up to the individual countries to devise their own laws on how to reach these goals. A "regulation" is a binding legislative act. It must be applied in its entirety across the EU. (Types of legislation | European Union (europa.eu)).
[19] For more information: Flyer EHDS2 v4 (ehds2pilot.eu).
[20] Joint Actions are a funding instrument under the third EU Health Programme. They are designed and financed by Member State authorities and the EU to address specific priorities under the EU Health Programme. More information: https://www.advantageja.eu/index.php/about-us/what-is-ja/.

European Commission in February 2021 as a reflection program bringing together 27 EU Member States and several HealthData@EU Pilot partners (TEHDAS, 2023). The purpose of TEHDAS is to help MS and the Commission in developing concepts and guidelines for the governing, usage and sharing of health data for secondary purposes (Hendolin, 2021).

As a matter of fact, many European countries possess substantial health data sets and data collections. However, health data is very fragmented in Europe. There exists a variety of data sources of diverging quality and different governance models and access policies for re-use and sharing. Still, in the context of the EHDS, much of the electronic health data already exists and is being collected by healthcare providers, professional associations, public institutions, regulators, researchers, insurers etc. in the course of their activities all over Europe.

Some categories of data are collected primarily for the provisions of healthcare in the form of electronic health records, genetic data, etc. Others are collected additionally for other purposes such as research, statistics, patient safety, regulatory activities or policy making in the form of disease registries, policy making registries, registries concerning the side effects of medicinal products or medical devices, etc. For instance, European databases that facilitate data re-use[21] are available in some areas, such as cancer or rare diseases (Hendolin & Pirttivaara, 2021). Nevertheless, much of the existing health-related data is not made available for purposes other than that for which they were collected, i.e., primary use.[22] This is seen as limiting the ability of researchers, innovators, policymakers, regulators and doctors to use those data for different purposes. While the GDPR regulation foresee the right to access and portability of data, its practical implementation is hampered by different structures of data, different coding and different standards for sharing data between data sources and MS (European Commission. Directorate-General for Health and Food Safety [SWD/131/final/ part1/4], 2022). Consequently, making health data more available for secondary use is one of the key goals that the EHDS aims to facilitate.

The expectations are that researchers, innovators, policy-makers and regulators will be able to have access to quality data for their work in a secure way, with a trusted governance and through a more streamlined process than relying on consent, and that this will support new and better prospects for both citizens and researchers. The main goal of facilitating easier

[21] Refers to use by natural or legal persons of data held by public sector bodies, for commercial or non-commercial purposes other than the initial purpose within the public task for which the data were produced.
[22] Use of personal health information by the organisation or entity that produced or acquired these data in the process of providing real-time, direct care of an individual.

secondary use is mainly to help patients and citizens through research basically by facilitating and providing access to data in a faster and more secure manner. However, researchers are expected to have the biggest benefit of the health data EU infrastructure because they are envisioned to have a much more streamlined approach on how to find and how to access data. As explained by the TEHDAS representative: “the EHDS aims to basically facilitate the whole process of a researcher finding the data, getting access to the data, analysing it, and taking it back to report. That's the main goal, and to do all of this in a secure way, so to have safeguards and making sure that the data - the health-related data - is always safe." (TEHDAS representative, June 20, 2023). A common framework for secondary use is as such not only envisioned to reduce the fragmentation and barriers for cross-border accesses but also to allow for easier use of health data for research, innovation, public health, and policymaking.

To reduce barriers within the Eurozone, in order to enable interoperability and harmonisation of data, emphasis is placed on the importance of FAIR data collection and storage. The FAIR principles were formulated to guide researchers to make their data more Findable, Accessible, Interoperable, and Reusable (FAIR), thereby propelling data sharing with the intent that these may act as a guideline for those wishing to enhance the reusability of their data holdings (Wilkinson et al., 2016). The importance of FAIRness is explicitly communicated as a key aspect of the proposal for regulation of EHDS: “Improving the quality and utility of datasets through informed customer choice and harmonising related requirements at Union level, taking into account existing Union and international standards, guidelines, recommendations for data collection and data exchange (i.e. FAIR principles: Findable, Accessible, Interoperable and Reusable), benefits also data holders, health professionals, natural persons and the Union economy overall” (COM/DG SANTE, 2022, p. 40). According to the TEHDAS representative, the EHDS is expected, by default, to incorporate and facilitate the FAIR principles throughout Europe:

> In the end of the day, I think this legislation of the EHDS by default will help a lot this FAIRness because if you think about it, it tells that every data provider, every data holder has to create the metadata record for the data sets. So already you have the findability covered. Then the accessibility will be organized through these health data access bodies, and it will be much more structured. So that's helping the accessibility. Everything will have to be published online somewhere, on a website, so that will be much more open as well, and structuring using common standards that will help interoperability so that data sets can be linked to each other. And all of these results in better re- usability of the data in the end. So everything is interlinked, basically. And the FAIRness principles are really the overarching aim (TEHDAS representative, June 20, 2023).

Another salient reason for the emphasis on information about the quality and utility of datasets is that it is expected to help significantly increase the value of outcomes from data intensive research and innovation, while, at the same time, promoting evidence-based regulatory and policy decision-making (COM/DG SANTE, 2022, p. 40). This translates into an emphasis on economic gains and benefits where health data re-use within the Eurozone is estimated to be worth around EUR 25-30 billion annually. [23.] Moreover, this figure is expected to reach around EUR 50 billion within 10 years (COM/DG SANTE/196 final, 2022). While the total economic benefits of the EHDS are expected, over 10 years, to be above EUR 11 billion, above the baseline (COM/DG SANTE, 2022, p. 14). Furthermore, researchers and innovators in digital health, medical devices and medicinal products are expected to bring with it benefits of over EUR 3.4 billion thanks to a more efficient secondary use of health data. And patients and healthcare providers/services are expected to benefit from EUR 0.3 and EUR 0.9 billion in savings thanks to access to more innovative medical products and better decision-marking. The more intensive use of real-world evidence in health policymaking is also expected to yield additional savings, estimated at EUR 0.8 billion, for policymakers and regulators.

All in all, the proposal for regulation of the EHDS reflects many of its priorities vis-à-vis innovation and digitalisation as expressed in earlier documents and policy agendas within the knowledge based bioeconomy (Clark et al., 2021; Doezema & Hurlbut, 2017; Hilgartner, 2007; Jasanoff, 2017). The benefits of sharing health data, they promise, will not only give better care, and better access to care, but also save public health care expenditure of several hundreds of millions of euros, along with additional incomes from health innovation and research. The document cites a litany of data-driven tools with the potential to "revolutionise" European health care through the usage of public registers, databases, and digital tools. The central claim of the proposal is that the availability of health data holds potential for benefiting society and research that implies that sharing will drive innovation and enhance PM to help solve both health and wider demographic challenges, and that realizing this potential is imperative for the future of Europe and its population: “This proposal is in line with the EU's overarching objectives. These include building a stronger European Health Union, implementing the European Pillar of Social Rights, improving the functioning of the internal market, promoting synergies with the EU digital internal market agenda, and delivering an ambitious research and innovation agenda” (COM/DG SANTE, 2022, p. 5).

[23] Note: secondary use of data is not the same as re-use of data.

Health data, harnessed by science, is thus envisioned to generate valuable technologies and new forms of preventive treatments in detecting, and rapidly responding to future health emergencies, as well as bringing with it additional societal benefits (COM/DG SANTE, 2022, pp. 13-14).

According to the EHDS proposed regulation document, the COVID-19 pandemic further highlighted the imperative of having easy and timely access to health data from MS:

> …the COVID-19 pandemic has shown even further the importance of electronic health data for the development of policy in response to health emergencies. It has also highlighted the imperative of ensuring timely access to personal electronic health data for health threats preparedness and response, as well as for treatment, but also for research, innovation, patient safety, regulatory purposes, policy-making, statistical purposes or personalised medicine. The European Council has recognised the *urgency* to make progress towards and to give priority to the EHDS (COM/DG SANTE, 2022, p. 1).[24]

It is expressed that such timely access could have contributed to more efficient public health surveillance and monitoring, leading to a more effective management of the pandemic, which ultimately could have helped saving lives.

Such expectations and visions, and the policies built upon them, have the power to influence technological design, channel public expenditures, and guide political decision-making. Hence, the EHDS proposal for regulation document can be read as a sociotechnical imaginary.

The next section will look more closely into exactly that – and on how these imaginaries are formed and presented. To further elaborate on the nature and scope of the expectations and social ties involved in the imaginaries of the EHDS, it is essential to bring the reflections made thus far into conversations and discussions with the body of literature on the promissory and performative role of future-oriented expectations, visions, and imaginaries.

4.2 The sociotechnical imaginary of a common European health data space

What seems to be apparent in the EHDS proposal for regulation document is a common optimism that the future can be managed, or at least steered. The EHDS, in many ways, introduces societal, economical, and ethical reorganizations, with its proponents (TEHDAS and HealtData@EU) pushing to create an environment where the imaginaries can be actualized. They project visions of what is good and desirable, and worth attaining for the EU;

[24] Emphasis added by me.

they articulate feasible futures and specific types of technopolitical order (Jasanoff, 2015). The imaginaries in question can be discerned in both the documents' explicit goals and their underlying assumptions about the promissory visions and expectations of its facilitation. By defining health data sharing broadly they also widen the scope of its benefits and highlight the need to nurture its facilitation and growth:

> The EHDS will also promote better exchange and access to different types of electronic health data, including electronic health records, genomics data, patient registries etc. Not only will this support healthcare delivery (services and personnel involved in providing health care or primary use of electronic health data), it will also support health research, innovation, policy-making, regulatory purposes and personalised medicine purposes (secondary use of electronic health data) (COM/DG SANTE, 2022, p. 2).

Health in the EHDS document, as correlating with the bioeconomy, therefore becomes a catch-all term for an array of practices, activities, and economic sectors that, together, are expected to generate value, support national competitiveness, and respond to grand European challenges (Mittra & Zouka, 2020, p. 15).

Moreover, by framing it in economic terms it becomes susceptible to treatment by the machinery of economic policy analysis located within the bioeconomy. The EHDS proposal for regulation document quantifies some of the advantages in financial terms, for example by listing how much money can be saved and how much money will be generated. Not really explaining how it will happen, but the benefits seem to be overwhelming. This is making it promissory, in that much of its value is speculative, based on estimations (Mittra & Zoukas, 2020). Hence, the visions of the EHDS imply normative connotations, with statements of desirable or preferable futures, while not necessarily including assessments of likelihood or plausibility (Konrad et al, 2017). As such, secondary use and re-use of health data becomes a central precondition for medical progress and public benefits with links to economic aspects of society (Starkbaum & Felt, 2019).

Furthermore, the promissory expectations and visions expressed in the EHDS proposal for regulation document are often evoked by using a language of urgency (Tarkkala & Snell, 2022). By several instances they even make explicitly use of the word ‘urgency’ in their descriptions. In this regard, the EC draw on urgency to foster and underpin the importance of health data. The European Council, in recognising the urgency to foster the EHDS, is placed as participants in driving certain policy ends in the name of scientific progress and innovations, essentially illustrating simultaneously the co-production of science and society (Tarkkala & Snell, 2022). According to Tarkkala & Snell (2022, p. 7), building on a sense of urgency can create pressure to act, and to an extent it might even be a condition of possibility

for rapid developments and even innovations. In particular, the EHDS builds on a sense of urgency stemming from the recent COVID-19 pandemic. The TEHDAS representative gives a clear account of how the pandemic promoted urgent change within the EU:

> Before the pandemic I don't think the EU members states would have allowed the commission to put a legislation and take their kind of competency because health was always a competency of only the member states, but now the commission is proposing a legislation that we have to be followed by all the member states. So that's a huge step that happened thanks or because of the COVID-19 pandemic (TEHDAS representative, June 20, 2023).

The role of the EU and the MS get singled out as someone who can and needs to manage some important data, or at least create a foundation for accessibility, findability, interoperability, and re-use of health data. A role legitimized by the urgency stemming from the pandemic and the risk of new ones, thus making it not only promissory but also performative. Calls for urgent adoption of new data handling systems was in this sense legitimised by allowing MS to share electronic health data of COVID-19 patients as an emergency solution, which showed, according to the EC, the need for "a structural approach at Member States and Union level" (COM/DG SANTE, 2022, pp. 21-22).

Additionally, by emphasising future risk and urgency, an increase in funding was justified. As highlighted by the TEHDAS representative stating that the pandemic brought the EU to severely increase their budgets: "For example, before the pandemic, DG Sante[25] was actually about to not exist anymore, and because of the pandemic, the opposite happened. Now we have budgets that are much bigger for projects and programs on health" (June 20, 2023). This showcases how expectations emerge as the result of strategic voicing and dedicated promotional efforts of actors, and as the aggregated effects of discursive dynamics or the outcome of collective anticipatory practices – a temporal underpinning visible in the aforementioned urgent need to act (Tarkkala & Snell, 2022).

However, urgency in the EHDS document is not only linked to the recent pandemic but also to the risk of missing a technoscientific or economic opportunity and suffering the threat of dire societal consequences. It becomes apparent how imaginations of desirable and desired futures correlate, tacitly or explicitly, with the obverse—shared fears of harms that might be incurred through the failure to innovate - building on an "interplay between positive and negative imaginings" (Jasanoff, 2015, p. 6). For example, the benefits of data-driven health

[25] The Commission department for Health and Food safety. More information: https://commission.europa.eu/about-european-commission/departments-and-executive-agencies/health-and-food-safety_en.

care and health research are expected to improve health and research as well as solving a broad set of demographic challenges, predominantly through the facilitation of PM (Hoeyer, 2019). On the other hand, to have inadequate or suboptimal governance would create barriers, meaning poorer innovation, subsequently leading to poorer health for the population. Such an interplay between positive and negative imaginings could be used to frame a need to foster innovation and research-friendly policies. The secondary use and re-use of data becomes a central precondition for medical progress and public benefits with links to economic aspects of society (Starkbaum & Felt, 2019, p 7). The EHDS is making claims about technological convergence, where a successful governance of the secondary use of health data implies significant socio-economic benefits.

A sense of technological convergence also became highly visible during the TEHDAS Stakeholder forum conference. One of the striking features of the conference was the sense of convergence; there was total agreement about being on the brink of something new, about needed investment, and about the considerable 'potential' in PM and sharing of health data and the potential downside or risk of Europe lagging behind (TEHDAS Stakeholder forum conference, June 14, 2023). Much attention was given to the scientific potential, future health care, and the uniqueness of Europe. Something that was explicitly communicated during the opening talk of the TEHDAS Stakeholders Forum by Jyrki Katainen, president of The Finnish Innovation Fund Sitra, and former vice president of the European Union and former prime minister of Finland:

> …The work we have been doing here together has created new opportunities for our citizens in terms of getting better health services in the future but it also function as an enabler to strengthen the EU and it also brings added value to our companies who are at the core of developing new innovations for health services and new innovations which will increase our competitiveness(…) So European health data space is basic infrastructure. Without that we can't expect better database services neither new innovations(...) Data is the fastest increase in raw material and its becoming political but it's also the biggest single source of economic growth and because its a source of economic growth we have to make sure that data is used for ordinary citizens and what would be the better thing to do but to use data for better social and health services. (TEHDAS Stakeholder forum conference, June 14, 2023).

Katainen presents health data sharing as an imperative element of the European knowledge-based bioeconomy. It makes visible how policymakers and political stakeholders seek to mobilize commitments, not so much through the use of data, but through narratives, narratives that are employed to argue the need for data sourcing so that future decisions can build on data (Hoeyer, 2019). The conference, through its broad future-oriented narratives, anticipates

and legitimates data-driven pathways for health care and health research (Konrad et al, 2017). Health data and the re-use of health data is more or less presented as a potential gold mine (Tupasela, 2017). Such techno-scientific promises further underpin a sense of urgency and a need to act now. Moreover, the conference had hired in a "Strategic Futurist" to talk about the future possibilities of PM, emphasising that with quality data and accessibility of such data, the EHDS can have the base infrastructure for helping all the European MS to move towards PM (TEHDAS Stakeholder forum conference, June 14, 2023). Thus, the EHDS comes to refer to coherent packages of potential future states where secondary use and re-use of health data is envisioned to enhance PM and presents these resources as unique elements of European society.

In this respect, Europe's wide sharing of health data also stands for the realization and strengthening of the European population. The imaginary of the EHDS is then being deployed to build a European future that seems to be about integrating the European population and preventing future health risks through the collection, accumulation and sharing of data. One can trace in this policy discourse the creation and legitimizing of new geopolitical boundaries (Jasanoff, 2015). The EHDS, therefore, does not only embrace a general trend towards expanding the scope of research participation. It also seeks to promote Europe as a political entity, promoting a strong Euro Zone by means of exploiting the uniqueness of health data within the EU. This way of envisioning a common European health data space as Europeanness offers opportunities for drawing together a diversity of actors and stakeholders under a single policy rubric – one that treats the notion of sharing of health data as fundamental for European future health.

Hence, the EHDS decrees a new sociotechnical imaginary of European health that links the power of science and technology to describe risks and propose preventive and innovative solutions to the power of social and political institutions to fashion order and health. All of it telling us that we face global risks and must act appropriately, as a unified Europe, to counter them. In this context, the imaginary of a common European health data space becomes a landscape in which policies will be shaped and scientific endeavours carried out; it is suffused with assumptions and expectations about digitisation, PM, and Big Data's transformative potential and thus legitimates certain pathways (Mittra & Zoukas, 2020). Consequently, sharing of health data are being embodied in new forms of governance, or "styles of anticipation": prevention, precaution, as well as pre-emption. The EHDS together with the expectations and visions of health data sharing is thus a political project, in that it is not only

seeking to anticipate the future but also seeking to shape and transform it. The perceived authority and legitimacy of these expectations and visions are underwritten by particular sociotechnical imaginaries—collectively held imaginations of right knowledge, legitimate authority, and progress that are expressed in scientific and technological visions and projects.

Understanding the EHDS as a sociotechnical imaginary underlines how health data sharing is not merely about medicine or health but very much about rearrangements being made and actions being taken that arguably are necessary for it to be realized. Efforts to define the importance of sharing health data through a common European health data space are not merely descriptive, as all sociotechnical imaginaries (Jasanoff, 2015), they also have a performative dimension. As presented in the theoretical framework, 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 and creating research policy priorities. Expectations also have a coordinating effect in that they bring actors, institutions, and networks together and organize practices and communities. Furthermore, they reconfigure and reorganize resources to highlight particular futures and shape practices, thus mobilizing futures today. In the end, the imaginary of Europe-wide sharing of health data does not only exclusively refer to the internal organization of science. Rather it combines imaginations of promises of biomedical technology, innovation driven progress, PM, Big Data, and the urgency of addressing global health crises, with the desire to restructure political and social spaces, where expectations and promises of a better future for health and medicine become key arguments in favour of sharing health data. The EHDS becomes a collection of actions in the coming years to boost digitalisation, digital transformation and data usage within health care and health research across Europe. Hence, the EHDS work through the global circulation of already powerful sociotechnical imaginaries- -which are then re-embedded into local constellations of production and practice (Jasanoff, 2015).

The next section will look into how the BBMRI-ERIC research network work within the sociotechnical imaginary of the EHDS, and especially how actors within this network envision health data sharing going forward.

4.3 The BBMRI-ERIC research network in the context of the EHDS

As already underlined in chapter 2, biobanks and biobank network infrastructures are seen as essential for data-driven health care and health research as they allow for the exchange of biological materials and data over time and space and the pooling of relevant resources to advance knowledge. BBMRI-ERIC's key mission is to establish, operate and develop a pan-European distributed research infrastructure of biobanks and biomolecular resources to facilitate the access to resources as well as facilities and to support high-quality biomolecular and medical research (BBMRI-ERIC, 2022). In the latest work program for 2022-2024, BBMRI-ERIC states that the goal for the coming period of BBMRI will be to leverage biobanks as trusted partner for science and development (BBMRI-ERIC, 2022, p. 22). The aim is to make QM Services available for biobanks to help to implement and work according to the principles of the international standard for biobanking (ISO), which is deemed important because it demonstrates that the biobanks work in a framework of transference and competence.

According to the TEHDAS representative, BBMRI-ERIC is highly involved in the HealthData@EU pilot project, and the BBMRI-ERIC representatives work mainly on the work package that deals with the quality aspects, looking at the quality of data sets for biobanks (TEHDAS representative, June 20, 2023). In the context of the EHDS, BBMRI-ERIC is expected to contribute with expertise on regulatory and legal compliance including data access procedures, as well as GDPR compliance to build a data access application for EHDS and allow cross-border use of data. BBMRI-ERIC's main function is described as facilitating access to samples and data and biomolecular resources mainly to advance and implement PM (EHDS HealthData@EU, 2023). Consequently, it becomes an important collaboration infrastructure for the envisioned EHDS.

When asked about the potential added value of joining the EHDS for biobanks and biobank research network such as the BBMRI-ERIC, the TEHDAS representative stressed visibility as an important aspect, in that samples, by being visible, can be used by more researcher across Europe: "it's bringing more effort from their side because they have to create a metadata record for every sample they have, but then after they've done this effort their samples can be seen by researchers across Europe and can be asked (for access) as well by researchers across

Europe. So, they would have more users basically as a biobank, and that's a benefit because I guess there's also a fee to ask for samples" (TEHDAS representative, June 20, 2023).

In the aftermath of the publication of the EHDS proposed regulation document, BBMRI-ERIC responded with an official statement containing the institutions stand on the proposal. According to BBMRI-ERIC, the development of the EHDS could not be timelier: "with the launch of groundbreaking initiatives across the competences of the Commission, ranging from health (Beating Cancer Plan, COVID-19 response) to research (Horizon Europe Missions), innovation (AI) that can all tie together under a new European Health Data Space to unlock the full potential of both a single European health data market" (BBMRI-ERIC, 2022, p.1). The statement further asserts how the COVID-19 pandemic highlighted the importance of having timely access to health data for research and policymaking purposes, and that the European Council did good in recognising the urgency to make progress towards the EHDS (BBMRI-ERIC, 2022). Amidst the COVID-19 pandemic, the BBMRI-ERIC research infrastructure facilitated access to quality-defined biological materials and data for research purposes so as to collect and make available information on available European COVID-19 relevant biobanking resources (Holub et al., 2020, p. 729).

Nevertheless, BBMRI-ERIC highlighted some potential challenges and made some comments to address these. BBMRI-ERIC stressed that along with legal clarity, operational harmonization would be essential, and that from the operational viewpoint, it must be considered that infrastructures differ within MS. Therefore, shared, standardised and common rules and practices are considered vital in order to build sustainable, solid and interoperable infrastructures that will ensure data access and data exchange for research purposes (BBMRI-ERIC, 2021). In this regard, BBMRI-ERIC asserted that the existing regulatory framework is insufficient to deliver on the promises of the EHDS, as health governance remains fragmented at both national and regional level. This is viewed to be hindering efforts to scale-up new research and healthcare solutions. Most importantly, BBMRI-ERIC stated that it is necessary to protect and promote the use of health data, defining clear pan-European rules to overcome exciting gaps in practice (2022, p. 4).

It is evident how, from an official standpoint, BBMRI-ERIC adopts and aims to bring forward the promissory expectations and visions of health data sharing. BBMRI-ERIC are even involved as work package leaders in the HealthData@EU infrastructure, making the research network an important collaboration infrastructure for the envisioned EHDS. Despite concerns regarding data QM, BBMRI-ERIC explicitly welcomes the initiative of the EHDS.

But how does this play out on a smaller scale, in different national contexts? How do Greek and Norwegian actors connected to the BBMRI-ERIC network perceive the tensions between potentials and limitations of a health data infrastructure as that of the EHDS? How are these official statements and the promissory expectations and visions contested, and/or stabilized by the different actors in the different contexts?

In the following section I will briefly map out the state of play in Greece and Norway based on information from grey literature and from the interviews conducted with the BBMRI Greece and Norway stakeholders. And I will outline how they themselves envision health data sharing going forward.

4.3.1 BBMRI Greece

The biobank landscape in Greece can be said to consist mainly of tissue and data collections created during clinical practice, with samples being subsequently repurposed for research (Tzortzatou & Siapka, 2021, p. 291). As of now, it is mostly based on peripheral nodes all over the Greek territory, with the Biomedical Research Foundation of the Academy of Athens (BRFAA) as the BBMRI Greece coordinator institution ((European Commission. Directorate General for Research and Innovation., 2022). The BBMRI directory, (accessed June 2023), registers three biobanks located in all parts of the country.[26] And BBMRI-ERIC membership contribution by Greece was 45.083,12 Euros in 2022, expected to rise to 46.039,86 Euros within 2024 (BBMRI-ERIC, 2022, p.69).

According to the EC Directorate General for Research and Innovation (2022), BBMRI Greece started its preparations later than the others, and with a limited budget, but it has made notable progress on many strategic fronts. However, it is declared that a transparently open access programme needs to be implemented (European Commission. Directorate General for Research and Innovation., 2022). BBMRI.GR was officially established in 2013, but in fact, as the BBMRI Greece Deputy representative puts it: “in reality, the network was established later when the first funding was received. So, I would say that the official birth year of the Greek network is 2018” (Deputy representative, June 20, 2023).

The main official objectives of BBMRI Greece, as stated on the BBMRI-ERIC’s country website, is to expand and upgrade existing collections of human biological material in Greece

[26] The BBMRI-ERIC Directory is a tool that collects and makes available information about biobanks throughout Europe that are willing to share their data and/or samples, and to collaborate with other research groups. More information: BBMRI-ERIC Directory.

by applying high-quality scientific standards for collection, processing, and storage; harmonising BBMRI Greece with BBMRI-ERIC (BBRMI-ERIC, 2023a).

While interviewing the BBMRI Greece Deputy, numerous of these goals and objectives were restated. Particularly on the importance of establishing common standards for the enabling of sample and data sharing. However, a problem within the Greek BBMRI-ERIC network, according to the Deputy representative, is that even though there exists a lot of repositories in hospitals, the conditions of sampling and analysing are not the same. They stress the importance of working under the IT system of BBMRI-ERIC in order to acquire the interoperability which is needed between biobanks so that samples and the following meta data will be accessible for other countries (BBMRI Greece Deputy Representative, June 20, 2023). As of now, samples and data are not really accessible for foreign researchers. Even for national researchers it is apparently very complicated to have access to data due to lack of harmonisation of data QM and accessibility (BBMRI Greece Deputy Representative, June 20, 2023).

The Deputy representative highly relates the lack of harmonisation of standards to problems regarding funding, stating that there is a need for public funding in order to maintain personnel that is well trained and skilled in QM Processes (BBMRI Greece Deputy Representative, June 20, 2023). Particularly pointing towards the absence of national funding, where the current funding cycling period, first initiated in 2021, has still not published its first call, meaning that there exists a two-year gap of funding (BBMRI Greece Deputy Representative, June 20, 2023). The deputy representative further states that they have to search all the time to look after project calls for funding (BBMRI Greece Deputy Representative, June 20, 2023).This is also visible in the Greek researcher's response, whose major concern is that they don't have enough funding to have people dedicated to their project: "I think that this is something that is needed if you want to build a biobank, you can't have someone taking a little bit of their time out of their rest of their schedule" (Greek researcher, June 26, 2023).

According to the researcher, biobanking does not seem to be very high on the Greek politicians' priority list, and therefore does not feel very confident that there will be any continuous funding from the government. There exist calls for personal research projects only, but this is not deemed adequate for the sustainability of biobanks: "you can't have gaps in the funding, like you get funding for a year, then you don't for another year and then you get

again for the third year. You need to have a continuous funding" (Greek researcher, June 26, 2023).

The researcher suggests that a good way to handle a biobank would be to request fees from outside researchers, while providing samples to your own researchers for free: “I wouldn't like to be involved in a commercial-type biobank, but I wouldn't be opposed if there was a fee just to cover some basic expenses in terms of consumables and personnel” (Greek researcher, June 26, 2023).

However, according to the BBMRI Greece Deputy representative, until now, they have not been allowed to “sell” (charge access to) samples but only to provide them without pricing, because the project of the Greek network was publicly funded, and it was a perquisite that the providing of samples and data had to be without pricing (BBMRI Greece Deputy Representative, June 20, 2023). This way, there is no compensation or income for biobanks that share their samples.

To make the funding situation more transparent and to support biobanks’ sustainability, the researcher underlines the need for a general document that could describe, by some general instructions, how each of the nodes is going to work: “like if someone requests samples from us, is it going to be a service that someone will pay a fee for? What type of institutions can ask for samples, anyone, or only academic institutions?” (Greek researcher, June 26, 2023). This is something that seems to be unclear within the Greek network. The Greek BBMRI Deputy representative explains how the network has not built a common conception of biobanks, and that biobanks are considered as “a research project, although it is not a research project, it is an infrastructure project” (June 20, 2023). The Greek researcher specifically mentions harmonization of standards and interoperability as a problem connected to sharing, affirming that there have not been interoperability standards defined and used throughout the Greek network before (Greek researcher, June 26, 2023). Only one biobank is said to be ISO certified in Greece (BBMRI Greece Deputy Representative, June 20, 2023). According to the Greek researcher, all laboratories need to obtain the ISO standard, but they themselves do not have it: “We don't have it yet, because *again* the problem is the funding you need money to be able to take care of all the issues for the different things that the ISO requires” (Greek researcher, June 26, 2023). Furthermore, they added that they think it is for everyone’s benefit to have an ISO in place. When asked about the FAIR principles and if they were in use, the Deputy representative specified that in principle they are obliged because they are European

directions (Deputy representative, June 20, 2023). Yet, the Greek researcher was not familiar with the FAIR principles (Greek researcher, June 26, 2023).

Nevertheless, GDPR seems to be well established and supported. When asked about the GDPR, the Deputy representative answered decisively: “Yes, yes, absolutely, it has been strictly applied in Greece, as in all of Europe, of course” (BBMRI Greece Deputy Representative, June 20, 2023). The researcher also affirmed that there are well-defined processes for GDPR, and that a lawyer, specialised in health data protection, participated in the creation of the consent form for their biobank project (Greek researcher, June 26, 2023).

When it comes to the proposal for the regulation of the EHDS, the Greek BBMRI Deputy representative made it clear that they have not felt any impact of the EHDS but are aware of the proposal for regulation. They believe that it will surely impact BBMRI-ERIC, stressing that it ought to be discussions about it in Greece (BBMRI Greece Deputy Representative, June 20, 2023). The Deputy representative believes that if the Greek government consider digital health data as a potential growth strategy for Greece, a lot of political activities surrounding the EHDS will follow: “When you see that that the policy of Europe is in that direction, of course Greece will follow. And I think that there is not for the interest of my country to have delays in following the European policy. Because when we had delays, the cost was much bigger” (BBMRI Greece Deputy Representative, June 20, 2023).

The researcher does not know the EHDS proposal for regulation that well, but is aware of it and thinks that for the next part of their project they should get more involved, declaring that: “I would like it to be as open as possible (…) I think that collaboration between institutions from different countries should also be encouraged (…) Even though we're different countries we are a *union*, and we can have multi- institutional collaborations for research and for the benefit of the patients”[27] (Greek researcher, June 26, 2023). They expect that the EHDS will help with guidelines and rules regarding data sharing and QM, while also opening up for international research grants. In addition, transnational collaborations between institutions and countries are envisioned to facilitate access to data from patients of different backgrounds which then can help to cover more aspects of various diseases and the development of therapeutic targets.

The Greek BBMRI Deputy representative also expressed some expected benefits of a future EHDS implementation:

[27] Emphasis added by me.

> For population it will mean better health because with more data you can go deeper to understand the disease mechanisms. And subsequently better health systems. Because if you can manage better a disease, you can support the health systems also with less days of hospitalisation - sometimes even avoid hospitalisation. For science and research, I think we live in this area now where data are, let's say, the basic material you work on. I think that in the next decades, science will change absolutely. And nowadays, first of all, everything became easier, cheaper, and the connection between countries is an everyday fact if you want (BBMRI Greece Deputy Representative, June 20, 2023).

Future benefits, expectations, and visions regarding biobanks and biobanking are put across, stressing that the role of biobanks could be reinforced: "The secondary use of data is something depending absolutely on the sample, so if biobanks have the data, and they can either provide or sell this, then I think it will accelerate the discovery of new pharmaceuticals, new therapies, and I think that the landscape of health will change" (BBMRI Greece Deputy Representative, June 20, 2023).

The Deputy Representative furthermore pointed towards an expected change in biobanks configuration and research work because the technical work will be more and more connected to the data: "They have to, let's say, to change, to evolve. Yes, it must be an *evolution* of their work" (BBMRI Greece Deputy Representative, June 20, 2023).

The researcher similarly brings up the imagined role of biobanks: "I think the role (of biobanks) is really central in research and all research projects. They have an added value if they have human specimens, and especially well annotated human specimens, because you can find human specimens say in most hospitals, but what you can't find is well annotated, like; What is the clinical information? What are the radiological images? What is the pathology? What is the therapy that the patient has taken? and this is the essence of biobanking. It's not just specimens or just the data, it is the combination of both" (Greek researcher, June 26, 2023). Ultimately, biobanks are seen as a core infrastructure, where the specimens and the data that they have can be utilized in projects of translational medicine.[28]

4.3.2 BBMRI Norway

BBMRI Norway is a large-scale national biobank research infrastructure for health sciences, including almost all population-based and clinical biobanks in Norway. Since 2013, Norway has been an observer state of BBMRI ERIC, becoming a full member state in 2016 (BBMRI-

[28] Translational medicine facilitates the characterization of disease processes and the generation of novel hypotheses based on direct human observation. An area of research that aims to improve human health and longevity by determining the relevance to human disease of novel discoveries in the biological sciences. More information: https://www.britannica.com/science/translational-medicine.

ERIC, 2023b). The project is coordinated by NTNU Norwegian University of Science and Technology (Biobank Norway, 2023). The BBMRI directory (accessed in June 2023) show 8 biobanks located in all parts of the country. BBMRI-ERIC membership contribution by Norway was 64.897,86 Euros in 2022, expected to rise to 66.798,57 Euros within 2024 (BBMRI-ERIC Work Program, 2022, p.69).

The official goals and visions of BBMRI Norway, as stated on their website, is to sustain and strengthen its role as a highly advanced and comprehensive national research infrastructure for health sciences. Additionally, BBMRI Norway aim to enhance the use of biobanks as a basis for excellent research and innovation. Reinforcing the ability to participate in international research is also viewed as essential, aiming to provide internationally competitive biobanking services for basic, clinical, and epidemiological medical research (Biobank Norway, 2023). According to the BBMRI Norway Director, the main focus is to contribute to expanding research both for national and international researchers (BBMRI Norway Director, June 16, 2023).

The core funder of the BBMRI Norway has been the Research Council of Norway (RCN)[29] Over the last decade they have provided funds of more than 300 million NOK[30]. The RCN has established an infrastructure call that is regularly announced. BBMRI Norway has applied for this four times and has been successfully funded all times. In addition to the contribution from the Research Council, there is a huge "in kind"[31] contribution by the partners, estimated to be more than a hundred million NOK[32] per year (BBMRI Norway Director, June 16, 2023). The BBMRI Norway director added that there has not been any direct funding from the Norwegian government (BBMRI Norway Director, June 16. 2023).

Despite the funding from the RCN and the "in-kind" contributions, the BBMRI Norway director is highly concerned about long-term funding and states that financial sustainability is a challenge for biobanks (BBMRI Norway Director, June 16. 2023). This is confirmed by the Norwegian Researcher, who stresses that there is a lot of work put into applications and that

[29] The Research Council is a Norwegian government agency that funds research and innovation projects. The Research Council works to promote international research and innovation, cooperation, and has several schemes to mobilize Norwegian applicants for the EU Research and Innovation Program. More information see: https://www.forskningsradet.no/en/about/.
[30] NOK 300 000 000,00 ~EUR 30.000.000. https://themoneyconverter.com/NOK/EUR.
[31] An in-kind contribution is a non-cash contribution of goods or a service. Those are either offered free or at less than usual charge for them. Similarly, when a person or entity pays for services on the committee's behalf, the payment is also considered as an in-kind contribution. In-kind services and contributions are valued at their fair market value or at their actual cost. In other words, they are valued at what you would pay for them if they were not donated.
[32] 100.000.000 million NOK ~9.000.000 million Euro (in August, 2023).

funding is lacking: “Even very good ideas and very good applications are not funded. I think that there should be more funding to help more people to do their projects and to fulfil their ideas, and probably longer stretches of funding, not, you know, one, two, three years, and then you have to apply again, and then when you don't get it, you have one, two, three years with no funding, and then you can’t continue, and then you have to find a new idea, you know, this kind of circle” (Norwegian researcher, July 4, 2023).

The BBMRI Norway Director mentioned user fees as something they have been asked to establish - a system where researchers are invoiced for biobank services - but that would never be able to cover expenses at large: “Maybe ten percent could be covered by user fees” (BBMRI Norway Director, June 16. 2023). Adding to this, the Director asserted that BBMRI Norway do not sell samples, “that’s a principle”. Rather they contribute with samples based on research collaborations for evaluation of research protocols (BBMRI Norway Director, June 16. 2023). The Researcher seemed more open to the idea of potentially selling samples and data: “you can maybe have some part of it as a service, or sell, or have a system to make, for example, a patent that biobanks can be a part of so that it can get more funds for continued functioning” (Norwegian researcher, July 4, 2023). Nevertheless, they do not want biobanks to become private companies. Still, the researcher advocated that it would be a good idea to try to incentivize researchers to work with companies if they have ideas that can be used for something that can be exploitable financially (Norwegian researcher, July 4, 2023).

When it comes to interoperability standards and guidelines, they are stated by the BBMRI Norway Director to be defined and used throughout Norway: “We have a high awareness of quality and always do what we can to keep the quality at a very high level. There is a saying in biobanking ‘garbage in is garbage out’ - if you collect samples in a bad way, you can never get them up to a higher standard” (BBMRI Norway Director, June 16. 2023). The same is described by the Researcher: “It's that what they say, ‘garbage in garbage out’, if you can't rely on the data that you have, and that it is correct, then it’s really difficult to trust analysis and results” (Norwegian researcher, July 4, 2023).

The Norwegian stakeholder’s assertiveness towards data quality is reaffirmed by the importance placed on ISO accreditation, which is expressed as having been a high priority since the very beginning of the establishment of the Norwegian BBMRI national node network. The biobank Norway network is certified by different ISO standards, and it has built up a system where you can go into any system at the biobank or at NTNU to look up all the different procedures, standards, security standards, etc. According to the BBMRI Norway

director, the FAIR principles for data handling are also in use within the network (BBMRI Norway Director, June 16. 2023). However, the Researcher has no knowledge of the FAIR principles (Norwegian Researcher, July 4, 2023).

The BBMRI Norway Director further declares that there is a very positive attitude towards secondary use of research data in Norway: "hardly any resistance at all". The challenge they face is more on the availability, how the sharing can be structured and organized in the best way to make it efficient, and how to secure that data can be handled out to the researchers within a reasonable time frame (BBMRI Norway Director, June 16. 2023).

Nonetheless, data is not accessible for foreign researchers in the same way. There exists a requirement from the ethics committee that the foreign researcher needs to have a Norwegian researcher on the team: "I think one of the main justifications would be that this would secure a better understanding of which Norwegian laws you have to comply with and so forth, and better insight into the research resource as such. So, it's actually an advantage for the international researchers to have a Norwegian researcher on the team. I will say more disadvantage for the Norwegian researcher that has to deal with a lot of paperwork" (BBMRI Norway Director, June 16. 2023).

The Norwegian Researcher also reflects on this: "You need a local researcher to be associated to the project. So, it is kind of shielding from researchers abroad in a way. You shield the accessibility. You press them to associate themselves with a Norwegian researcher. The good thing is that for the Norwegian researchers they can collaborate with the foreign researchers on projects, *that's very good*. But if a foreign researcher doesn't have a collaborator in Norway, he cannot access (…) it is too difficult to access from other countries and even maybe within Norway" (Norwegian researcher, July 4, 2023). The Researcher further admitted that they themselves find it somewhat difficult to connect biobanks and share data even within Norway:

> We tried to connect with […] a biobank[33] to get some genetical data, it was a long process, and they had to have some ethical applications, but also some other applications, and then it was difficult to get exactly the things that we needed. We wanted to test our hypothesis in another biobank (…). It took a lot longer time than we expected (Norwegian researcher, July 4, 2023).

[33] More information: https://directory.bbmri-eric.eu/menu/main/app-molgenis-app-biobank-explorer/biobankexplorer#/biobank/bbmri-eric:ID:NO_UiT.

Following up on this reflection, the researcher explicitly expressed that it should be easier to share health data: “If you have to spend a year or more just to get the paperwork done, you get, you know, disappointed from the beginning” (Norwegian researcher, July 4, 2023).

For the BBMRI Norway Director, the GDPR legislation has brought with it some unwanted challenges for the operation of biobanks and the sharing of data: “Since the establishment of GDPR, things have become a lot more challenging, a lot more bureaucracy of the paperwork, and also a lot more restrictions that have been introduced. That's not been very positive. And there is a saying that health data in Norway is more or less as a *gold mine*, but it’s really not a gold mine if it can’t be accessed or used due to inefficient administrative systems and some legal constraints” (BBMRI Norway Director, June 16. 2023).

The Researcher thinks that the GDPR is good. However, they asserted that as long as the personal ID of the people is protected and they have given their consent, the data should be used more extensively for research: “They have signed up for it, you know. So why should some people try to stop researchers from doing research and make it very, very difficult for them. As long as the ID is not available, you know, it would be very nice to be able to use data from different biobanks and to link them” (Norwegian researcher, July 4, 2023).

When it comes to the EHDS, BBMRI Norway seems to be quite extensively involved, at least from the Director’s perspective. They stated that they are working with European collaborators to create or set up a health data space through involvement in several EU projects and EU applications, where the aim is to establish a central system, and look into how the systems at the national level are compliant with what will be developed through the EHDS project. Supposedly there are a lot of infrastructures, institutions and organizations trying to take on the responsibility to make it happen (BBMRI Norway Director, June 16. 2023). They think that collaboration within the European Research community extremely important and that they would like to see it (the EHDS) happen: “It's challenging, but I think on many levels, also official levels, E-Health directorate and other different institutions have infrastructures that fit into the idea of European Health Space. Maybe it's a bit of around political answer, but there is no resistance. I think it's quite very positive” (BBMRI Norway Director, June 16. 2023). According to the Director, there is currently a lack of common transnational analytic platforms where one can retrieve and analyse data. If the EHDS can facilitate such a platform the output is expected to be *tremendous*. The Director emphasises how an increase in the number of available cases and research data could benefit research on

rare diseases, give sufficient statistical power, and thus "enable help in a meaningful way" (BBMRI Norway Director, June 16. 2023).

The Researcher, on the other hand, did not know anything about the EHDS but thinks that easy access to European data and samples is important:

> I think it would be very, very, very good for the European population, for the world population, because the results from these studies would be applicable to other places as well (…) We have a *unique* opportunity to follow people in their lives and connect (their data) to diseases and to find risk factors and to find models and to search for drug targets, biomarkers and so on. So, I think that these biobanks, they're under used and one of the reasons are difficult access to them, and lack of promotion of them also (…) This is a source that is, it's *gold* in a way, it's gold for research and for knowledge (Norwegian researcher, July 4, 2023).[34]

The Researcher further asserted that the state should fund biobanks to help innovation and help create things that can be used and exploited: "(I) think that a lot of the talk about innovation and economic exploitation of biobanks and research in general, it's a lot of nice words but not so much in practice. It's not so easy to get funding, so how can you do innovation and new products and so on if you don't get funded?" You really need great funding to do great research" (Norwegian researcher, July 4, 2023).

5 Discussion

In this chapter, the findings are reviewed in order to answer the second and third part of the research question, namely what this tells us about how imaginaries of EHDS sustain and promote promissory expectations and visions of health data sharing, and whether such expectations and visions are contested and/or stabilized by stakeholders within national BBMRI nodes and how they themselves envision health data sharing going forward. Once again, I turn to the main STS concepts and discuss the implications of the findings derived from the important dynamics and concerns that were uncovered in the analysis. Based on this discussion, I propose some important aspects that ought to be taken into consideration for the facilitation of enabling environments for health data sharing within biobanks and biobank networks, and for the future implementation of the EHDS. Finally, there is a review of how the findings fit into the literature and what areas should be studied further in order to gain more insight into the topic.

[34] Emphasis added by me.

5.1 Implications of the findings

We have arrived at a time in which many of the world's imaginings of health research and health care differ vastly from half a century ago. Phrases like "Health data" "Big Data" and "Personalized Medicine" may be mere word combinations. Yet, today, these phrases cohere in the thoughts of world elites, biomedical professionals -and even occasionally among publics- in a way that in prior times they would not. This coherence suggests a linguistic trace of a deeper sociotechnical imaginary, which links new forms of data-driven health care and health research, new infrastructures of health and research, new patterns of social organization, and new possibilities of politics and governance, together into the configuration of a knowledge driven bioeconomy. The constellation of the EDHS policy agenda can be conceptualised as a specific kind of "bioeconomy"—a system built around the sharing of health data that aims at creating added value and innovation, as well as solving wider European challenges – with its creation of value and innovation being funded in sociotechnical imaginaries (Felt, Metzler and Ferent, 2020). The sharing of health data not only aligns with current dominant imaginaries within the bioeconomy, like that of the promissory values of Big Data and PM as an answer to many of the population health related questions, but it is also imagined as an enabler for the facilitation of such.

However, it is important to consider the fact that, as STS scholars have pointed out, large-scale issues involving the status, power, and authority of technoscience become localized and complicated in specific moments of formulation, enactment, and learning (Downey and Zuiderent-Jerak, 2017, p. 240). Often there exists a tension between the actual practices and the frameworks promoted by governments and institutions: "What policymakers need and what scientists find interesting are often too different" (Parmiggiani & Grisot, 2019, p. 4).

The Greek and the Norwegian cases show that focusing on just the promissory discourse promoting sociotechnical imaginaries based on the visions of "experts" and policymakers and treating them as purely performative, risks overlooking the potential challenges encountered in their realization. This underlines how the sharing of health data is not merely about health care or health research but also very much about sociotechnical rearrangements being made and actions being taken that, arguably, are necessary for it to be realized.

The interviews show that when biomedical professionals contribute to the building of research infrastructures, they might reimagine their purposes, which can be different from the top-down envisioned ones. In the EHDS proposal for regulation document, not much emphasis

was placed on the actual process of creation and maintenance of data. The data seems to just magically come into existence or already being there ready to be exploited. This aligns with STS scholarly work on the policies of "open science", in that it tends to imagine that material and information will flow if only an infrastructure is provided and a demand of sharing is installed (Hoeyer et al.,2017; Mirowski, 2018). However, expectations of open-data from the top do not always align with the actual practises on the ground. In my case study, stakeholders sought to make possible the sharing of health data, through emphasising the importance of European research and cross-border sharing and use of data. But even though there might be shared expectations regarding sharing of health data among the stakeholders in both countries, the enabling environments for such are not always in place. Consequently, reconceptualizing biobanks and stakeholders to fit under the EHDS expectations and visions of health data sharing seems to be translated into tension with old practices and arrangements, in particular regarding interoperability and accessibility of biobanks and their infrastructural assemblages and financial needs.

In regard to the enabling environments, in both cases, there was an apprehension towards the financial sustainability of biobanks. Financial sustainability was identified as a major problem for all of the interview subjects. Even the BBMRI Norway Director, whose node can be said to be well funded, emphasised that financial sustainability is a challenge for biobanks (BBMRI Norway Director, June 16. 20203). While the Greek BBMRI Deputy representative stressed that they must search all the time to look after project calls for funding and revealing that there exists a two-year gap of funding from the national government (BBMRI Greece Deputy Representative, June 20, 2023). The relation between intergovernmental and supranational forms of governance surface here in concerns regarding funding and sustainability and national preparation and infrastructures.

Financial apprehensions were mainly discussed along two dimensions: the importance of ensuring funding of the infrastructure as such (for material needs and long term sustainability), and in the need and the commitment of staff to find time and resources to handle new regulations and data QM. All stakeholders lamented how the 'core' budget is not sufficient. It was then further expressed that the budget therefore needed to be structurally complemented with project funding. As identified by STS scholarly work (e.g., Tupasela, 2017; 2021), project-based funding is not considered sustainable for biobanks, since biobanks are infrastructures that need continuous maintenance. What seemed to be missing for the stakeholders in question was a clear guidance to how biobanks should operate financially. For

instance, selling samples was not a valid option, as it was seen as a breach of the BBMRI-ERIC's network principles and/or contradicts national governmental demands or regulations.

Nevertheless, interviewees showed high awareness of how a health data collection and sharing should imply a necessity to be attentive to data QM and standardisation like the ISO. Despite a lack of ISO certified biobanks in Greece, the stakeholders expressed a very positive attitude towards the importance of pursuing ISO accreditation. Again, visions for the future and the importance of interoperability in order to enable sharing came to the fore. But issues regarding funding turned out to be overarching. This was explicitly communicated by interviews in the Greek case. The fixed costs will have to rise to cover the overheads associated with the implementation of quality procedures and the professional specialists required to run different aspects of the operation. They expressed how their cost structure is becoming more complex and requires stable, long-term funding sources and a funding model that does not centre on a small number of specific short-term research grants. As such, the interviews revealed continuing discrepancy between the expectations identified in the official EHDS document and the practical complications regarding the facilitation of health data sharing. In the EHDS proposed regulation document, the facilitation of health data for secondary use has been framed mostly as a technical problem of database interoperability and integration (COM/DG SANTE, 2022, pp. 13-14). However, data QM involves a lot of work and cost, and this is often not recognised or underestimated by policymakers (Grisot & Vassilakopoulou, 2017; Parmiggiani & Grisot, 2019). The interviews showed how difficult the creation of a single standard will be, for there is no ready agreement upon a common vision by all stakeholders, not even within the same national contexts, meaning the national networks of BBMRI. STS have showcased how there have been considerable differences between countries and biobanks as to how samples and data are shared, and that this is, perhaps, one of the greatest challenges in fostering a common culture of sharing in Europe (Tupasela, 2017;2021).The existing regulatory framework is insufficient to deliver on the promises of the EHDS, as interoperability standards and data QM remain fragmented at both national and regional level. Even within the Norwegian BBMRI network, which has several biobanks ISO credited, the Norwegian Researcher expressed some concerns and difficulties in sharing and connecting biobanks both internationally and nationally (July 4, 2023). National ethics regulation was viewed as potentially hampering and possibly excluding foreign researchers from getting access to data.

Data sharing in the majority of the examples I have discussed posed a challenge to what the stakeholders had been doing or prompted discussion about what they would like to do. For all stakeholders, sharing as a practice and a general ethos was associated with the availability of common funding and interoperability and data QM standards for such tasks rather than with personal commitments or relations with the samples and data that were available (Tupasela, 2021). Facilitating easier interoperability is one of the main expectations and visions for the EHDS, particularly through the use of the FAIR principles. Both stakeholders working at the organisational level of their respective BBMRI node answered that FAIR is widely used, and that it is a requisite in place for the use of this. However, neither of the researchers had any acquaintance with the FAIR principles. Alluding to discrepancies between top-down and people on the ground, demonstrating how institutional goals may differ greatly from individual goals and interests (Tupasela, 2021, p. 527).

Nevertheless, both the Greek and the Norwegian stakeholders emphasised promissory aspects of biobanking, both implicitly and explicitly. When describing health data sharing and the promissory aspects of biobanking it is important to be attentive to the words and phrases chosen by the different stakeholders. As the Norwegian case shows, using words like 'unique', 'gold' and 'goldmine', while emphasising words as 'crucial' and 'tremendous' builds on the expectations and visions of the bioeconomy regarding promissory value of data-driven health care and health research. In addition, low data QM was explicitly described as garbage, using the phrasing 'garbage in, garbage out'. Biobanks were described as a 'the people's bank' in the sense of benefiting (future) society, pointing to the collective benefit flowing from giving broader access to data, emphasizing more strongly ideals such as equity and solidarity within the biobanking community (Starkbaum & Felt, 2019).

Furthermore, the imaginaries of health data sharing brought forward performative aspects, where several of the stakeholders alluded to the fact that biobanks would need to evolve in order to fit under the future prospectives of data-driven health care and health research. Perhaps most visible in the Greek case, were the Greek Deputy Representative (June 20, 2023) stated that it must be an 'evolution' of biobanks and biobankers' work, and the Greek Researcher explaining the essence of biobanking as the combination of specimens and the data (June 26, 2023). Moreover, several of the stakeholders emphasised how biobanks were underused, indicating a risk of missing out on technoscientific or economic opportunities. Again, it becomes apparent how imaginations of desirable and desired futures correlate,

tacitly or explicitly, with the obverse—shared fears of harms that might be incurred through the failure to innovate (Jasanoff, 2015).

Accordingly, the sharing of health data was imagined by all stakeholders as being very positive for the European population. As such, how the stakeholders envision health data sharing going forward aligns with numerous of the expectations and visions found in the predominant frames for reasoning of the EHDS.

The promissory sociotechnical imaginary of the EHDS will only become more binding at later stages, and this creates a political pressure to respond to the expectations and visions of data-driven health care and health research. The imaginary of the EHDS is already in several ways institutionalised, as it builds on legal arrangements of GDPR, as well as being integrated in funding schemes regarding European digitisation. Furthermore, TEHDAS' recommendations for implementations are expected to turn into future road maps for the EHDS (TEHDAS, 2023). Finally, as a European regulation, the EHDS will come into force in all member states. Therefore, within the European context, the imaginary of the EHDS is not a mere illusion because it is sought out to perform certain policy functions. The powerful policy drivers to regulate the EHDS, whether or not their promissory visions are realistic, will have a performative function and will have an impact on organizational practices. As such, the EHDS will unquestionably shape future health research and health care within the Eurozone.

As the above discussion suggests, the visions of the EHDS are far from apolitical. For this reason, the EHDS visions warrants ongoing, reflexive examination.

5.2 Aspects to be taken into consideration for the making of enabling environments

Based on the findings of this study, there are at least three clear aspects that need to be taken into consideration for the making of enabling environments for health data sharing within a future EHDS. These aspects are not exhaustive but build on former STS work complemented by insights derived from this study.

First of all, policy makers and policy agenda-setting institutions like the EU should be aware of the many complexities and discrepancies involved in health data sharing. The discussions surrounding data and sample sharing need more nuance, whereby sharing is not necessarily a yes or no decision but can also represent concerns regarding funding, national policy initiatives, new QM tasks and social relations between different actors. In the context of

biobanks and biobank networks, this creates a need to develop a more nuanced theory of biobanking politics, where the interests of scientists who control samples and data are better understood and recognized in relation to the more normative political expectations associated with sample- and data-sharing set out in policies (Tupasela, 2017). The way the people "on the ground" relate to data work is important to not only help with facilitation and enabling environments but also to increase the chances of the expectations and visions coming to benefit the society. Hence, the needs and interests of stakeholders should be presented in any attempt to facilitate health data sharing, so as to enable professional users and participants to make creative contributions in the formulation of future needs and to be engaged in development choices, drawing from their expectations, knowledge, and experiences. Being attentive to this can help bring performativity back into the picture (Jasanoff, 2015). The rise of data-driven health care and health research should therefore be understood in the context of changing socio-technical practices in the assemblages of biobanks, including how attributions of responsibility are made in relation to data-based decision making and data QM (Hoeyer, 2019).

Secondly, expectations and visions are in fact performative. For example, when a new regulation emerges, such as the EHDS, the relations in the biobank and biobank network assemblages and the infrastructure might possibly have to be rethought and rearranged in ways that meet the expectations and visions of the policy makers. For instance, as made clear by STS scholarly work, in the context of the implementation of GDPR, biobanks were placed in an environment characterized by uncertainty that incessantly required flexibility in regard to the very idea of what biobanks were and what was expected from them (Felt, Metzler and Ferent, 2020; Starkbaum & Felt, 2019). For the EHDS context, this would mean looking into different kinds of biobanks, what they share and how they differ, and to follow that up over time by trying to capture change and the debates reflecting the need for adaptation. The sharing of health data for research in many ways rests on an infrastructure of biobanks that creates an enabling environment for quality health data sharing and pools the necessary data. Therefore, being more attentive to infrastructure can help revealing the state of the enabling environments for implementation of the EHDS regulation.

The last aspect that could provide valuable perspectives on the enabling environments needed for implementation is bringing attentiveness towards the EHDS being somewhat compatible with the pre-existing systems that are located in different national contexts, biobank assemblages, and data sharing rules and systems. Greater attention and qualitative research

focusing on biobankers practices and country-specific concerns are needed in combination with scrutinizing policy documents to identify and to describe unattended interpretations, shifts, and parallelisms between pan-European policy prospects on infrastructures and their doings at different levels (Argudo-Portal & Domènech, 2020, pp. 3-4). To understand what the EHDS will produce locally, we therefore need to follow translations in specific settings (Hoeyer, 2019). Disregarding cultural specificities and the particularities of different contexts can jeopardize the implementation of the practices that are envisioned. So, to be effective, policy agendas for the sharing of health data also need to be articulated and embedded in practical measures for facilitating health data sharing in concrete ways and in actual political, economic, biomedical research, and health care settings. As such, hollowing out countries and regions capability and capacity should be an object of debate for the EHDS going forward.

5.3 Implications of the pertinent literature and further studies

Through comparing Greece and Norway, focusing on the promissory aspects of the EHDS proposal for regulation policy agenda and looking specifically into health data sharing within biobanks under the BBMRI-ERIC network, I have contributed with an insight into a new case on how EU policy agendas founded within the knowledge bioeconomy impose expectations and visions on to biobank stakeholders and how these are contested and/or stabilised. The thesis has built on the assemblage of key ideas in STS on the performative role of future-oriented expectations, visions, and imaginaries in health data and biobanking within the promissory bioeconomy. By comparing the two cases, both distinct characteristics of Greece and Norway have been outlined and highlighted, and more general insights have emerged.

Nonetheless, there are some clear limitations to the analysis conducted for this thesis. Firstly, as the EHDS proposal for regulation is yet to be regulated, it is difficult to generalise too much on the performativity of its expectations and visions. Moreover, health data sharing is evidently a salient and ever-emerging topic, and throughout the research there was more and more relevant information being published. Therefore, at some point in the research it became necessary to cease the data collection process and focus on the data already gathered.

Another limitation could be due to the number of participants and to the concrete contexts in which they were recruited, for instance, by only speaking with stakeholders already connected to the BBMRI network. As such, this study could have been improved by including interviews with actors from the countries' public health authorities and the BBMRI-ERIC Europe.

Additionally, there exists a language barrier regarding the Greek language, which could have possibly prohibited me from researching all the available sources and documents.

One might speculate that similar comparative data and indicators of matureness to join the EHDS can become quite significant politically. Such data could play a substantial role in facilitating and implementing the EHDS as a matter of heightened policy concern. For example, by placing countries in a comparative context might be conducive to highlighting issues of MS competitive advantages and disadvantages, by enhancing societal capacities to measure, monitor, model and care about the current and future 'health' of an increasingly tangible entity: the European population.

It could even be relevant to conduct a similar, though more extensive, case study looking at Greece and Norway, as there are more and more initiatives taken. Health data sharing is an emergent field, things are constantly changing, new policies and strategies emerging, and even more in the making. And as Greece and Norway find themselves at substantially different levels regarding the technical maturity and efficiency of health care, further comparative research can question taken-for-granted practices, institutions, and structures. Such research can showcase how despite making reference to ostensibly the same scientific and technological rationality and to shared values, different nation-states will sometimes draw fundamentally different conclusions, which might affect implementation and facilitation of said values (Felt et al., 2017). In other words, further comparison can raise awareness of technoscientific divides within Europe, of the diverse technopolitical cultures that develop within different places and embrace or reject knowledge and innovations. As made clear by STS scholarly work, empirical qualitative comparative research on the lag between European policy projects and biobanks' transformations in different contexts is valuable in understanding not only these infrastructural transitions but also scalability in contemporary technoscientific projects (Argudo-Portal & Domènech, 2020, p. 13).

Such further research could expand on the following aspects and questions:

- How will the EHDS impact biobanks and sharing of health data in the future? In particular, how will the people on the ground relate to data work needed and demanded for its facilitation? (Metzler, Ferent, and Felt, 2023).

- How does the EHDS affect the infrastructure of biobanks and the research infrastructure of BBMRI-ERIC? Looking into infrastructure means bringing the

research and information practices of a set of actors – ranging from different kinds of researchers, but also including policy makers who support the formation of such infrastructures – into one socio-technical network. This sociotechnical network includes many different contexts of use, and it stretches over a number of otherwise nationally or locally organised biomedical infrastructures, and thus calls for comparative work (Felt, Metzler and Ferent, 2020).

- Analyse how the sociotechnical imaginary of EHDS is fused in practice by studying national strategies that pursue the promises of health data sharing, by being attentive to how national strategies perform and produce visions that are mutually constitutive with the sociotechnical imaginary of the EHDS; study actual strategies, roadmaps, proposals for and projects involving experimentation, iteration and implementation of techniques, and practices of making health data findable, accessible, interoperable, and re-usable - focusing on reasoning over the objectives, milestones, measures to be taken, issues to be improved, and resources to be mobilized for facilitation of cross-country sharing of health data (Tarkkala et al., 2019).

- Look into whether the EHDS further shifts the paradigm of consent to the benefit of citizens within biobanking, by analysing whether interventions by actors from data-dependent fields of science to the EHDS negotiations contains a shifting of discourses in which Big Data approaches are increasingly framed as necessary innovative modes for knowledge generation to serve the public good (Starkbaum & Felt, 2019).

- Finally, whether data collection initiatives like the EHDS can be used to legitimatize postponement of action through promises of future gains, rather than acting and caring for the present - both within MS states and EU as a whole (Hoeyer, 2019).

6 Conclusion

In order to understand more about how the promissory imaginaries of the EHDS are expressed and reasoned for and on how the imaginary is shaped by and contested around the expectations and visions inscribed into them, I have conducted a comparative case study. I focused on how expectations and visions of stakeholders within the BBMRI-ERIC's national nodes of Greece and Norway regarding health data sharing generates tension with old

practices and arrangements, in particular regarding interoperability and accessibility of biobanks, and the struggle for financial sustainability. Specifically, I have explored how imaginaries of a common European health data space are:

i) visible in the predominant frames for reasoning in the proposal for regulation of the EHDS policy document.

ii) constructing promissory expectations and visions of health data sharing.

iii) contested and/or stabilized by actors within the Greek and Norwegian national BBMRI nodes and how they themselves envision health data sharing going forward.

Through an abductive approach, I have analysed the empirical data consisting of the EHDS proposal for regulation document, other publications, and five qualitative interviews, while trying to find perspectives on health data sharing within biobanks and biobank networks discovered in STS studies. By moving back and forth between theory and data, I ended up with the main concepts on the salience of promises, expectations, visions, and imaginaries in health data and biobanking within the promissory bioeconomy.

In the two cases, the sharing of health data is perceived as something necessary and important for health care and health research. Thus, one could claim that the sharing of health data has managed to become "collectively held, institutionally stabilized, and publicly performed visions of desirable futures" (Jasanoff, 2015.p. 4), although it is not always technically or financially feasible today; in other words, it constitutes a wish to share, but it is not always possible to do so, at least not yet. So, one could claim that the expectations are common to some degree, but the possibility of implementation remains stratified.

In the Greek case, the EHDS is expected to contribute to greater data QM and better funding opportunities. In addition, the role of biobanks is envisioned to be enhanced through promissory of data-driven health care and health research.

In the Norwegian case, the expectations were explicitly connected to the importance of easier enabling of cross-border data sharing and international research collaboration. Even though the Norwegian BBMRI national network is evidently more 'established' than the Greek one, (well-funded, good data QM routines, several ISO certified biobanks, and more national political support), it seemingly still faces the same fundamental problems regarding health data sharing as the Greek case, however at a somewhat different scale.

Both cases focus on and prioritize the harmonisation of standards and data QM for improved data curation in order to enable more or less open sharing. However, the lack of long-term funding affected the enabling environments to do so due to structural factors related to it, where biobanks are sometimes simply not able to find the funds that were needed to share (Tupasela, 2021, p. 527).

Hence, rather than being mere empty policy vessels, the imaginary of the EHDS shows that the expectations and visions for sharing of health data are open to interpretation and given various meanings in different contexts. Within the research infrastructures of BBMRI-ERIC in Greece and Norway, the imaginary is shaped by and contested around the expectations and visions inscribed into them. These include imaginations of European integration through data-driven health care and health research, technological convergence, and financial sustainability, where certain sets of values come in conflict with others.

This can shape the conceptions of what the EHDS is supposed to be or to become, and what are considered to be plausible and legitimate promises and concerns relating to it. Realizing this vision necessarily requires finding ways to connect the expectations of health data sharing to the ongoing different practices and activities, and to make the data creators and data holders follow and believe in the work that is set out to be done. The challenge is nothing less than that of finding 'European common ground', agreeing on shared ground rules (e.g., FAIRness), articulating the abstract idea of Europe in dealings with specific countries and institutions, and linking the infrastructure policy with the everyday praxis of research communities and individual researchers on the ground (Grisot & Vassilakopoulou. 2017; Jasanoff, 2015; Tamminen, 2015).

In the end, the thesis contributes to the analyses of sociotechnical imaginaries (Jasanoff & Kim, 2015) and the discussion about promissory and performative expectations and visions surrounding data-driven health care and health research. The case presented has drawn out a more fluid, dynamic, and perhaps unstable picture of the relations among science, technology, and society—a picture that reveals the frequent re-inscription of inequalities through science and technology but one that is perhaps also more open to proactive redesign toward implementation of the EHDS. Scientific collaboration and European policy agendas for cross-country sharing of health data get, to some extent, jointly imagined and materialized. However, one cannot expect that policy framings for sharing of health data through a common European health data space will converge over time from Brussels to Athens and to Oslo. The emergence of infrastructures is not only a question of purposeful design, nor is it just

‘happening’ without some intentionality involved; it is primarily an open process with many interdependencies that need to be dealt with. For instance, whether and how the visions and expectations of the EHDS can be delivered for health care and health research depends on the tools and assumptions used when assembling, interlinking and integrating genomic data with other types of biomedical data –a task fraught with technical, ethical and social challenges. If the EHDS wants biobanks to do things that are going to be very different from what they are currently doing, or to have an expanded role, or to have infrastructures that increase data-driven health care and health research involvement in the way decisions are made and in the way things are done in society, then there needs to be some kind of capabilities and capacity that exist and that can be reconfigured. Otherwise, it might be difficult to achieve the expected and envisioned goals for the future. Thus, the EHDS should be attentive towards being somewhat compatible with the pre-existing systems that are located in different national contexts, biobank segments, networks, and data sharing rules and systems, and turn analytic attention to less obvious spaces where imaginaries shape how health data sharing takes place by taking into consideration the people and the facts on the ground (Metzler, Ferent, and Felt, 2023; Moen, 2022).

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8 Appendix

Informed consent form for participation in master thesis research project

Information sheet

Working title of the master thesis: "Health Data Sharing under the Imaginary of a Common European Health Data Space - A Comparative Study of Biobanking Expectations and the Enabling Environments for Sharing of Health Data"

The thesis is written as a part of the Interdepartmental Program of Graduate Studies in Science, Technology, Society – Science and Technology Studies and the European Master's Programme on Society, Science and Technology (ESST). Website: https://sts.phs.uoa.gr/.

Host Institution: Department of History and Philosophy of Science, School of Science, National and Kapodistrian University of Athens.

Research conducted by:

Anders Korsgaard, postgraduate student

Contact information: email andkors98@gmail.com / tel. no (+47) 90020267

▸ Project description

The research aims at exploring the enabling environments for health data sharing within the biobanking network of BBMRI in Greece and Norway. This is connected to the collection and sharing of data and metadata (secondary use) within the context of the European Health Data Space (EHDS).

Biobanks exemplify a discourse about progress that is based on the beneficial impact of science, technology, and medicine on healthcare, with future expectations for implementations and scaling-up of precision-based medicine. These expected impacts are explicitly communicated in the latest EU Commissions mission letters as well as in a proposal for regulation of the European parliament and of the council on the European Health Data Space (EHDS) - which is expected to run from 2025 (dependent on when the regulation takes effect). The research aims at understanding how the expectations and visions of EHDS materialize within the biobank network of BBMRI in Greece and Norway, especially on how it affects expectations regarding sharing of health data. Drawing on approaches from the interdisciplinary field of study known as: 'Science, Technology, Society' or 'Science and Technology Studies' (STS), the research sets out to analyse the currently predominant frames for reasoning for promoting EHDS.

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The research aims at adding to the STS study of sociotechnical imaginaries of EU policymaking, while at the same time, offering a more comprehensive basis for comparisons of Member States readiness to join the EHDS. The research findings will be communicated through a final thesis dissertation.

Data collection for the thesis research consist of bibliographic research, document analysis, and of semi-constructed qualitative interviews conducted, recorded and processed for scientific purposes only.

Thank you for your willingness to meet with me and possibly consent to an interview.

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Informed Consent to Participate in Master Thesis Research

Your participation in the research project is voluntary. You are free to voluntarily consent to participate, and to withdraw your consent at any time. Part of the research findings may be published or made available to the public for scientific, research, cultural and educational purposes. Together with the other interviewees, your knowledge and insights will contribute to a better understanding of the emergence and operation of a European Health Data Space. We deeply appreciate your testimony, and we kindly ask you to consent to your participation in the research by signing and completing the following form.

• Declaration form

I declare that I participated in the research carried out for a master thesis project conducted by the researcher. My participation has been voluntary. I agree to take part in the research with a recorded interview. I permit its use for scientific, research, cultural and educational purposes. My words from this interview may be quoted in research outputs (academic publications, reports, etc.).

Restrictions:

□ I want my anonymity to be ensured (I do not agree for my real name to be used in the research outputs).

□ I want to review the transcribed text.

Date: __/__/2023

Name and signature of participant

Name and signature of researcher

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