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Precision medicine as an "elite sociotechnical imaginary": sociotechnical imaginaries at the intersection of Biobanks, Precision Medicine and Big Data.

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Περίληψη

Η παρούσα μελέτη αφορά στη δημιουργία Βιοτραπεζών και την εφαρμογή της Ιατρικής Ακριβείας στην Ελλάδα μέσα από το πρίσμα της μεταξύ τους επιστημονικής και τεχνολογικής αλληλεξάρτησης, αλλά κυρίως μέσα από το πρίσμα της STS ανάλυσης. Η δημιουργία προσδοκιών στην κοινωνία από τα επιστημονικά και τεχνολογικά επιτεύγματα αποτελεί αντικείμενο STS ανάλυσης. Οι προσδοκίες της κοινωνίας ενδέχεται να σχηματοποιούνται σε «φαντασιώσεις» μέσα από την ενέργεια συγκεκριμένων κοινωνικών ομάδων και πολιτικών και, ειδικότερα, σε «κοινωνικοτεχνολογικές φαντασιώσεις»: *«Ένα όραμα για ένα επιθυμητό μέλλον, το οποίο βασίζεται, και απαιτεί συνεχώς, έρευνα και τεχνολογία, και συνεπώς κοινωνικές προσπάθειες, για την εκπλήρωσή του»,* όπως περιγράφονται από τη Sheila Jasanoff. Ωστόσο, όταν σχηματοποιούνται σε «ελίτ κοινωνικοτεχνολογικές φαντασιώσεις» όπως το προσλαμβάνει η Melanie Smallman, αναδεικνύοντας τον ηγεμονικό ρόλο συγκεκριμένων ομάδων και πολιτικών, η STS ανάλυση μπορεί να αποτελέσει μοχλό για τη σωστότερη και πιο δίκαιη υλοποίηση συγκεκριμένων ερευνητικών πολιτικών.

Η Ιατρική Ακριβείας αποτελεί σύγχρονη αντίληψη για την κλινική πρακτική, βασισμένη στα αποτελέσματα της βιοϊατρικής έρευνας του 21^{ου} αιώνα. Η Ιατρική Ακριβείας δεν θα μπορούσε ποτέ να υλοποιηθεί χωρίς βιοτράπεζες. Για τον λόγο αυτό, οι βιοτράπεζες προσεγγίζονται ως προϋπόθεση για την ανάπτυξη της ιατρικής ακριβείας.

Στις βιοτράπεζες πραγματοποιείται η φύλαξη ανθρώπινων βιολογικών δειγμάτων που είναι απαραίτητα για τη σύγχρονη βιοϊατρική έρευνα, η οποία γίνεται όλο και περισσότερο μεγάλης κλίμακας, διεθνής, συνεργατική μεταξύ δημόσιου και ιδιωτικού τομέα και μεγάλων δεδομένων. Στην περίπτωση των βιοτραπεζών, οι πρακτικές και οι προσδοκίες βρίσκονται σε συνεχή αλληλεπίδραση: είναι αλληλένδετες και αλληλοδιαμορφώνονται. Οι βιοτράπεζες βρίσκονται «στο μεταίχμιο της έρευνας, της γενετικής, της γονιδιωματικής, της κοινωνίας, της ηθικής, του νόμου και της πολιτικής» (Tarkkala, 2019).

Στην Ελλάδα, ακολουθείται η Ευρωπαϊκή πολιτική σχετικά με τις βιοτράπεζες και, ως εκ τούτου, αποτελούν βασικές υποδομές για έρευνα, ανάπτυξη και καινοτομία, καθώς και εκφράζουν τη δέσμευση της βασικής έρευνας προς όφελος της κοινωνίας, γεγονός που νομιμοποιεί τη δημιουργία δικτύων βιοτραπεζών, οργάνωσης αυτών, διοίκησης και χρηματοδότησης.

Την πρώτη δεκαετία του 21ου αιώνα, καταβλήθηκε μια συνεχής εθνική προσπάθεια δημιουργίας ερευνητικών υποδομών και δικτύων όπως οι βιοτράπεζες, για την προώθηση και την ανάπτυξη της εξατομικευμένης ιατρικής και της ιατρικής ακριβείας. Πρόκειται για πρωτοβουλίες που αναλαμβάνονται προς όφελος της υγείας των πολιτών και της οικονομικής επιτυχίας που θα προκύψει από την ανάπτυξη των δραστηριοτήτων καινοτομίας και των επενδύσεων.

Στην παρούσα μελέτη προσπάθησα να συνδέσω τις βιοτράπεζες με την ιατρική ακριβείας, μέσα από το πρίσμα μιας ελίτ κοινωνικοτεχνολογικής φαντασίωσης (Smallman, 2020).

Abstract

This thesis studies the creation of biobanks and the implementation of precision medicine in Greece through the prism of their scientific and technological interdependence and, especially, by subjecting them to an STS analysis. The emergence of societal expectations due to certain scientific and technological achievements constitutes a major STS topic. Through the action of certain social and political groups, society's expectations may be shaped into 'imaginaries' and, particularly, into 'socio-technological imaginaries'. "A vision for a desirable future, which is based, and continuously requires, on research and technology, and therefore social efforts, to fulfill it", as described by Sheila Jasanoff. However, when they are shaped into "elite sociotechnical imaginaries" (as perceived by Melanie Smallman, highlighting the hegemonic role of specific groups and policies), STS analysis can be a lever for a more correct and fairer implementation of specific research policies and technology.

Precision Medicine is a modern understanding of clinical practice based on the results of 21st century biomedical research. Precision medicine could never be implemented without biobanks. For this reason, biobanks are seen as a precondition for the development of precision medicine.

Biobanks are carrying out the storage of human biological samples that is necessary for modern biomedical research, which is becoming increasingly large-scale, international, collaborative between the public and private sectors and big data. In the case of biobanks, practices and expectations are in constant interaction: they are interlinked and mutually modulating. Biobanks are "at the crossroads of research, genetics, genomics, society, morals, law and politics" (Tarkkala H., 2019).

In Greece, the European policy on biobanks is being followed and biobanks are addressed as basic infrastructure for research, development and innovation. Biobanks express the commitment of basic research to the benefit of society, which legitimizes the establishment of networks of biobanks, their organization, administration and funding.

In the first decade of the 21st century, a continuous national effort was made to create biobanking research infrastructure and networks in order to promote the development of precision medicine. These initiatives are taken for the benefit of

citizens' health and the economic success that will result from the development of innovation activities and financial investment.

In this study I have tried to link biobanks to precision medicine through the prism of an elite socio-technological imaginary (Smallman, 2020).

Contents

Introduction

This study in the field of Science and Technology Studies (STS) investigates *biobanks* as a prerequisite for new biomedical translational research and, especially, *precision medicine* (PM). The new structure of biomedical research through biobanks (Tarkkala et al., 2018) is investigated against the backdrop of precision medicine as an "elite sociotechnical imaginary": "a vision of a desirable future, which is both built on, and continuously requires, science and technology, and therefore societal efforts, for its fulfillment" (Jasanoff and Kim, 2009; Smallman, 2019) .

The Human Genome Project (HGP) announced its first results, the first sequences of human genome in June 2000. After this flagship date a rapid development of population genomics changed the field of life sciences by bringing in new forms of socio- and bio- politics and of biocapital. The study of the genetic variation between humans (after solving the technical issues related to the sequencing and analysis methods) was the principal step in order to further investigate new biomarkers for complex diseases, through a genetics approach. The HGP inevitably lead to the generation of large-scale population-based genome research resources. As Ho Chih-Hsing argues, this step has been crucial for the further development of genomics research which, ultimately, transforms informatics to therapeutics (Ho, 2012).

In the actual postgenomics era, the further development of PM, became a dogma of biomedical research. The aim is to develop diagnostic and therapeutic tools based on genomics, tailored to individual patient, on the basis of its genetic profile. In parallel, pharmacogenomics promises to tailor drugs based on individual genetic variation, raised hopes for the optimization of drug therapies ensuring maximum efficacy with minimal side effects.

The connection of biological material and genetic information seemed to be of paramount importance. Thus, biobanks where collections of human biological materials are linked to the related genetic information have attracted considerable attention, since they provide the necessary link between genes and diseases. Biobanks have been recognized by many scientists and geneticists as the infrastructure making it possible to translate genomics into clinical applications. Many countries have joined this emerging global field of biobanking, so as to set up their own large-scale population biobanks and support the application of genomics research. One milestone at the state level is that of capitalizing on a state's genetic resources. Then, biobanking

turns into a new technology assemblage that a state/nation can utilize to "incorporate the biological existence of its population into a series of political and economic concerns" (Ho, 2012, p.10) "The dual investment in public health and economic growth characterizes biobanks as both generators of pioneering scientific knowledge and a new technique for the advancement of the health and wealth of modern states. The latter may now take its stewardship responsibility for generating technologies of government by rearranging its resources in the name of collective security and the public good" (Ho, 2012, p10).

Biobanks are addressed by Heta Tarkkala as conditions of possibility for precision medicine, as machines to make a future. Tarkkala speaks about "a sociotechnical imaginary of PM", within which, "rearrangements of scientific practices and of the organization of samples of human origin are legitimized and reasoned. The samples are assigned different characteristics: for example, they seem to be able to serve both the health and the economy, both nationally and internationally, both now and in the future" (Tarkkala, 2019, p.21). Moreover, regulatory, societal, and ethical issues are continuously of practical concern. Erik Aarden has argued that biobanks mirror "how imaginaries of desirable futures that inform science policies are reflected, negotiated and contested in the configurations of material infrastructures for knowledge production" (Aarden, 2017, p.754).

Why consider biobanks as conditions of possibility for PM? There are three reasons for such a role of biobanks: first, the high quality of samples; second, the politics about the research "populations" of biobanks and, finally, the "hybridity in knowledge production articulated through the goal of translational medicine in general, part of which is PM" (Tarkkala, 2019, p.22).

The subject of this study is "the sociotechnical imaginaries at the intersection of Biobanks, PM and Big Data", which are investigated by focusing on PM as an "elite sociotechnical imaginary" and on biobanks as a prerequisite for both PM and the maintenance of such an imaginary (Tarkkala, 2019). The aim is to unpack certain claims related to biobanking and PM in Greece, as they are presented and interpreted, from published policy materials, state documents, press releases and webpages, reports of scientific meetings and slide presentations.

This work deals with expectations and futures involved in making and maintaining biobanks as valuable tools for PM, itself also an evolving imaginary constantly being reshaped (Tarkkala et al., 2018). Nationally, these processes have

been dictated through a top down policy, as is shown by the cases of the early years of the Greek Biobanks Network (BBMRI-GR) and the National Flagship Inititative on Precision Medicine, which outlines, according to my own judgement, the blueprint of an "elite sociotechnical imaginary" (Smallman, 2020). In this context, biobanks are placed in an environment characterized by uncertainty that continuously requires flexibility in regard to the very idea of what biobanks are, what they offer as infrastructure, and what can be achieved through them.

Finally, the question raised by Tarkkala is always valid: "What do the expectations related to biobanks as conditions of possibility for PM tell us about the role of biobanks in it?" (Tarkkala, 2019, p.21).

The potential of biobanks for translational medicine is analyzed on the basis of field notes from my participation in meetings of "Biobanking and BioMolecular Resources Research Infrastructure" (BBMRI-ERIC) and BBMRI-GR, and, also, of publicly available materials (such as newspaper articles).

Chapter 1

1.1. Sociotechnical Imaginaries.

Scholarly work in STS has done much to reveal complex social dynamics in the production of scientific claims (Jasanoff, 1995), the design of technological artifacts (Winner, 1980), the assessment of risks and benefits (Wynne, 1992), and the formation of expert knowledge and cultures (Jasanoff, 1990). STS has challenged the role of the state in defining the purposes of publicly supported science and technology: what constitutes the public good, which sections of the public should be served by investments in Science and Technology (S&T), who should participate in steering science and by what means (and in which way) should controversies be resolved regarding the direction of research and development? Only by addressing such questions one begins to understand why S&T policies are formed the way they are, why they often diverge radically across nation states, and how S&T policy-making could better serve democratic interests in an era of globalization.

My approach to the theoretical concept of ‘‘sociotechnical imaginaries’’ stems from the work of Sheila Jasanoff and her colleagues through the years. Sociotechnical imaginaries are defined as ‘‘collectively imagined forms of social life and social order reflected in the design and fulfillment of nation-specific scientific and/or technological projects.’’ (Jasanoff and Kim, 2009, p.120). Imaginaries, in this sense, describe “attainable futures and prescribe futures that states believe ought to be attained”(ibid). In my opinion, a salient example of a sociotechnical imaginary can be found in President Barack Obama’s Precision Medicine Initiative in the USA and, concerning Greece, in the Hellenic Precision Medicine Network launched by the former Greek Minister for Research, Constantinos Fotakis, in 2018 as a state mission to plan and execute technological feats for achieving better health and well-being for the citizens, while also promoting biomedical research.[1] Such visions, and the policies built upon them, have the power to influence technological design, channel public expenditure, and justify the inclusion or exclusion of citizens with respect to the benefits of technological progress.[2]The concept of socio-technical imaginaries has its origins in

[1] See https://oncopmnet.gr/.
[2] See: https://steps-centre.org/pathways-methods-vignettes/methods-vignettes-sociotechnical-imaginaries/.

the philosophy of Cornelius Castoriadis, who introduced it in his book "The Imaginary Constitution of Society" (Castoriadis, 1987) as a deeply ingrained and largely unconscious set of constructs that shape a given generation's understanding of reality and, hence, determine for them the limits of practical possibility. Even though, for Castoriadis, the social imaginary was pervasive, for later theorists (such as Charles Taylor) it has been pluralized: several (possibly many) distinct social-imaginaries emerge and compete with one another (Taylor, 2004). The notion of a social imaginary has been enriched by Sheila Jasanoff, who emphasized the role of science in fixing modern conceptualizations of the real. The sociotechnical imaginary is offered as a theoretical construct for organizing both historical and sociological analyses of technological innovation in a given sector or region. The construct is intended to stress both the co-production of technical means and social institutions and, also, the sense in which the innovation and implementation of a sociotechnical system is temporally structured. In a collaboration with Sang-Hyun Kim, Jasanoff argues that changes in sociotechnical systems occurring over time can be mapped in terms of a plan or anticipatory sequence (Jasanoff and Kim, 2009; 2013).The concept of sociotechnical imaginaries partly builds upon the growing recognition that the capacity to imagine futures is a crucial constitutive element in social and political life. Imagination is no longer seen as a mere fantasy or illusion, but as an important cultural resource that enables new forms of life by projecting positive goals and seeking to attain them. Rather, imagination helps produce systems of meaning that enable collective interpretations of social reality (Castoriadis,1987); "it forms the basis for a shared sense of belonging and attachment to a political community (Anderson 1991); it provides the gaze through which ''the Other'' is constructed and represented (Said, 1978) and as Michel Foucault, writes "it guides the simplification and standardization of human subjects so as to govern them more efficiently" (Foucault, 1979). Sheila Jasanoff stresses imagination that an "organized field of social practices serves as a key ingredient in making social order" (Jasanoff et al., 2009, p.122).

As far as scientific and technological discoveries are concerned, imagination appears primarily in the creative minds of individual scientists and engineers in very specialized fields.

STS scholars have long worked on the concepts of promises, visions and expectations of future possibilities as political tools for the social organization and practices of science and technology, because they influence and shape trajectories of

research and innovation (Borup, 2006). In his interesting book about the "Technoscientific Imaginaries", George Marcus (1995) emphatically argues that ''technoscientific imaginaries'' are not tied to future possibilities solely through scientific or technological practices. "They are almost always imbued with implicit understandings of what is good or desirable in the social world—for instance, how science and technology can meet public needs and who even are the relevant publics. In that sense, technoscientific imaginaries are simultaneously also ''social imaginaries,'' encoding collective visions of the good society. Imaginaries are not the same as policy agendas. They are less explicit, less issue-specific, less goal-directed, less politically accountable, and less instrumental; they reside in the reservoir of norms and discourses, metaphors and cultural meanings out of which actors build their policy preferences. Neither are imaginaries simply master narratives that justify scientific or technological investment, such as the pervasive modern narrative that equates science with progress. Unlike master narratives, which are often extrapolated from past events and serve explanatory or justificatory purposes, imaginaries are instrumental and futuristic: they project visions of what is good, desirable, and worth attaining for a political community; they articulate feasible futures" (Jasanoff and Kim, 2009, p.123).

Imaginaries have a special role in accompanying innovation and the risks and uncertainty going together, in activating collective consciousness. Imaginaries help create the political will and "sociotechnical imaginaries are associated with active exercises of state power, such as the selection of development priorities, the allocation of funds, the investment in material infrastructures, and the acceptance or suppression of political dissent" (Jasanoff and Kim, 2009, p.123).

Through the time, despite the increasingly global flows of capital, media, knowledge, and skills, the framing and bounding of S&T projects and related policies remain closely intertwined with nation-building (Jasanoff et al, 1995, 2005). Of the multiple sociotechnical imaginations at play in any society, some tend to be more durable at the national level because powerful instruments of meaning-making and goal-selecting often lie within the control of nation states (e.g., political campaigns, official policy narratives and instruments). "National imaginations can penetrate the very designs and practices of scientific research and technological development. Hence, the resulting politicy of science and technology may shape not only the narrow issues surrounding those specific enterprises but also wider social and political

understandings about a nation's past, present and future" (Jasanoff , and Kim, 2009, p.124)

Jasanoff and Kim, since 2009, have been approaching the sociotechnical imaginary in order to understand the social dimension of technological change at the national level. Within this context, an "imaginary is not a mere illusion or fantasy because it performs a certain policy function. When members of the policy community share the same imaginary, the policies they design are similar in that they pursue the same sociotechnical vision and sociotechnical imaginaries can also evolve into institutional norms or imperatives that sometimes shape the way members think and act. Moreover, sociotechnical imaginaries are not always static, but certain sociotechnical imaginaries in the history of technology policy can be more durable than others. The longer they survive, the more similar policies become, and the more members of policy community take them for granted. As a result, a unique sociotechnical policy culture is formed" (Jasanoff and Kim, 2009, p.122).

Recently, there has been a growing interest in societal challenge-driven innovation, which prioritizes solving social problems rather than economic development. For instance, the US and EU create visions of human enhancement or sustainable development as sociotechnical imaginaries of technological convergence.

1.2. Elite sociotechnical imaginary of precision medicine (PM)

The recent work of Melanie Smallman (2020) gave me the opportunity to face PM intiatives, movements and policy through her concept of the "elite sociotechnical imaginary".

During the last decade, the discussions regarding the democratization of science and technology have been lively and intense in the scientists' milieu. This has been proved to be a significant theme among STS scholars as well. Science and technology affect the lives of citizens and the inherent uncertainty both to science and technology is understood with difficulty. Alongside this, a perception of a wider democratic deficit emerged in the 1990s in Northern Europe and the USA, resulting in new techniques to involve citizens in policy decisions and research, which constitutes the narrative of the European Responsible Research and Innovation policy. Through Smallman's work, the evaluations of the public participation "approach to democratizing science and technology often conclude that it is problematic, finding little evidence that public

perspectives are taken up by policy" (Smallman, 2020, p.590). According to Smallman this "resistance of policymakers to public perspectives tend to focus on the dominance of technoscientific perspectives and cultures within policy-making institutions". Certainly, policies supporting the normative motivations of science have adopted (at least, at the European level) the belief that science is a reflexive practice and that the public lack similar reflexivity, which is still a current prinicipal narrative. "The lack of reflexivity of the technoscientific viewpoint, describing an 'elite' attachment to 'promethean' views of science that leaves little space for more precautionary public perspectives that the policymakers might view as slowing down progress" (Smallman 2020, p.590).

Smallman argues "that while the public perspectives elicited during public engagement might be relevant and insightful to policy, the public sociotechnical imaginary revealed within them, which sees downsides as inherent to and inseparable from the science itself, is more complex than the dominant scientific-led sociotechnical imaginary, which sees downsides as separate epiphenomena to be managed away, and is therefore perhaps too difficult for policymakers to act upon". In terms of the mechanism of power, these "technoscientific viewpoints" may exclude other perspectives (Smallman, 2020).

Drawing on Bachrach and Baratz's argument "power means more than simply the power to make decisions – it also means the power to decide what decisions cannot be made" (Bachrach 1963, p.948). In a similar approach, Welsh argues "that science is given authority beyond its role of providing facts and information to inform policy. It is also being allowed to declare which information is salient and which is not, and in so doing, science is given authority to decide public meanings" (Welsh 2013, p.544). Similarly, in the field of neuroscience, Pickersgill (2011) looks at how legal policies were formed by considering the 'sociotechnical imaginaries' at play. He concludes that "the dominant sociotechnical imaginaries shared by those setting up anticipatory discourses determined which possible futures were on the table and which ones were not". Likewise, Hurlbut describes how, "by promising to address societal challenges, scientific imaginaries of synthetic biology give science the authority to declare what technological futures are possible, desirable, and good (Hurlbut, 2015,p.113).

The aforementioned approaches are valuable because they give a sense of how, under particular policy situations, "public perspectives might be crowded out or deemed irrelevant by the dominant perspectives" (Smallman, 2020, p.591). The

question Smallman asks is more than relevant: “What is it that gives this power imbalance, and the technoscientific viewpoint, such strength and durability across time, geography and issue, despite deliberate efforts to disrupt it?” What is it that makes public policy resistance to public perspectives so enduring and what mechanism lies behind this resistance? Using Jasanoff’s theoretical concept of sociotechnical imaginaries to examine the relationship between knowledge, its application and power, Smallman (2020) argues that the ‘soft ties’ –the norms and collective understandings shared amongst policymakers– do indeed explain some resistance to public perspectives. However, it is how policy-making structures, laws and institutions have been built by those holding this technoscientific viewpoint that gives it its power, strength and endurance (Smallman, 2020).

An “elite sociotechnical imaginary” influences the way science is perceived and how public perspectives are expressed in public dialogue. “The dialogue process is often dominated by expert understandings and imaginaries, rendering some futures possible and closing down others” (Smallman, 2020, p.591). Narratives are adopted to bring emerging technologies to life, and are effective in shaping the discussion towards the elite imaginary (Welsh , 2013). Example of such a narrative is the ‘science to the rescue”, when extreme conditions or terrible diseases are used to exemplify the purpose of a new technology. In this context, the elite imaginary’s understanding of science becomes a problem-solver: PM and new drug treatments fit particularly in this context (Precision Medicine Initiative, “All of Us” Programme, White House of USA) (Tarkkala, 2019).

Through the European reports (such as the European Science Foundation’s on Precision Medicine), one can understand that the social and ethical issues are addressed as an outsider of the very same scienctific process and this reflects the concept of the elite imaginary, because both issues are inherent parts of the science and technology. The lay public may have a lot of reservations and fears about specific technologies and policies, often because of missing information. “Aspects of the elite imaginary create a situation where the public’s views can only be expressed and interpreted as a series of issues to be addressed or conditions for proceeding, both by shaping the form of the debate and by shaping how the debate is heard” (Smallman, 2020, p.593).

Generally, the public opinion is far from prohibitive or aiming to hold back science. The public is broadly supportive of science, sharing with the elite imaginary a sense of the progress that can be delivered by science and technology, albeit tempered

by concerns about possible downsides. Smallman suggests that the elite sociotechnical imaginary is "acting as a filter, rendering subtle public perspectives as simple objections that can be ignored" (Smallman, 2020, p.594).

Smallman explains how the elite imaginary of 'science to the rescue' (eg. PM in oncology) excludes public perspectives through the norms, cultures and practices of policy-making and the perspectives of policymakers. Instead of the elite imaginary itself constraining the agency of policymakers to listen to public perspectives, the opposite may occur, e.g. "how the machinery of policy-making has been shaped around the elite sociotechnical imaginary. Forcing evidence and expertise to take a particular 'form' prevents policymakers from taking publics' views into account. This in turn gives durability to the technoscientific viewpoint: to be dealt with in the policy-making process, all issues are forced to take the form of the elite sociotechnical imaginary, regardless of the shape of the matter in hand, or the perspective of the policymaker(s) operating the system. Alternative views of science – even if they are considered to be sufficiently expert and are understood correctly – simply cannot be accounted for within the policy-making structure and process" (Smallman, 2020, p.601).

The result is that the imaginary becomes more robust while continusly perpetuated. Scientific rhetoric and evidence are prioritized over other positions and alternative evidence. The primacy of scientific advice is based around the elite sociotechnical imaginary of "science to the rescue" – especially the understanding of science as a solver of problems, and of risk and uncertainty as quantifiable, manageable and addressable with more research (Smallman, 2019).

"In conclusion, the technoscientific viewpoint is dominant in policy-making, often resistant to alternative perspectives – especially those expressed by the public in attempts to democratise scientific decision-making" (Smallman, 2020, p.602). The theoretical framework of sociotechnical imaginaries, in addition to policies involving public perception are mechanisms that explain the power, strength and endurance of the technoscientific viewpoint, despite deliberate efforts to disrupt it. Policy-making structures and processes in the USA, UK and EU are shaped by those holding the 'elite' sociotechnical imaginary of 'science to the rescue' (e.g. oncology precision medicine). "The elite sociotechnical imaginary – and the technoscientific viewpoint – is enacted, elicited and perpetuated, thus accounting for its persistence and resilience" (Smallman, 2020, p.601). In the context of a policy-making system shaped around the

‘science to the rescue’ imaginary, nuanced arguments that leave issues open and see risks or uncertainties as inherent to new technologies and unknowable are rendered invisible, misunderstood as opposition, or impossible to take into account.

While STS challenges technoscientific views and assumptions in policy-making (so as to democratize science and technology through the advancement of public participation), it is obvious that this is problematic in the face of the machinery of policy-making.

Chapter 2

2.1. Biobanks

''What's in a name? That which we call a rose by any other name would smell as sweet'' is a well known phrase from Shakespeare's Romeo and Juliet.

Historically, the phrase has been used to imply that the names we use to describe things do not always reflect what they actually are. However, names are very important and do have important connotations and implications that must be considered. Although the term ''biobank'' did not appear in the literature until later, the term ''biobanque'' may have been first used in 1992 by a pharmacist in the Picardie Regional laboratory to describe a collection of valuable biospecimens from a sexually transmitted disease (STD) clinic accompanied by full clinical and laboratory annotations. In this context, the word was chosen to convey safe storage for future use, as for money in a financial bank. The term ''biobank'' first appeared in the scientific literature in 1996 (Loft, 1996) and till 2000 was used mainly to describe human population-based biobanks. In recent years, the term has been used in a more general sense and there are currently many different definitions to be found in reports, guidelines and regulatory documents.

Some definitions are general, including all types of biological sample collection facilities. Others are specific and limited to collections of human samples, sometimes just to population-based collections. There is consensus that the term biobank may be applied to biological collections of human, animal, plant or microbial samples and should only be applied to sample collections with associated sample data, and to collections that are managed according to professional standards. There is no consensus on whether a collection's purpose, size or level of access should determine whether it is called a biobank (Hewitt, 2013; Ho , 2012).

A variety of different definitions have been used. For example, the International Society for Biological and Environmental Repositories Best Practices for Biorepositories (ISBER) defines a biobank as ''[a]n entity that receives, stores, processes, and/or distributes specimens, as needed. It encompasses the physical location as well as the full range of activities associated with its operation" (Watson, 2019, p.204). In recent decades biomedical samples and data have been organized into

large depositories such as biobanks, allowing for increasingly large-scale, international, and data-intensive biomedical research. We have entered a new era, the age of biobanks, where life is collected, classified and stored. In these spaces the heritage of the past projects to the potential uses and applications of the future. Biobanks live a life of their own by rearranging, dispersing and exchanging the material components of organisms: tissues, cells and DNA. They not only gather together the biological substances of plants, animals and humans, but are far more than mere archives: they generate forms of life and create bodies of their own (Watson , 2019).

Biobanks tend to collect not so much material as data. More precisely, the materiality of the samples tends to take second place to its encryption in readable form, biology as text. The molecularization and digitalization of life allows bodies to be regarded more in terms of molecular software than physical substrates. Encoding life as text, with DNA as a universal code, blurs the boundaries between plants, animals and humans. Life forms are treated as information that can be read, stored and rewritten. The changing "substance" of life and its recoding as text alter the conditions and contexts that determine the government of life. Within the Foucauldian concept of biopolitics (Foucault, 1980), the individual and the mass replaced with 'dividuals' and "samples, data, markets, or 'banks'." Unequivocally delineated individual and collective bodies with clearly defined boundaries and internal hierarchies of function are being replaced by flexible codes and non-entities that enable or inhibit communication processes and access. Bodies thus appear to be the product of heterogeneous assemblies; the result of hybrid aggregations. With the shift towards "banks," traditional dichotomies and opposites such as natural/artificial, organic/cybernetic, human/animal or human/machine lose significance. The storage of "living texts" in biobanks requires the decomposition of temporal and spatial contexts. In temporal terms, the life forms collected in biobanks escape natural life cycles, they can be stored and used in every time, time does not exist. The corporeal materials of humans and animals are extracted from their bodies and stored in collections of samples and on storage media – there is no cultural and social exchange (Lemke, 2012).

As mentioned before, the term "bank" included in "biobank" suggests economic issues. Apart from the fact that the question of the value of life brings ethical issues into play alongside economic interests, biobanks might create economic interest

through complex historical pathways, through which biological substances became valuable "resources". Scholars such as Melinda Cooper have theoretically approached the value created by human specimens through the legal option of patenting life forms and biological substances have come to be seen as potential sources of wealth, as "resource stores" and "reservoirs of raw materials" (Cooper, 2008).

2.2. Biobanks and biomedical research

Heta Tarkkala studies the impact of biobanks in the changing of biomedical research and their contribution in the "rearrangement" of the contemporary biomedical knowledge production that takes place in "highly regulated settings, if the own biobanks being reshaped as operations, conventions, regulatory frameworks, and if new expectations are linked to the imaginary of PM and require that action be taken. The different levels of stakeholders, regulations, developments, and projects that condition and constrain biobanking and hence knowledge production, have, and continue to have, an effect on what biobanks are considered and understood to be, and the kind of knowledge and scientific practices they could foster" (Tarkkala 2019, p.3).

Jim Vaught suggests that biobanking is not merely "the simple technical and logistical approaches to collecting, processing, and storing biospecimens (the term biospecimens, includes liquid samples such as blood, urine, and saliva, as well as tissue and cellular samples)" (Vaught, 2016, p.212). In our imagination, biobanks are usually huge freezers with frozen blood or tissue samples, or pathology departments with collections of formalin-fixed, paraffin-embedded (FFPE) tissues. This was the fact over 100 years ago. These collections, generally of the FFPE type, were (and still are) necessary for patient diagnoses in clinical centers. Nevertheless, biobanking evolved during the last 20 years, and such collections may contribute significantly to biomedical research. One of the oldest and largest such collections, the Armed Forces Institute of Pathology (which closed in 2011 and is now part of the US military's Joint Pathology Center) was started during the US Civil War. Over the decades, the value of such pathology collections to research led to more organized efforts to leverage diagnostic biospecimen collections into translational research programs. Meanwhile, over the past 30 years, studies involving biospecimen collections became more prevalent in clinical trials, epidemiology studies, biomarker discovery and development, and other assorted applications.

Biobanking is now considered a cornerstone in the development of PM (Tarkkala, 2019). The core idea for the reproductibility of research results is absolutely related to the quality of the biological material and the technical processes, and they have to be adequately controlled. This principle led to the development of best practices, the evolution of biospecimen methods research and the general recognition that biobanking needed to come of age and become a science in its own right (Vaught, 2016). Thus, biobanks are vital for both contemporary biomedical research and the development of PM, which can lead to the treatment of individuals based on validated knowledge and the utilization of different types of genomic and phenotypic data.

Biobanks are considered to be promising infrastructures for biomedicine and related to biomedical knowledge production as well. The main argument is that the very idea of biobanks is being reshaped, as actual operations, conventions, regulatory frameworks, while new expectations are linked to the PM imaginary and require that action be taken (Tarkkala, 2019).

In the context of the European Research Policy, the development of a European Research Infrastructure (BBMRI-ERIC) gathering stakeholders from different countries, regulations, developments, and projects that condition and constrain biobanking have had (and continue to have) an effect on what biobanks are and what kind of knowledge or scientific practices they could produce and are not merely constrained to technological themes. Instead, they also highlight matters of informed consent, ethics or the relationships between publics and biobanks.

2.3. What are biobanks?

Different kinds of biobanks may be, for example, clinical, disease-specific, or population based (Gottweis, 2012). Internationally, there is not a clear definition of biobanks as they come in different forms, for different purposes, are administered differently, and work according to different governance requirements. Hewitt and Watson reach the conclusion that a biobank could be defined as a "facility for the collection, preservation, storage and supply of biological samples and associated data, which follows standardized operating procedures and provides material for scientific and clinical use" (Hewitt, 2013, p.314).

Biobanks, over time, firstly focused on collecting large numbers of biospecimens. Quantity was believed to be required for methods such as the Genome

Wide Association Studies (GWAS), which led to the conclusion that biobank networks were needed. Subsequently, biobanking focused more intensively on quality, as it became evident that inconsistency in this area is a problem for the credibility and the validity of research. Biobanks then moved on to emphasize their sustainability hence enhancing of value for society is what is also expected from biobanks in Europe, which link health efforts with the innovations and policies of knowledge-based societies. (Ho, 2012)

2.4. Why biobanking?

Since the late 1990s and early 2000s, there has been a growing emphasis on establishing biobanks, both internationally and nationally (Tupasela, 2016). The first collections, clearly preceding contemporary biobanks, were already in place in the 1990s: as an example, in Iceland and Estonia. At the end of the 1990s and at the turn of the millennium, typical cases of biobanks included, for instance, the Danish neonatal serum bank and the biobanks of the United Kingdom and Japan. However, probably the most famous biobank project has been that of Iceland. The Icelandic biobank, DeCode Genetics, accompanied by the Health Sector Database, has served internationally as an example and reference for later projects, accelerating the development of these kinds of databanks elsewhere. Indeed, numerous countries now have their own biobank projects: Japan, Taiwan, Canada, China, Iceland, United Kingdom, Sweden, Singapore, and Estonia to name a few. However, the Icelandic case also exemplifies the hurdles and challenges to such projects (Ho 2012).

In order to investigate the complex mechanisms underlying diseases, large populations need to be studied, a requirement which led to considerations and claims about what populations are most suitable for this endeavor (Tupasela, 2016). One result of this was that many countries claimed that their own collections are drawn from populations offering especially high potential for biomedical research (Tarkkala et al, 2018).

Simultaneously, the data that biomedical research enterprises require must be harmonized in order to be as widely usable as possible. Therefore, current biobank projects are often accompanied by a number of complementary projects and organizations aiming to foster and harmonize practices relating to the standardization of sample quality and data in Europe. For example, BBRMI-ERIC is playing a key role

in developing common practices and guidelines for the European biobanks and biomolecular resources.[3]

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

In many ways, biobanks represent a continuation of the history of medical collections, particularly when we consider the earlier clinical samples and population cohorts on which many biobank collections are based, especially in Greece. These specimen collections and their accompanying data, now translated into biobank collections, have thus existed for decades. Bruno Strasser has put the collecting and the resulting collections into historical context from the viewpoint of the present, observing "Yet biobanks are built on a history of medical collections and only the new samples are collected using the standardized protocols of today. Thus, these collections, both old and new, are part of a longer history of collecting as a scientific practice. Moreover, there have been kinds of circles of exchange on the side of more institutionalized medical or research collections: in the history of natural collections, the establishment of the circulation of samples was crucial, while in medical research, the circulation of certain samples has been a routine practice among researchers.

Nowadays, exchange in biobanks is institutionalized and stabilized and, some say, even democratized compared to past. What we can see in biobanks and the organization of their samples for molecular biology is the merging of two traditions in the natural sciences: scientific experiments and collecting as it was enacted in natural history collections (Strasser, 2012).

Therefore, the DNA sequence database GenBank, for example, –which is an important tool for researchers– does not only represent the "cutting edge of biology",

[3] For more, see www.bbmri-eric.eu

but is also part of a "tradition of natural history" characterized by "collecting, naming, comparing, and organizing natural objects" (Strasser, 2008). Thus, databases such as GenBank exemplify a hybrid culture based on natural history and the experimental sciences. In this sense, biobanks are also part of the crucial kind of knowledge production that accrues from the "collection, comparison, and computation of biological data", and, thus, does not only pertain to the triumph of experimentation (Strasser, 2012).

The merging of experimentation and collecting is demonstrated by the biobank samples and the reasoning regarding their purpose. The possibility for experiments needs to be maintained – only in this way can biobanks contribute to the identification and development of new tools such as biomarkers. In the same manner, Strasser emphasizes the required connection to experimenting: one can spot connections between different outcomes from the databases, but these connections need to be verified by experiments (Strasser, 2012). Thus, the samples in biobanks (both as data and wet samples or virtual and material to be worked on) seem to allow the finding of connections and as well as their experimental verification.

Indeed, the biobank materials are not only intended for comparison but, also, for the experimental production of new knowledge; they both enable and are built on experimentation. Strasser highlights the "hybrid character" of producing "knowledge through both experimentation and collection" in "current biomedical research" that combines "the data-driven and hypothesis driven, the comparative and the exemplary, the experimental and natural historical" (Strasser, 2012). With this hybrid way of doing biomedical research, the "boundaries between specimen collections and molecular data collections are becoming increasingly blurred" (Strasser, 2008, p.539).

2.5. Biobanking, translational expectations

Translational medicine is a term often connected to biobanks in Greece and elsewhere. The concept has been discussed thoroughly at events and public lectures and it has also appeared in the medical literature on the topic (Collins, 2011). While in recent years it has been related to efforts to pursue PM, it is more descriptive of a way to work and organize activities carried out between private and public actors and institutions, as well as research and clinical care, with an emphasis on fostering closer and faster

translation of research results into clinical care and allowing clinical needs to drive research.

Promoting translational medicine was listed among the main goals of the first biobanks in Greece, whose operation was expected to encourage care and research that intertwine and overlap, with biobanks themselves being increasingly utilized in clinical care. Regarding the translational medicine of biobanking, examples of its expected hybridity of clinical care and research were clearly visible when biobanking was in its infancy. In biomedicine, innovations and routines are often intertwined and co-produced. Biobanks are founded in a world where numerous boundaries (such as those between "clinical and research laboratories") have in many places already "become porous" (Tarkkala, 2019). Translational medicine casts light on the medical landscape in which biobanks participate and to which they contribute. Research and care figure together, overlap, and, yet, also remain separate in the biobanking context, examining this from four perspectives: first, the potential to develop individualized cancer treatments in the context of disease-specific cancer biobanks; second, the stratification and validation of populations in clinical biobanks; third, the issues related to the validity of potential secondary findings; and, fourth, the utilization of clinical data analytics (ibid).

The needs of knowledge-building in biomedical research articulate the contingency of boundaries between care, research, laboratories and clinics, as well as the benefits of hybridity. Biobanks are expected to enhance clinical care, indicating the perceived need for *hybridity in knowledge production* of contemporary biomedicine. This means that the expectations tend to illustrate how biobanks have been seen as a possible solution to this kind of situation: enabling something that otherwise is not easy to accomplish in biomedical clinical practice. The expectations of translational biobanking –when the close contact of research, clinics, and public-private partnerships is underlined– reveal a lot about knowledge production and its needs in highly regulated biomedical contexts.

In establishing biobanks in Greece (e.g. through the public funding of BBMRI-GR), the vision of fast translation to patient care was an explicit goal. The network of BBMRI-GR suggested that research-based benefits would accrue more swiftly to the patients and new ways to use research results to inform care would become possible. During the years in which the legislation was being prepared, medicine progressed,

with genome sequencing, for example, becoming available: this meant that the benefits of biobanking could be returned to clinical care.

Another important area of biobanking in which the potential of translational medicine has been made evident is cancer care and cancer research, which are often identified as the forefront of PM. More widely, this also relates to visions of a genomic era of medicine. Among others, Guttmacher and Collins envisioned in 2005 that "it will become the standard of care to sequence cancer patients' tumors and use that information to refine prognosis and guide therapy" (Guttmacher 2005, p.1400). This notion was also reflected in the establishment of disease-specific cancer biobanks. Indeed, in Greek biobanking, the PM approach to treat cancer and tailor treatments was among the identified translational possibilities. This also echoes translational medicine's role as one of the key framings of biomedical oncology since the 1990s (Keating, 2016).

However, while it is anticipated that individualized care can be achieved with the help of biobanks (sometime in the future, biobanks being one of the building blocks in this development), in practice biobanks neither organize nor provide individualized care. In a recent essay about PM, Jorge Alberto Bernstein Iriart (2019, p.2), connects the important outcomes of genomics and molecular biology and claims that this "has raised great expectations concerning its impact on the transformation of medicine". The recent molecular genetics technique known as next generation genome sequencing, becomes increasingly cheaper with increased throughput, rendering this technology more accessible for research. Iriart makes a very important remark, writing that "although the translation of genomic information and technology to clinical practice has not occurred at the pace initially anticipated by enthusiasts of genomics medicine, some authors contend that medicine is undergoing a process of "molecularization" and that some areas, such as oncology, are being profoundly transformed by the incorporation of new knowledge and technologies" (Iriart, 2019, p.2)

A leading movement in the transformation of medicine is that of the so-called personalized or precision medicine, which aims to customize treatment according to the biological characteristics of individuals or subgroups in the population.

Chapter 3

3.1. Meanings and assumptions of PM

Many researchers and clinicians use the terms "personalized medicine" and "precision medicine" interchangeably. In fact, as Iriart (2019) notes that there is a certain fluidity in the way these concepts are defined and used. The term "personalized medicine" is older and was used quite widely in the last decade but, in recent years, has been replaced by "precision medicine", the latter lending its name to recent major research projects in genome sequencing in the United States and China. The term emerged in the late 1990s and was heavily marked by pharmacogenomics and the promise of developing adequate drugs for the genetic characteristics of population subgroups. However, its meaning has changed, with some authors defending a more comprehensive approach, including not only a subgroup's genetic and molecular information, but also other biomarkers and lifestyle, diet, and clinical data. (Iriart, 2019). The following excerpt is taken from a European Science Foundation document (ESF, 2012, p.7), which defines personalized medicine as "a new approach to classifying, understanding, treating, and preventing disease based on individual biological and environmental differences. It seeks to integrate data on the entire dynamic biological makeup of each individual as well as the environmental and lifestyle factors that interface with this makeup to generate a complex, individual phenotype".

Those who prefer the term "precision medicine" note that the concept of personalized medicine is not new, and that medicine has always been somewhat personalized in clinical practice (Tutton, 2014). They argue that the term may be misinterpreted, leading one to believe that it is the development of treatment and preventive measures specific to the individual, rather than population subgroups.

The term precision medicine was used for the first time in 2011 in a report by the U.S. National Academy of Sciences that proposed the groundwork for the elaboration of a new taxonomy of diseases based on molecular biology (NRC, 2011). The report uses the term as a synonym for personalized medicine. The definition in the American project *Precision Medicine Initiative* is also quite similar to the way personalized medicine has been conceived: i.e., as "an emerging approach for disease

treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person" (Duffy, 2016, p. 497). The similarity between the two terms has led some authors to ask whether the new denomination may also represent a way of lending a fresh new start to the movement, leaving personalized medicine's unfulfilled promises behind (Iriart, 2019).

The central thrust of PM is the focus on the individual's quantifiable data: genetic predispositions, lifestyle, diet, and clinical data to be incorporated into personal maps. Importantly, these data are not qualitative data reported by the same the patients, but structured, digitized, quantified, and computerized data. The personalization of medical treatment is intensely characterized by the individual's quantifiable data in different stages of health and disease over the course of their life. Thus, PM depends on data and computational technologies capable of simultaneously examining huge databases.

"Precision medicine has emerged as a computational approach to functionally interpret omics and big data and facilitate their application to healthcare provision. In this new era, patients are not segregated by disease, or disease subtype. Instead, the aim is to treat every patient as an individual case, incorporating a range of personalized data including genomic, epigenetic, environmental, lifestyle, and medical history" (Duffy, 2016, p.494).

Hence, genomics is not the only factor in PM's purview, since other agents also influence its workings. From a theoretical biology standpoint, the completion of the Human Genome Project seriously shook the belief in genetic determinism, as the mapping and dissemination of the results of genome-wide association studies proved the low predictive power of genes. The interactions between genes, lifestyle and the environment (which are studied under the umbrella of proteomics, metabolomics and epigenetics, all at the molecular level) lead to a complex understanding of health and disease.

Scientists defending PM "expect that computational algorithms will allow forming a virtual representation of the patient and developing predictive models based on known interactions between molecular, environmental, and lifestyle data, which in turn will allow individualized treatment decisions" (Duffy, 2016, p.498). As a result, the future will pertain to the maintenance of the individual's health through personalized preventive medicine (Iriart, 2019).

New technologies such as artificial intelligence are emerging approaches for dealing with enormous structured and unstructured databanks (big data) and promise that the expectations surrounding PM will become a reality. These new technologies allow the entirety of an individual's data to be transformed into medical data; to become powerful data sources for predictive analysis. Many scientists defend a "personal data-driven economy", arguing that patients should have complete knowledge and control over their medical data as a whole and should be able to manage them and be compensated for producing research data or for commercial purposes, besides incentives for monitoring health (Iriart, 2019).

Clarke and colleagues introduced the term "biomedicalization" to refer to this process of intensification of medicalization based on the technoscientization of biomedicine. (Clarke et al, 2010). Technoscientization may lead to the commodification of health, turning it into a consumer product, while biomedicalization extends medical jurisdiction beyond disease, encompassing health itself. The focus on health unfolds with the emphasis placed upon practices that concern risk and susceptibility assessment and a constant monitoring, aimed at staying healthy (Iriart, 2019).

From a political point of view, PM is positioned within the biomedicalization movement, placing the individual at the center of its epistemological and political perspective, in keeping with the dominant neoliberal philosophy. Individuals are urged to learn about their susceptibilities in order to monitor them, considerably increasing the amount of information they should consider when making decisions, as well as their responsibility in building a healthier future for themselves based on constant anticipatory orientation. This emphasis on the individual also contributes to shifting the responsibility for healthcare from the social and political arenas to the individual level (Iriart, 2019).

3.2. Personalized-Precision Medicine (PM) "movement"

In his essay, Iriart (2019)presents a stimulating analysis of the PM "movement" (in the scientific sense) as sparking highly controversial debates. The promises of PM raised great expectations concerning the potential of the new genomic and molecular technologies for the prevention and treatment of complex diseases. However, evidence suggests that caution and more restraint are necessary when it comes to the promises of

personalized medicine. While huge progress has been recorded in our knowledge of the molecular mechanisms of disease and in the development of drugs with an enormous impact on, for instance, the treatment of certain types of cancer, these successes cannot be interpreted as a paradigm shift, since there is still no evidence that this pattern will be reproduced in other complex diseases (Iriart, 2019).

In fact, the focus is put on the individual –a concept not really new, as this was Hippocrates' core teaching– and on high-cost technologies. Thus, it is obvious that PM may not benefit all people. Consequently, the most common health problems will not be reduced internationally. On the contrary, inequalities will probably be increased and people who already have the best access to health will continue to benefit from these new medicinal approaches. Such inequalities will probably be much more striking in countries of low or average wealth when compared to richer ones. "For the incorporation of new technologies in personalized medicine, it is essential to undertake a cost-benefit assessment from an ethical perspective that considers whether these will be accessible for everyone to benefit rather than exacerbate the existing health disparities" (Iriart, 2019, p.3).

The emphasis on individuals and genomic knowledge needs to be counterbalanced by resorting to the subjects' perceptions within their sociocultural, political, and economic contexts and, also, by a comparable investment in actions focusing on the social determinants of health. The STS perspective reveals that biomedical technologies are not neutral. They have a history, they are part of a moral context, and their clinical application is heavily influenced by cultural norms, political and economic interests, and dominant scientific trends. A critical analysis is thus essential regarding the assumptions, practices, and possible consequence of PM. STS can contribute to this undertaking, situating the subject and the biological body in their historical, political, environmental, and economic contexts. It can gauge the repercussions of the implementation of new genomic technologies on clinical practice by utilizing local knowledge and the experience of health professionals, patients, and communities directly affected by these technological innovations.

In conclusion, social sciences have to play an important role in the analysis and discussion of these movements towards the transformation of medicine, because science and medicine are social practices embedded in a historical, political, and sociocultural context. The incorporation of new technologies into medical practice is not solely guided by their clinical usefulness. Movements in the transformation of

medicine are influenced by the political, historical, and socioeconomic contexts in which different stakeholders act. These stakeholders can be identified in the pharmaceutical and biotechnology industries, researchers, health professionals, politicians, patients' associations, citizens, the media, and NGOs.

Personalized medicine / precision medicine's meanings have also changed in the last decade, due to the emergence of new terms (e.g., precision medicine) and the coexistence of groups that defend different directions for the movement, the transcendence of its initial focus on pharmacogenomics and the incorporation of new biological, epigenetic, and socio-environmental markers (Patrinos , 2014).

3.3. The "technoscientization" of medicine and molecularization

In order to understand the personalized /precision medicine movement, it is necessary to situate it in the context of the transformation of biomedicine in recent decades, towards what Clarke calls technoscientific biomedicine. Anthropologists use the term "biomedicine" to refer to modern medicine due to its ontological and epistemological emphasis on biology. Biomedical discourse was built on the basis of scientific rationality and a biomechanistic conception of the body, itself heavily grounded in technologies for the diagnosis and treatment of diseases. According to Clarke, since the mid-1980s, biomedicine has undergone a transformation in various directions, based on technoscientific innovations (computer and information technologies, molecular biology, biotechnologies, genomics, telemedicine/telehealth, etc.) that radicalized the process of technoscientization. The new technologies are causing institutional transformations with impacts on the production, distribution, and management of health information, diagnoses and treatments, and on the very concept of what constitutes health and disease. This transformation at the political and economic level occurs in the integration between biomedicine and capitalist interests, in what authors call the "*Biomedical Technological Services Complex*", referring to the increasingly industrialized medical-industrial and scientific complex, which moves trillions of dollars around the globe (Clarke , 2010).

The molecularization of biomedicine is part of this technoscientific transformation in which a new way of viewing and understanding the body at its molecular level complements or even supplants the traditional clinical view (Rose, 2007). This process is characterized by a modification in the biomedical ways of

thinking, assessing, and intervening, entailing a new conception of life as a set of vital mechanisms that can be identified, isolated, manipulated, mobilized, and recombined in new practices of intervention at the molecular level. Rose (ibid) emphasizes the idea that biology is no longer viewed as one's fate, but as an opportunity for technological intervention. Biology has become amenable to intervention as well as an area of major capital investment by the health industry.

Precision medicine is developing in the political and economic context of globalized capitalism, one key characteristic of which is what Rose calls "economies of vitality". This is a new economic space, the bioeconomy, with a new form of capital, biocapital, in which the manipulation of life by biotech companies generates value.

Institutions such as the National Research Council of the National Academy of Science (USA) and researchers defend the need for a taxonomic change in the classification of diseases, based on their molecular characteristics. Based on the understanding of genomic and molecular variations in common diseases such as hypertension, the authors criticize the way diseases are still diagnosed as if they were homogeneous entities. The new taxonomy will no longer rest on the constellation of symptoms, the affected organ, or its anatomical characteristics, but on the disease's molecular characteristics and pathways.

3.4. Personalized medicine and its promises, breakthroughs, limits, and critiques

It is difficult to tell the expectations created by PM that will materialize from those that will fail (or the hype from the legitimate expectations), given the inherent uncertainty of any scientific undertaking (Iriart, 2019). PM was thought to be a revolution in medicine, proclaimed during the Human Genome Project, has still not materialized, maybe it is only a matter of time (ESF, 2012). One reason for skepticism lies with the enormous complexity of the disease process in the more common non-communicable diseases. Unlike monogenetic diseases, most of these diseases are caused by complex interactions among multiple genes which further depend upon environmental factors. All these pose a major challenge for the realization of personalized medicine. According to Duffy (2016), PM has still little to offer regarding the treatment of complex, multifactorial diseases – with the exception of cancer.

Complete genomic sequencing became faster and less expensive with the introduction of new generation sequencing starting in 2005, when it became more

accessible. Thus far, however, it has not proven particularly useful in clinical practice, with the exception of rare genetic diseases.

Oncology is the medical field that is incorporating the most out of the new genomic technologies, as it utilizes them in the identification of the tumors' molecular profile. This results to the use of targeted drugs, including immune therapy, which is frequently cited by PM as a success story. Treatments with targeted drugs that act on genetic mutations have generated significant improvement in clinical results for some types of cancer (for instance, in breast and colorectal cancer).

3.5. The high cost of targeted drugs and the inequalities in access to the benefits

One of the great promises of precision medicine is to reduce the cost of medical care by achieving a greater efficiency in the use of drugs, avoiding their use by patients for which they would be ineffective or by avoiding side effects. However, this promise has not materialized. To the contrary, the high cost of targeted drugs produces inequalities in access to the drugs' benefits and challenges for the health systems' sustainability (Iriart, 2019).

The high cost of targeted drugs will entail inequalities of access to their benefits in high and middle/low-wealth countries and, within the latter, between populations from different social strata. For low-wealth countries, which often experience difficulties in accessing basic health technologies for their populations, the costs of the new treatments are prohibitive. Most low and middle-wealth countries are unable to provide their populations with all the drugs that are considered essential by the World Health Organization (WHO). Thus, PM may concentrate resources in the part of the population that already has higher purchasing power and better access to health services (Iriart, 2019).

3.6. Shifting research priorities

Finally, one of the problems detected by critics of PM concerns the degree to which the emphasis by governments, funding agencies, the pharmaceutical industry, and the scientific community on genomic and molecular health research is changing research priorities and relegating any attention to the social determinants of health and preventive measures of greater impact for the population. The NIH (National Institutes

of Health) for research areas that included the words “gene, genome, or genetic” was 50% greater than for areas that included the word “prevention”. NIH funding for research in public health has declined in the last ten years, while funding for genomics research has grown substantially.

If we want to challenge the importance of the impact of PM in public health, we have to question what are PM’s contributions in dealing with the major global public health problems. Will PM reduce the main causes of morbidity and mortality? Importantly, studies about the social determinants of health show that the main public health problems will not be affected by PM if the primary underlying social causes of these problems are not effectively addressed (Tarkkala, 2019). The great strides in the improvement of the population health indicators resulted from improvement in the population’s socioeconomic conditions and relied upon key measures for certain population groups, such as basic sanitation, vaccination, and tobacco control programs. It is quite probable that the predominant PM approach (which emphasizes on high-cost drugs that benefit small populations) will not only fail to produce an impact for the greater population, but may also override low-cost and more effective interventions and policies (ibid).

Chapter 4

4.1. The sociotechnical imaginary of PM and the role of biobanks

Biobanks are an important factor in the creation of expectations and prospects and vice versa. The same expectations and prospects contribute to the development of biobanks and, ultimately, of PM. According to the theoretical concept of sociotechnical imaginaries developed by Sheila Jasanoff, "imaginaries and expectations related to infrastructure such as biobanks are what make things happen" (Tarkkala, 2018).

4.2. Expectations and sociotechnical imaginaries

Contemporary medicine, biomedicine, and genomics raised hopes, promises, potential, and future imaginaries and orientations. Social science and STS studies address the role played by future orientations, or the creation/maintenance of certain futures in contemporary societies (Jasanoff, 2015).

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: 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.

Particularly biobanks (due to the role they seem to be playing in pursuing genomics and personalized or data-driven medicine) mobilize these futures in the present, regardless of whether the expectations placed in them are eventually met. Biomedicine and its ability to produce hope has been discussed in terms of medical imaginaries (Del Vecchio, 2003).

Science and technology are likely to play key roles in our understanding of what should be achieved in our societies and through which means. Thus, sociotechnical imaginaries also highlight the co-production of science and society (Jasanoff, 2004).

Moreover, imaginaries such as PM often come with specific local characteristics (Jasanoff, 2009, 2013, 2015). Genomics in Latin America (for example,

in Brazil and Mexico) are very much built on racial heterogeneity, while in Singapore the goal is to stay competitive and put the heterogeneous "Asian" populations onto the map of biomedical research, thereby ensuring that the needs of these groups are met.

4.3. Personalized-precision medicine as a sociotechnical imaginary

Personalized/precision medicine, as a term, currently refers to a more individualized way of treating patients. Offering the same standard treatment to everyone is no longer considered an option; instead, every patient and every disease is regarded as potentially one of a kind (National Research Council USA, 2011). According to Tutton, personalized medicine rearticulates "long-standing debates in medicine about how to make sense of individual differences and what they mean for disease prediction, treatment and care" (Tutton, 2014, p 3.). While there is no official definition, in the European Union Council conclusions on personalized medicine for patients (2015) it is defined as follows: Personalised medicine refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention (European Union, 2015).

Simultaneously, in this term notions of stratified medicine and precision medicine overlap in many ways and can be regarded as virtually synonymous, sharing the idea of accuracy and efficacy that goes far beyond treating the average with standard treatments offered for many diseases today.

Hood and Friend have envisioned medicine becoming "predictive, personalized, preventive and participatory" – otherwise referred to as P4 medicine (Hood, 2011). These four P's are usually part of what is understood within the scope of personalized medicine as an expectation for patients to assume increasing responsibility and more active roles when it comes to their health and disease prevention, so as to receive more individually tailored treatments (Prainsack, 2017; Tutton, 2014). Indeed, for personalized medicine to become reality, it is argued that patients need to be active: new alliances and partnerships are expected and needed. This is something Prainsack has identified as the novelty of personalized medicine (Prainsack , 2017).

In practice, it means that patients are, according to Prainsack, becoming "prosumers", as they participate both in the production and the consumption of the goods, contents, products, and services in the field of health, since personalizing treatment has changed from "family and social relationships" and "mental state" into a data package of "genetic predispositions", "lifestyle information", and "clinical data" (Prainsack, 2017).

The first reading of the human genome, at the beginning of the millennium, raised hopes for a new kind of medicine based on better knowledge about diseases and human bodies, and better-serving public health. It was expected that human traits would be linked to common genomic differences, which was believed in the past. However, biology turned out to be more complex than it had been believed to be. The only well-known examples of individually tailored treatments are the targeted medical substances used in cancer care.

The promises of biobanks gain credibility and power from the general visions and actual efforts that relate to PM, which legitimizes biobanking and its re-purposing and reorganization of samples and health data. Simultaneously, both health and monetary values are linked to these efforts. It is no surprise, then, that Tutton has wondered whether personalized medicine is "a powerful vision of the future to be likened to a national infrastructure project, merely a marketing strategy, or an approach to patient care that emphasized the whole patient. Tutton describes the imaginary of PM as "the speculative, propositional fabric of scientific thought concerned with the application of genomic knowledge and technologies to the biomedical enterprise" (Tutton, 2014). Imaginaries rely on culturally intelligible fantasies which, for PM, is the ideal of individuality (Tarkkala, 2019).

However, in this dissertation, I examine PM in relation to biobanks through the theoretical lens of the sociotechnical imaginary (Jasanoff, et al., 2013, 2015). Discussions and visions concerning PM provide good examples of sociotechnical imaginaries. PM in many ways indtroduces economical, societal, and ethical reorganization, with its proponents pushing to create an environment where the imaginary can be actualized (Tarkkala, 2018).

Understanding personalized medicine as a sociotechnical imaginary underlines how PM 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 (Tarkkala, 2018).

The European Alliance for Personalized Medicine, for example, claims that the "European Commission, the European Parliament and EU member states" should "improve the regulatory environment so that Europe's patients and citizens can have early access to personalized healthcare" (Official Journal C 421 of the European Union Volume 58 English edition Information and Notices 17 December 2015). Similarly, the International Consortium for Personalized Medicine (founded under the EU) states in its action plan that personalized medicine hinges not only on widespread use of health data and "improved understanding of the biological mechanisms and environmental interactions that govern disease progression", but also on a supportive "policy and regulatory environment" (International Consortium for Personalized Medicine, 2017). Indeed, regulation and policy are not without significance: indicatively, in recent years, Greece created "enabling legislation" in order to realize Precision Medicine as a response of the State to a major societal challenge.

Seeing PM as a societal phenomenon with links to interests, policy, and regulations underlines this that "the sociotechnical imaginaries one can distill from policy documents and the public sphere reflect the attempts of governments to integrate expected developments in conceptions of the future world and how we should relate to it and engage with it" (Tarkkala, 2019, p.18). Furthermore, PM as an imaginary that shapes biomedicine, comes with intense expectations of economic value, growth, and profits (ibid).

4.4. Personalized Medicine needs for Political Support. The Political background of Precision Medicine

"And the goal of the Precision Medicine Initiative is to figure out how to break down some of the structural or institutional barriers that prevent us from making the big leaps over the next several years".—**President Barack Obama (White House 2016)**

It can be argued that the narrative of precision medicine, as manifested in the USA through its political support and sizeable public funding, represents a stereotypical sociotechnical imaginary.

In a relevant paper, Alessandro Blasimme and Effy Vayena present the history of the PM top-down political initiative in the USA. "In the first decade of the new century, while scientific circles elaborated and refined the very idea of personalized

medicine, politicians turned toward it as well. In particular, in 2006, then-Senator Barack Obama (D-IL), introduced a Genomics and Personalized Medicine Act intended to provide institutional support to the development of this field. The 2006 Act was the first of a series of four legislative initiatives bearing the same name, all aimed at fostering the promise of improving the accuracy of prevention, diagnosis and treatment. The other three were introduced in 2007, 2008 and 2010, respectively. Despite growing expectations surrounding personalized medicine, however, none of these bills eventually passed into law.

Against the backdrop of the historical trajectories identified thus far, in January 2015, President Obama announced the launch of a flagship plan to finally realize the promise of personalized therapy. In practical terms, the PMI distributes $215 million from the President's budget to the NIH ($130 million), the National Cancer Institute ($70 million), the FDA ($10 million), and the Office of the National Coordinator for Health Information Technology ($5 million), in order to conduct a series of activities that should support the development of precision medicine. The goal of the initiative is ambitious, as it aims to revolutionize how we improve health and treat disease (White House, 2015a,). Under the new banner of precision medicine, the White House designates "an innovative approach to disease prevention and treatment that takes into account individual differences in people's genes, environments, and lifestyles" (White House 2015a), the "All of Us Program" (Sankar, 2017,p. 743).

The envisioned goals of PMI are the acceleration of tailored cancer treatments, the constitution of a voluntary research cohort, protection of the participants' privacy, regulatory modernization, and public-private partnership, without a fixed center of political coordination. All of these present a more federalized structure.

A broader societal vision encompasses the idea of engaging and empowering participants with the use of their own data so as to improve their health. This represents a distinctive cultural feature of the whole initiative. Interestingly, the research participant prefigured by the PMI research cohort is, therefore, both a contributor and an end user of the data. This feature aligns with the anticipated diversity of the data to be extracted from the PMI cohort. Recently, PM seems to have incorporated the idea that the development of patient/public participation and the integration of all kinds of data will bring PM beyond the "inflection point", at which occasion a "dramatic change" can happen (Blassime, 2016).

The role that research participants might play in moving beyond that inflection point is a novel and distinctive feature of the PMI. The PMI research cohort is imagined to rely on two modes of recruitment: direct volunteering and solicited enrollment during clinical interaction (Blassime, 2016).

"Reminiscent of its participatory ethos -also initially developed by the proponents of P4 medicine- the PMI thus explicitly sets out to promote a cultural as well as a scientific revolution (PMI Working Group 2015), capitalizing on people's willingness 'to be active partners in modern science' (Blassime, 2016, p.2). Public engagement in the governance of the cohort is, thus, imagined to ensure that its activities respond to the expectations and values of those who personally contribute to it. The expected advantage of this partnership, as imagined in the PMI, consists in fostering collaboration between participants and researchers in the design and management of the cohort, thus ensuring trust and sustainability for the initiative (White House, 2015b). The vision of the PMI in this domain, though, goes beyond issues of governance. In exchange for their participation, volunteers will also get access to the information generated about them through their data, thus being empowered to potentially use that information for health purposes (Blassime, 2016).

"Precision medicine, therefore, does not only embrace a general trend towards expanding the scope of research participation. It also seeks to promote a culture of personal responsibility for one's own health, and does so by using the language of empowerment. But because terms like "participation" and "empowerment" carry positive connotations, we should be attentive to the full spectrum of ethical implications, both positive and negative, that these terms might have on the public perception of precision medicine (Blassime, 2016).

Chapter 5

5.1. Precision Medicine, the Greek Landscape

In this section, the making of a medical future in the activities launched in Greece during the past decade to advocate in favor of PM is studied with relevance to the European Research Policy.

In this work, it is demonstrated that national strategies perform and produce visions that are mutually constitutive with the elite sociotechnical imaginary (Jasanoff and Kim, 2009; Smallman, 2019).

The empirical case (the development of the National Flagship on Precision Medicine in Oncology and the creation of the Hellenic Precision Medicine Network) is an example of such a co-constitution, since the promotion of PM is an essentially state-driven, top-down political endeavor in Greece, in accordance to the European Research Policy and the Precision Medicine Initiative of the USA.

Inspired by the work of Tarkkala (Tarkkala, 2019) regarding Finland's PM landscape, the analysis of the performative and practical aspects of Greece's case is based on a technoscientific viewpoint analysis within the frame of problem-setting and sense-making in policymaking and governance, which is related to the elite sociotechnical imaginary concept.

5.2.European Research Policy: Regulations promote elite sociotechnical imaginaries

According to Smallman, the primacy of scientific evidence is raised particularly in the context of European regulations, which offer little space for non-scientific matters to be considered. "The elite imaginary is perpetuated by the administrative requirement for scientific evidence. Since there is no way for social and ethical concerns to be dealt with in this process, policymakers describe how they are forced to separate them from the science. However, this does not mean that decisions are being made in a purely technocratic way. In order to account for social and ethical concerns and bring about the desired policy outcome within a system that does not allow them to be considered legitimate sources of evidence, they express these concerns by challenging the science. Since economic or social evidence is an inadmissible basis for decision-making within

European regulations, the process that elicited these responses from policymakers is evident in the European Commission's decision-making process, or the 'ordinary legislative procedure'. That is, the elite sociotechnical imaginary is clearly embedded and perpetuated in the separation of social and ethical issues at the heart of the legislative process" (Smallman, 2019, p.598).

The European Commission's description of the decision-making process begins by explaining how social, ethical and economic consequences of particular actions are dealt with before any new policy initiative is proposed: before the Commission proposes new initiatives, it assesses the potential economic, social and environmental consequences they may have. This is done by preparing 'impact assessments', which set out the advantages and disadvantages of possible policy options (Europa, 2017). These impact assessments are seen as the key point at which the public can participate in decision-making, with a four-week period of public consultation built in them. "These consultation periods, however, are considered unnecessary when decisions are based upon scientific opinions from an agency or scientific committee, on which a public consultation has already taken place. The terms of reference of such scientific committees typically limit the basis of comments to scientific matters. These 'rules of procedure' explain how the focus of submissions must be based upon the scientific review, rather than any wider issues of risk or policy impact" (Smallman, 2019, p.598).

The objective of public consultations is to gather specific comments and suggestions on the scientific basis of the opinion, as well as any other relevant scientific information regarding the questions addressed, in order to allow the scientific committees to focus on issues which need to be further analyzed. This consultation process shall not deal with policy or risk management needs and measures. Regarding PM, a foresight study (BOHEMIA contract N° Contract PP-03021-2015), designed specifically to support the preparation of the next framework programme, was conducted on behalf of the Commission. The study put forward policy recommendations for the next framework programme [Horizon-Europe], based on a foresight processes involving scenario development, a Delphi survey and an online consultation. As part of its recommendations, the study identified 19 likely future scenarios with disruptive implications and associated priority directions for EU research and innovation.[4] Precision Medicine is the targeted scenario number 14: "It is

[4] The full range of the results of the study is available at: https://ec.europa.eu/research/foresight.

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2040. Precision medicine has taken off. Accounting for individual variability in genes, environment, and lifestyle for each person allows accurate predictions on which treatment and prevention strategies will work best. Precision medicine is not a new idea, but its widespread use and the availability of large amounts of data had been prevented by cost/benefit considerations. Those considerations changed as our understanding of biological processes improved, our data processing capacity grew, and new techniques were developed allowing interventions that were not possible before. Increasingly powerful big data analyses help to identify genetic causes for diseases, and genetic engineering develops focused cures. Precision medicine includes the use of new diagnostics and therapeutics, targeted to the needs of a patient based on his/her own genetic, biomarker, phenotypic, or psychosocial characteristics. In particular, advances such as cell sorting, epigenetics, proteomics, metabolomics, and more are converging with informatics and other technologies, rapidly expanding the scope of this field. For example, advances in DNA synthesis and assembly methods over the past decade have made it possible to alter DNA or RNA and to construct genome-size fragments from oligonucleotides. Change is slow, however, and while epigenetics found their first non-medical applications relatively early, precision medicine targeting individual patient's genetic makeup is still a rare procedure. Predictive Medicine is more and more individualized. Continuous advances leave little doubt that precision medicine will continue to grow, e.g. through pharmacogenomics. However, to enable applications of precision medicine on a large scale, knowledge of biological phenomena has to be deepened. Understanding and mapping out the interactions between human organisms and their environment is still a huge project, as is the mapping of the human and non-human microbiome. Sensors and apps monitor an ever expanding spectrum of such interactions. Data ownership and privacy regimes incentivize data-sharing and enable projects with greater access to clean, individuated information sets - especially for the combination of precision with prediction medicine. Precision medicine with genetic engineering, alongside the transformation of the individual microbiomes, has opened up new pathways for human enhancement. Some epigenetic and genetic engineering questions raise no ethical concerns (e.g. immunotherapy with own cells) whereas others remain problematic (stem cells). Implications for EU policy The key implications for EU policy lie with medical regulation, research and ethics and organization of health and insurance systems. As the diversity of treatments increases, health insurance systems are challenged by

precision medicine and also its sub-discipline predictive medicine. Until now, no regulation for the predictive treatments exist (e.g. amputations in case of the threat of cancer). Economic considerations are in the forefront, but also ethical considerations come to the fore (e.g. who is entitled? in which cases?). Precision medicine approaches are still expensive and rare. But how can there be a clinical trial for individualized treatments? Education of medical personnel is still lacking appropriate courses on how to deal with the "feasibility estimations" in precision and predictive medicine and how to communicate with the patients. Patients' rights are not clear. As in precision medicine, many personal data are generated, related, hosted in databases and retrieved, policies concerning data and their security are as important as the health considerations. Overall many different policies (e.g. health, population policies, economic policies, digitization policies etc.) are related to precision medicine and have to be linked and coordinated." (Precision Medicine Targeted scenario N°14 Glimpses of the future from the BOHEMIA study,2018 p.6)

The PM imaginary is a landscape in which medical genomics is assembled, policies are shaped, and scientific endeavors are carried out, in Greece and elsewhere.

This work represents an attempt to analyze how this elite sociotechnical imaginary is fused in practice by studying the Greek strategy that pursues the promises of genomics and precision medicine. The focus is on the practical dimensions and measures by which the imaginary is promoted and maintained. Jasanoff et al. remark that the "mechanics of the interconnections between technoscientific and political practice have not been articulated in detail or systematically" (Jasanoff and Kim 2015), especially not in relation to innovations.

Tarkkala distinguishes two narratives about PM: "There is a distinction made between two levels of framing upon expectations. The first level –rhetorical framing– comprises general schemes of persuasive argumentation that describe and organize how the expectations, promises and advocacy of precision and personalized medicine are attached to certain objects, objectives, activities, and actors in a consistent and justifiable way. The second level of framing regards more directly policy programs and implementation (Tarkkala, 2018, p.752). Within this second framing, specific expectations and practical steps and demands for achieving precision medicine in Greece are defined and outlined within this second framing of policy programs.

Within the context of the elite sociotechnical imaginary, effort is put on the analysis of the practical or even material side of PM's elite sociotechnical imaginary.

Expectations attached to biomedicine have to be constantly maintained and iterated by means of science, politics, administration, and economy, oriented towards a future conceived as opportunities involving unpredictability and uncertainty. The future must be kept open by creating prospects and by pointing out and mobilizing opportunities and resources that biomedical R&D, clinical care, health care management, policymaking, and even personal self-help may utilize – and, sometimes, business too (Tarkkala, 2018).

When scientific, administrative, political, and business-making practices search for opportunities to harness the potential of PM, they bring together many kinds of stakeholders and actors to pursue biomedical innovations in global and local settings. Hence, *Governance* becomes a top priority and, at the same time, a handicap. PM governance may be summarized as a governance of innovation.

In the domains of medicine and health care, the practices of governance manifest themselves by, for example, endless rearrangements of environments and assemblages of biomedical science, medical business, and clinical care in local, national, and transnational settings. In this work, I try to analyze how governance and expectations work and are configured in the pursuit of sustaining and promoting medical genomics under the imaginary of PM in Greece. In particular, it is attempted to show how such governance reconfigures the elite sociotechnical imaginary.

The actual strategies (‘roadmaps’) are proposals for and projects involving experimentation, iteration and implementation of techniques, and practices of future medicine in Greece. They provide the reasoning over the objectives, milestones, and measures to be taken, the issues to be improved, and the resources to be mobilized for the realization of precision medicine. Of particular interest is the fact that expectations about the future of precision healthcare are aligned with the ongoing creation of large depositories of digital health data and of the imaginary of economic growth, which supports the maintenance of the elite sociotechnical imaginary through the efforts to advance PM, supported by biobanks. Maintenance requires the reshaping of expectations, the readjustment of prospects, and their introduction to new contexts with new alliances.

5.3. The Research Material

The research material analyzed in this dissertation consists of (a) the main Greek strategy papers that outline policies related to biomedicine and health technology from 2005 to 2020; (b) press releases and news posts related to the strategies, biobanks, and the Flagship Initiative on Precision Medicine from 2016 to 2020; (c) presentation slides by different stakeholders and field notes from seminars and events concerning health technology, biobanks, and genomics from 2013 to 2020; and, (d) the relevant European strategy papers and reports.

The analyzed strategies represent the most influential and cited policy frameworks that are guiding the development of national infrastructure and strategic funding. In these texts, the future of Greek healthcare, medical genomics, and biomedicine are envisioned from scientific, political, administrative, medical, and commercial perspectives. The main corpus of the strategies analyzed is comprised of documents published from 2013 to 2020. The analysis of the documents showed an attempt to transition from health to wealth, which is apparent in the strategy and policy papers. The main publishers of these strategies were the Ministry of Education (ME) and the Ministry of and Health (MoH).

Press releases and posts from the Internet related to the strategies and reports published by Greek biobanks, the Flagship Initiative on Precision Medicine and key funding agencies are the fundamental material to describe and promote the Greek health ecosystem. These posts and the presentation slides essentially come from events and meetings I personally participated in.

Since 2007, I have been following the field in Greece and Europe and my analysis is informed by my experience and different projects in which I have been involved. In these projects, I have followed closely the development of biomedicine, biobanking, and medical genomics in Greece and the European Union as well.

The material forms a corpus that represents the official Greek strategy framework as well as how stakeholders, such as biobank networks and funding agencies, reproduce the sociotechnical viewpoint in their own materials and presentations. This material also describes how the overarching technoscientific viewpoint about biobanks and PM, has been presented in, e.g., the National RoadMap for Research Infrastructure (General Secretariat for Research and Technology 2014). Within this empirical material the kind of promises and expectations articulated is

revealed. Within the innovation policy framing, the expectations of PM are primarily associated with economic value, growth and competitiveness, since the research policy in Greece is built on market and economic-growth-oriented science.

In the context of the Greek discourse, data-driven medicine highlights the possibilities of public registers, databases and digitalisation to enhance PM and presents these resources as valuable elements for the benefit of Greek society.

This work specifically focuses on the practices required to achieve PM, specific expectations and the technoscientific viewpoint that applies to domains of both innovation policy and data-driven medicine. Some of the practices identified are: the centralization of data management, the modification of clinical and administrative practices to serve data collection, the creation of enabling regulation and, finally, a special governance scheme which includes a Steering Committee and a Technical Committee.

Within the technoscientific viewpoint, both performative and practical aspects of sustaining PM (and not only visions and objectives) are created and reasoned over. Also, concrete measures and action plans are outlined and discussed. After identifying the framing in the strategy papers and the press releases, news, and seminar/conference presentations, it has been found that a two-level framing was present in them, too: i.e., the political narrative of economic growth and national competitiveness after a decade of austerity and consolidation programmes and the practical support through special funding for the science of PM, by launching a national Flagship Initiative concerning PM in Oncology.

The analysis focuses on Greece, but similar strategies to harness the potential of genomics have been developed in other countries as well; for example, in Great Britain[5], Singapore (Ong,2013), Canada[6], and Denmark (Ministry of Health 2017). Thus, the Greek case illustrates a more general tendency to attribute economic value to population, genomics, and health data.

[5] See (https://www.genomicsengland.co.uk; https://www.gov.uk/government /publications/life-sciences-industrial-strategy)
[6] (http://www.genomecanada.ca)

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5.4. National Strategies: Creating Value

The first European strategy papers in formulated genomics as a rising field with huge scientific and medical potential have been centering on BBMRI-ERIC, a European Network of Biobanks Infrastructure that was included in the very first European Research Infrastructures RoadMap of 2006, because biobanks are regarded as offering a practical possibility to enhance genomic research and medicine. Accordingly, in Greece, the preparation of the national BBMRI-GR and the establishment of a biobanks network started in 2010. Greece is a founding member of BBMRI-ERIC since 2013. This has followed a political decision and the related financial commitment. In parallel, expectations of PM were placed on biobanks and biobank networks, which were seen as the platform on which PM would be built. Biobanks in Greece are very much part of the international enterprise to establish biobanks and organize the collection, storage, and distribution of samples and data, according the OECD (2007, 2009) regulations and European Union Policy (2009) ESFRI Roadmap 2006, p.46; BBMRI-ERIC; National Roadmap for Research Infrastructures: BBMRI-GR). The intensified creation of biobanks during the first two decades of the 21st century has also resulted in developments for the life sciences, bioinformatics, and technologies. The national project BBMRI-GR outlines the earlier pursuit of covering Greece with biobanks linked to university hospitals and research centres, with an ultimate goal to promote translational research and human genomics and better serve the needs of industry and research groups in gaining access to data. It is worth noting that public or patient participation was not anticipated. The BBMRI-GR network received public funding in 2019 as part of a Research Infrastructures RoadMap National Project, in parallel with the recently launched Flagship Initiative on Precision Medicine in Oncology, aiming to foster precision medicine for cancer treatment at the national level.

Concomitantly to the development of biobanking in the context of the BBMRI-GR project, the "Hellenic Network of Precision Medicine on Cancer" was founded on 17/05/2018 as a Flagship Initiative of the Research and Innovation Sector of the Ministry of Education, Research and Religion, in close collaboration with the Ministry of Health. The Network is funded by the Framework of the Hellenic Republic – Siemens Settlement Agreement. Its mission is to integrate the Network with the National Health System, to provide high-quality health services to Greek citizens, to enrich

diagnosis knowledge and prediction outcome, and improve the targeted therapeutical treatment of cancer patients. The preparation of the strategy was initiated and backed up by the Ministry of Education and the General Secretariat for Research and Technology, Fund "Hellenic Republic – Siemens Settlement Agreement".[7]

The following part of a press release from the Minister of Research and Innovation Prof. Costas Fotakis stated: "Realizing that Precision Medicine (PM) is no longer a promise but rather a reality that will transform how we prevent, diagnose, treat and predict the outcome of disease, the Sector for Research and Innovation of the Ministry of Education, Research and Religious Affairs of Greece, in collaboration with the Hellenic Ministry of Health, has established a Precision Medicine Network (PMN) in Greece with a view to integration it into the Public Health system in order to provide modern, high quality and efficient health services to citizens. Initially, the focus of the Hellenic PMN will be on cancer, however, it was agreed that there will be future network expansion to address other disorders, including neurodegenerative and cardiovascular diseases.

Leading national research and academic institutions engaged in research and clinical applications of molecular biology, medicine and data science participate in this network. Gradually, the Hellenic Precision Medicine Network (HPMN) is antipicated to forge close links with oncology/hematology clinics and diagnostic laboratories with relevant expertise across Greece, so as to provide state-of-the-art early diagnosis and monitoring services to cancer patients based on next generation sequencing technologies.

The HPMN's policy focus on the implementation of a carefully conceived strategy by capitalizing on: "biomedical excellence in cancer expertise in bioanalysis, in both research but also, importantly, diagnostic settings a wide network of national and international collaborations with academia, research and healthcare institutions, patient groups and patient advocacy groups, authorities and the pharma and biotech industry. The strategy is essentially grounded on a zoom in-zoom out approach, whereby the focus will first be on paradigmatic cases and, subsequently, the lessons learned will be applied to more generic categories: with time and expansion to cover novel clinically validated indications, such approach." (Personal communication of the Head of HPMN, Dr. Konstantinos Stamatopoulos).

[7] See: https://government.gov.gr/ti-ine-ke-pious-tha-ofelisi-to-ethniko-diktio-iatrikis-akrivias-stin-ogkologia/

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The HPMN exemplifies future visions of biomedicine, and articulates the imaginary of PM. The imaginary is built on preceding visions and expectations of Greek medical genomics, biobanks, and biomedicine in general, but it also promotes an idea that biobanking. Even though this is a prerequisite for the implementation of PM, it is not enough for achieving it. The HPMN in oncology is closely linked with other strategic endeavours in Greece that are implemented and revised simultaneously, and they are promoted and supported by the same actors. Thus, the strategies are interconnected: cf. the national Digital Health plan, the Flagship Initiative for Neurodegenarative Diseases and the very recent Flagship Initiative for the SARS-CoV-2 pandemic. Thus, HPMN is part of an overarching policy framework that places high expectations on genomic data and PM. It emphasizes Greece's potential to become an internationally attractive partner for cutting-edge research and healthcare utilizing genomic knowledge and promoting the development of the health care sector, after almost ten years of financial austerity. Additionally, it professes that strong national coordination and common infrastructures and institutions are needed for the full-scale utilization of genomic knowledge and biobank resources.

The realization of the vision of PM and the of the promises of medical genomics are increasingly directed by ideas and projects funded in the national innovation and growth strategies. Biobanks are still part of these new visions, but they are now expected to form an integrated entity and be more closely connected to the HPMN on oncology. Their potential is no longer regarded as being enough to sustain expectations and create a new competitive edge, so that they contribute to the maintenance of the imaginary (Tarkkala, 2019).

5.5. The sociotechnical viewpoint

A sociotechnical imaginary like PM requires the adoption of a special discourse to become effective and "fused in practice" (Jasanoff and Kim, 2009). The policy makers and the advocates of medical genomics presented research as an important element of the Greek "knowledge-based economy" and "innovation system". The makers of innovation policy considered medical genomics to have considerable business potential. Much attention was given to the scientific potential, future health care, and public health, in accordance to the European research policy. (Tarkkala, 2019)

The political basis for the establishment of the HPMN in oncology highlights research action as a response to a societal challenge – in other words, as "science to the rescue", as described in the frame of the elite sociotechnical imaginary, a top down policy taking into account mainly the technoscientific viewpoint (even though it is legitimated by the societal mission) (Smallman, 2019).

The aspect of the development of infrastructures for biomedical research, driven by a focus on the economic and commercial prospects of science is not emphasized, although the terms "development" and "growth" are salient in the discourse. This has been a significant policy framing of genomics, biobanks, and biomedicine in many countries for the last two decades, starting for example, from deCode Genetics Ltd and the Health Sector Database in Iceland (Tarkkala, 2019).

The development of PM in Greece follows a similar path. The establishment of BBMRI-GR biobanks and the launching of projects for translational genomics were parallel processes in the mid-2010s. They have been directed by a rationale according to which developments in medical research and care inevitably lead toward data-driven medicine. In congruence with the new focus on the promise of PM, the strategy papers have redefined the assets and competitive advantages Greece may achieve in the field of medical genomics – both scientific and economic. Furthermore, Greece's competitive advantage is anticipated to not lie merely in data collections *per se*, but in the expertise of managing such data.

Launching the HPMN for oncology in Greece (where no public health data bases are in place) required policy support and political will. In the analyzed material, the societal aspect of this action is emphasized and "institutionalized", although it is a purely top-down decision: no public dialogue has been organized before, which outlines a scheme fitting the "elite sociotechnical imaginary" of Smallman (2019). The policy makers only took into account the technoscientific viewpoint, since other opinions have not been expressed. In the sociotechnical imaginary of data-driven PM, data, people (or the population providing biological and health data) and the public institutions that generate and collect the data are considered natural resources (Tarkkala, 2019). Thus, within the transnational field of PM, the Greek imaginary is framed as a national effort.

5.6. The practical measures

The strategy documents and policy makers' declarations include many practical measures for the implementation of PM in Greece. Despite the expectations, the standardization, coverage, and effectiveness of Greek health care institutions in collecting, managing, and circulating patient and "-omics" data should be vastly improved. Specifically, the full potential of biobanking in Greece can only be realized if three requirements are met: standardization/integration, annotation [electronic health record/electronic medical record], and funding to attain critical mass. This sentence summarizes the research policy of the last decade in Greece, the establishment of BBMRI-GR and the strong Informatics research community among strong Molecular Biology and Oncology academics.

The elite sociotechnical imaginary mobilizes funding and other practical measures in order for the scientific viewpoint to become a reality.

At the national level, the Flagship Initiative on PM in oncology involves the following practical measures:

- financial resources are placed first (Siemens Agreement)
- scientists and academic organizations support the enterprise by lending their expertise and infrastructures (the elite research centres and universities are members of the HPMN, shaping the sociotechnical viewpoint)
- political support through two Ministries (Ministry of Health and Ministry of Development via the General Secretariat for Research and Technology and the National Organization of Social Security)
- Governance scheme (Steering Committee, Technical Committee, Ethics Committee)
- Patients advocacy

Finally, strategy papers and statements by the advocates of PM express that ethical procedures, regulations, and legislation related to the collection, storage, and appropriation of health data need to be updated to enable more intensive utilization of Greek databases and biobanks by academic and commercial R&D. The enabling regulation to create and sustain competitiveness is an important element of the innovation policy and the subsequent funding for the establishment of the HPMN in May 2018.

Chapter 6

Discussion

A detailed analysis of the concept of *sociotechnical imaginaries* and of the *elite sociotechnical imaginary* has been presented, based on the work of Sheila Jasanoff (Jasanoff and Kim 2015) and Melanie Smallman respectively (Smallman, 2019) in Chapter 1 of this thesis.

PM is what is to come and what needs to be acted on for societies in Europe and elsewhere to care for their citizens appropriately (European Commission, 2013;). In other words, PM represents the promise and, hence, it creates expectations. In this context, the development of the strategy for the establishment of biobanks, the expectations surrounding them and medical genomics in connection to innovation policy and commercial prospects pushed the focus from them being depositories of tissue samples to being digital databases that enable the combination and circulation of data from tissue sample collections, patient records, and population registers (Tarkkala, 2019). On the other hand, molecular biology and bioinformatics as a key technology of medical genomics have become a part of data-driven medicine. Consequently, the sociotechnical imaginary of PM has been almost completely colored by expectations attached to ICT capacity to collect, manage, and compute more kinds of health-related data (Tarkkala, 2019).

This dissertation is built around the idea that PM implementation in Greece fits the theoretical concept of the elite sociotechnical imaginary proposed by Melanie Smallman. (Smallman, 2019) Policy and decision makers, together with scientists create and adopt technoscientific viewpoints, which become overarching discources in comparison to other scientific views and they establish networks and take practical measures, rendering PM 'science to the rescue' since it "shapes how public perspectives are heard and distinguishes what is considered to be legitimate expertise" on the other (ibid, p.589). Oncology is the field where PM, under the "science to the rescue" framework, can be realized *par excellence.* Cancer is a devastating disease affecting people worldwide. A lot of scientific work is already done, the pharmaceutical industry has invested a lot of funds in anti-cancer drugs. Consequently, the elite sociotechnical imaginary of PM is strongly shaped and legitimated without

taking into account the social determinants underlying cancer, as well as the differing scientific views.

Working and belonging to the world of biomedical research, I always wondered how some scientific concepts shift to dominant discourses while equally valid others did not. During the last two decades in Greece, medical genomics, biobanks, and biomedicine have been promoted and supported by the flourishing IT research. This development is not chiefly resulting from a national research policy but, rather, from the fact that the Greek academic biomedical research system is more advanced than the policy makers, as it closely follows the European and American research policy, creating a similar scientific environment. Hence, the technoscientific viewpoint is established in the exchanges among researchers and, on occasion, businesses from Europe and USA. The policy makers enter the scheme at a later phase, when funding and the relative discourse is necessary for the realization of the elite sociotechnical imaginary.

The European Research System is profoundly top-down, even if it is legitimated by open consultations with the public. In the latter cases, the "public" primarily consists of scientists. Opinions, fears, reluctances of the lay public are rarely heard and integrated into the final decisions. In Greece, the lay public is rarely represented in the decisions surrounding research policy. Its participation in the research programmes and research governance is, therefore, not institutionalized and rather limited.

Regarding biobanks and PM, the Greek society's attitudes have never been put on record, since no relevant mechanism was in place.

The Flagship Initiative on Precision Medicine in Oncology (even though it will yield interesting results and benefits for the patients) remains a top-down political decision, documented by the technoscientific viewpoint. The initiative has mobilized important funding (which is similar to what the relevant initiative in the USA brought about) without any open call and peer-reviewing system in place.

The PM imaginary fits the elite sociotechnical imaginary conceived by Melanie Smallman, because, in the Greek research policy discourse and relative technoscientific viewpoint, PM was formulated by the creation of the Hellenic Precision Medicine Network – an absolutely top down activity with a dedicated governance scheme, presented and legitimated as a response to a societal challenge for the better cure of cancer patients. It is worth noting that ethical issues and patient

participation are addressed. This is, perhaps, due to legitimization issues or by virtue of an exact 'transplantation' of applicable USA and European PM initiative models.

The analysis also points out that, due to its iterative, flexible character, the promotion of biomedicine is almost inevitably fused with the *politicization* of PM's sociotechnical imaginary. PM has become an important policy matter as well as an object of interest to policymakers, especially within the realm of the Greek government's innovation policy. When the Initiative started, it represented a "new" way for the reestablishment of Greece's development and growth, after almost a decade of recession.

Expectations and visions for the future of biomedicine are not rigid and static but are continuously under transformation, which changes the very meaning of what the imaginary of PM entails (Tarkkala, 2019). In Greece, efforts to maintain the promise of PM are rearranging the idea and future vision of an oncological healthcare with a societal mission.

The personalized medicine imaginary is, then, being deployed to build a future that would be more oriented towards the improvement of the citizens' health services. Consequently, despite its conformity to an "elite sociotechnical imaginary", the Hellenic Precision Medicine Network brings promises of public and personal benefits for patients – as well as opportunities for economic growth.

Finally, PM seems to be about building a new national oncology healthcare scheme and the activation of the national pharmaceutical industry.

The HPMN is only two years old. Understanding the political background of its establishment may prove quite helpful in shaping the context of its functioning and its future – which, essentially, has been the ultimate purpose of this thesis.

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