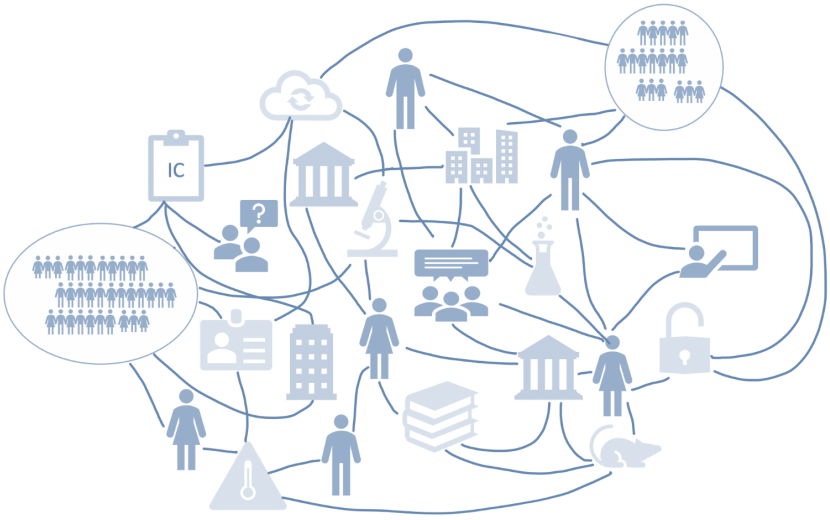
WP4

Societal Engagement with Biobanking

Report on the State of the Art



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1. Introduction

In contemporary biomedicine, biobanks have become important infrastructures for collecting, storing and providing a large variety of biological materials and data, which are often combined with clinical information. Such infrastructures are essential for research as they allow exchange of biological materials and data over distance and across a variety of sites – to different national contexts, as well as to different research fields and institutions, ranging from basic research, over translational research to bio-industrial applications. Biobanks also open up new temporal dimensions in biomedical research, allowing to collect samples and data over time and thus to cover aspects hardly possible in the framework of classical project-oriented research. Biobanks allow the pooling of relevant resources to advance knowledge and innovation through "bringing different people, objects, and spaces into interaction and forming the base on which to operate" biomedical research in new ways (Larkin 2013, 330). Biobanks cross time and space and open up novel possibilities.

Work package 4 (WP4) is integrated into the Austrian node of BBMRI, which is an emerging research infrastructure for biomedical research. Our mission is to contribute to **responsible research and innovation practices** and to the sustainability of this research infrastructure (Felt 2018). We do this by conducting social science research (based on qualitative research methodologies) and discussing our findings with our partners from the BBMRI.at consortium to get feedback and refine them.

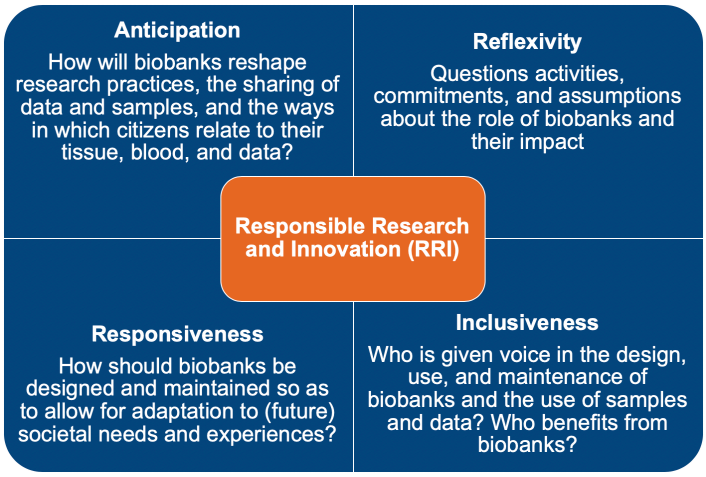

Figure 1: Key dimensions of Responsible Research and Innovation

The concept of **responsible research and innovation** (RRI) forms the wider frame for our research. RRI invites to not only focus on the (market) value *of* innovation, but to be attentive to other values embedded in innovations (Felt 2018). It means asking questions of direction and scale of innovations (Felt et al. 2007). More specifically, RRI is meant to draw our attention to four key-dimensions to be fostered in research and innovation processes, namely: "anticipation, reflexivity, inclusion and responsiveness" (Stilgoe et al. 2013, 1570) (see Figure 1). **Anticipation** refers to systematic thinking of the different potential outcomes

of innovations while being attentive to the unintended, collateral effects innovations might produce. It brings our attention to the role of (often implicit) future visions and promises in realizing such endeavors. **Reflexivity** points to critically question "one's own activities, commitments and assumptions, being aware of the limits of knowledge and being mindful that a particular framing of an issue may not be universally held" (ibid., 1571). This becomes particularly salient, for example, when imagining citizens' values and concerns when becoming part of a biobank through the donation of samples. **Inclusion** reminds us of power relations at work in biobanking and invites to carefully consider who is given/not given voice in shaping the infrastructure and the research done on the basis of samples/data provided by citizens or patients. Finally, **responsiveness** stresses the need to adjust "courses of action while recognising the insufficiency of knowledge and control" (ibid., 1572). This means admitting our limitations in considering outcomes and being ready for adjustments all along the innovation and research trajectories. Together, the four dimensions should help to "provide a framework for raising, discussing and responding" (ibid., 1570) to the key questions relevant to the sociotechnical innovation of biobanking and related research. In particular, this approach supports "those prospective, forward-looking dimensions of responsibility, (notably care and responsiveness) which allow consideration of purposes and accommodate uncertainty, a defining feature of innovation" (Owen et al. 2013, 29).

1.1. How we conceptualise a biobank

We understand **biobanks as a social and technological (a sociotechnical) assemblage** having to bring together a large diversity of humans and non-human elements and create stable relationships between them (see figure 2). This invites to explore how a large variety of material and conceptual elements have to come together and stabilise to form an **infrastructure** that supports biomedical research and – on the long run – also therapies. The elements forming an assemblage include:

(1) human actors such as donors, citizens at large, researchers, industrial players, policy makers and many more;
(2) non-human elements such as the samples collected, the data related to them, the technical devices needed to prepare and store them, the tools developed to make them accessible;
(3) institutional/organisational actors such as universities, ethics committees, or funding agencies;
(4) practices in research and beyond as well as relationships pre-existing the biobanks; and
(5) regulations, norms and values, including questions like the use and ownership of samples and data, standards/standardising procedures, protection of data and privacy issues.

In the process of bringing such a sociotechnical assemblage – biobank – into being and stabilising it, both a specific set of values is integrated, while this infrastructure and work performed through it is also generative of values.

It is key to observe **how all these different elements come together**, how they can create a whole and stabilise over time, i.e. create **a sustainable biobank**. Therefore, it is essential to not only be able to point to the different elements involved in the assemblage but also **to understand the multiple relationships between the different elements**. It is thus crucial to look at explicit strategies for connecting and aligning elements in such a way that they form a sustainable sociotechnical assemblage. Relationships can be of

different strengths. Some demand the investment of a lot of work to hold, others are more robust. For example, we could ask how much engagement is needed to convince researchers to store their samples in a biobank, to agree to share them and thus to integrate them into the assemblage. Social scientists developed specific terms to capture what is happening during the creation and stabilisation of such a biobank assemblage. For example, we speak of "**enrolment" and "translation"** to describe the work of transforming actors into new allies (enrolment) in making a biobank and of aligning actors' (e.g. researchers) interests with those of the overall assemblage (the biobank). At the same time, the assemblage can become fragile and break if an important actor leaves the assemblage and cuts the relationship (e.g. when funding is refused or a legal framework changes substantially).

Although assemblages can become temporarily stable, they are always in-the-making (Law 2004). For a biobank this means that, e.g. when a new regulation emerges, such as the GDPR, the relations in the assemblage have to be rethought and rearranged in ways to stabilise the biobank again. In terms of rendering a biobank sustainable, this means that the relations in the assemblage need continuous work and care to remain in place. Assemblages, despite being always in change, also have to show both **consistency and coherency** (Deleuze and Guattari 1988). While "coherency" refers to the internal order and organisation in a biobank infrastructure, "consistency" points to the needed capacity to integrate the biobank into a world of external relations, i.e. a biobank has to fit the broader cultural context but also with what is regarded as adequate in the scientific context or what is ethically acceptable.

Understanding a biobank as always in-the-making, helps to understand the lively debates we have been witnessing for more than two decades concerning the past and future role of biobanks, what biobanks mean for both science and society, what role they will play for the future of biomedical research and care, about the value they generate and the values they stand for, who is needed to support them and who is supported by them and many more. In particular with the entry into force of the EU General Data Protection Regulation in May 2018 also new questions and debates around how biobanks can be used by researchers or how they (can) build stable relations to users and donors arise and corresponding adaptations need to be done (Starkbaum and Felt 2019).

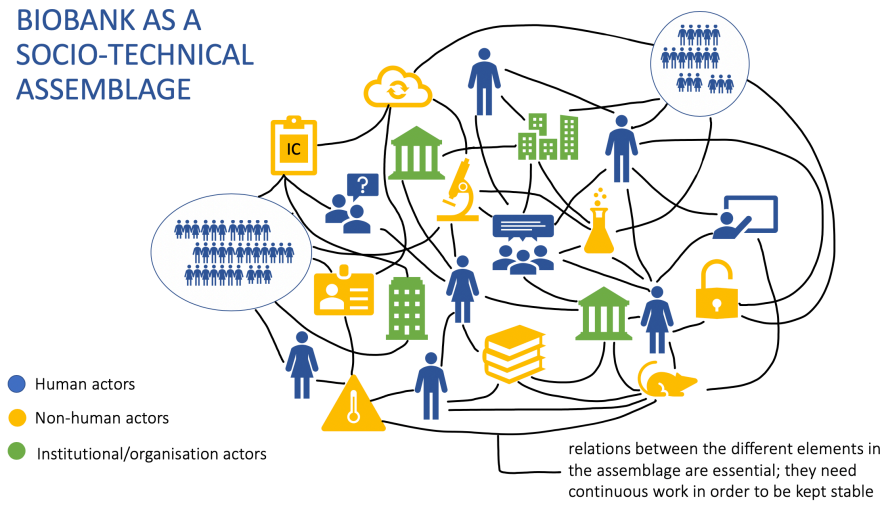

Figure 2: Biobanks as a socio-technical assemblage

1.2. Project objectives

As the authors of this report are members of the BBMRI.at consortium, we aim to contribute to a better understanding of how to make biobanks societally and scientifically sustainable, i.e. to assure the long-term support of biobanks by societies and stakeholders. For this objective, it is key to understand what different actors expect from a biobank infrastructure, where they see the promises of biobanks for health-related research and care and what future of biobanking they want to contribute to. It is thus important to grasp why they find it worth contributing to, using, maintaining and supporting biobanks. But we also have to engage with potentially shifting understandings and self-understandings of scientists, citizens and patients once a focus on data becomes key to understand health-related phenomena. Simultaneously, building and maintaining a biobank always means engaging with diverse value systems and expectations of those actors who potentially use, support and provide samples and data, and reflecting on their associated understandings on appropriate distributions of responsibilities (Akrich 1992) as users, donors or supporters of biobanking. For those involved in biobanking — so also for the BBMRI.at consortium members — it is crucial to know, understand and consider these aspects across sites (locally and globally) and across actor groups.

From their inception, all biobanks stand for particular values and expectations, carry visions of potential future developments (see chapter 2.2) and contexts of use and contain specific ideas about who has to care for issues of ethics and responsibility. Participants' consent, for example, is one important element to be cared for. It expresses the values and aims of a biobank, its potential use as well as the rights of those providing samples (and data), assuring a stable relationship between biobank research and society. However, also researchers' ways of collecting, standardising, sharing and using material from biobanks express values in research, how potential problems are anticipated and responsible use is ensured. Current discussions on the fostering of *Translational Science* is a further domain where values, rights and responsibilities will be negotiated.

In workpackage 4 of BBMRI.at#2, we explore a broad range of socio-economic arrangements that accompany the establishment of biobanks and study their consequences, including: who contributes, who can get access to information and data, how is access organised, who owns samples and data and who benefits from them (Jasanoff 2003). We will explore these questions together with academic and industrial researchers (within and beyond the consortium we are part of), policy makers at different levels, citizens and donors along the project duration in an empirical manner. This report is meant to summarise the main debates and insights that form the background for our work. It points to the conceptual framings we will engage with and partly adopt and outlines the larger challenges of biobanking on an international level.

We seek to facilitate reflections, dialogues, and mutual learning processes via research, that aims at exploring the broader range of societal questions that accompany the establishment of biobanks. This means asking: who contributes to the successful development of a biobank (from donors to those taking care of the infrastructure), who can get access to samples and data, or who owns data and who benefits from them.

Specifically, WP4 seeks to:

(1) provide a better understanding of how biobanks are valued by different kinds of actors; engage with different "value systems" and "value generation models" at work; in short: look at **value(s) in and of biobanking;**
(2) explore how the growing importance of data through data processing and digitisation processes is changing what we know about ourselves and our health, how this knowledge is generated, and how this affects the self-understandings and agency of citizens; in short: we seek to understand **"bio-data citizenship"**; and
(3) investigate how the **General Data Protection Regulation (GDPR)** transforms practices of biobanking, the use and sharing of material and data, and the practice of providing material for research.

Box 1: Objectives of workpackage 4

Objective 1: Value(s) in biobanking

A core objective of our empirical work is to investigate **how different actors related to biobanks value this infrastructure and the possibilities it offers**. We are interested in understanding the different models that actors develop and use in attributing value to biological samples, their collection and sharing. In a broader sense, we look into **a specific kind of "bioeconomy"**—a system built around biological samples that aims at creating added value and innovation. While there is a body of literature that ties the rise of biobanking and the proliferation of biobanks to the so-called bioeconomy, we will argue in favour of using the term of bioeconomy in a much broader way.

In policy discourses and frameworks, the term "bio-economy" or (the "knowledge-based bio-economy") (Tupasela 2017) denotes a vision of a new economy, that draws on biological or natural resources (including wood or fish) to reboot economies. Policy frameworks for a bio-economy have been described as representing "simultaneously a political project as well as a scientific agenda" (Tupasela 2017, 191). They have been promoted in particular by the OECD, from where these travelled to the European Commission, and national governments (Chiappetta and Birch 2018, 64; Tupasela 2017, 191). While the term proliferated in policy discourses, it also became more ambiguous. The OECD framed the bioeconomy as the ambition to capture the "latent value in biological processes and renewable bio-resources to produce improved health and sustainable growth and development" (OECD 2009, 9, quoted in Tupasela 2017, 191-192). In the meantime, the term has been adopted in different ways in specific settings, yet, it tends to be associated with "new ways in which market forces can be introduced into the scientific research system" (Tupasela 2017, 191).

In the social sciences, the term "bio-economy" has been used to conceptualise (and very often also to criticise) new entanglements between "technoscience and capitalism" (Chiappetta and Birch 2018, 63), the emergence of a new political economy, or a new epoch in liberal market economies.[1] Following

[1] For instance, following Cooper (as paraphrased by Tupasela (2017, 187-188), "emerging biotechnologies reflect a new form of post-Fordism where life (microbes, bacteria, genes, etc.) become central elements in the processes of

Chiappetta and Birch, this literature documents and elaborates on the "change in the political economy of research and innovation (R&I), specifically the increasing commodification, commercialization, privatization, and marketization of scientific research (Lave et al. 2010)" (Chiappetta and Birch 2018, 63).

At the risk of simplification, we can say that while some refer to the "bioeconomy" as an explanatory factor or as a driver that underpins current transformations in the life sciences, others refer to the "bioeconomy" as the outcome or effect of a number of practices and processes that need to be explained and understood. Within the latter understanding of the bioeconomy as an *explanandum* (as something that needs to be explained), rather than as an *explanans* (a given context variable that can be mobilised to explain), some authors neither narrow down the economy to a market economy, nor value to financial value. They seek to pay attention to the ways in which economic value, ethical, social, and cultural value(s) are enmeshed, intertwined and mutually supportive (see section 3.1 for more details).[2]

In using the notion of (bio)economy in the context of this report, we aim at **extending the current understanding of bioeconomy**, by reminding the reader that the notion of economy goes back to the ancient Greek notion of "oikonomia" (Leshem 2016). While economic theories of 20th century have understood economy as "in principle independent of any particular ethical position" (Friedman 1953, 4), the notion of *oikonomia* was much more closely linked to an explicit consideration of selecting between possible ends which can be achieved by given means and to an explicit consideration of what constitutes a good life. Therefore, economy and values/ethics were seen as much more closely connected. In that sense we embrace Callon and coauthors' (2009, 109) phrasing: "If the end justifies the means, only debate can justify the end". It is engagement that needs to connect means and ends, which we aim to contribute to through our research.

Embracing such an understanding of bioeconomy therefore goes beyond other, more narrow understandings (Helmreich 2008). As a consequence, we will engage with a broad spectrum of different actors related to biobanks, aiming at understanding the "folk theories" of **value generation** they hold. Using the notion of "folk theories" points to our interest to unpack often "intuitive causal explanatory 'theories' that [different actors in and around biobanks] construct to explain, interpret, and intervene in the world around them" (Gelman and Legare 2011, 379). In our case how they see the needs, directions and challenges related to sustainable biobanking efforts. We will be interested to identify where these explanatory efforts converge and where they differ, what value means and how value is generated within each of the explanatory accounts and how these are related to making sense of biobanks and their personal involvement in them.

capitalist value creation and productivity and are supposedly meant to offer new forms of sustainable development derived from scientific research."

[2] For instance, in his comparative work on three biobank initiatives, Erik Aarden (2017a, 164) argued that "the idea that the production of values in the life sciences is predominantly framed in terms of contemporary logics of capital is biased towards a particular, market-based understanding of value (Nelson 2002) that obscures other ways in which biomedical research may be considered beneficial".

We are thus concerned with how value is produced, diffused, assessed, and institutionalised across a range of settings where biobanks matter, but also whose values come to matter in the building and using of biobanks. Concretely we will trace the values which matter when:

- donating (e.g. people could decide to donate for many different reasons such as solidarity, implicit hope for knowledge about the personal condition, vision of future knowledge through research, gratitude to the person who asks for a donation of samples/data);
- using samples for research (in academic research, translation and industrial innovation);
- funding biobanks and related research and innovation activities;
- maintaining biobanks;
- but also when regulating biobanks and many more.

Studying the values actors see or do not see realised through biobanking is essential to explain why some actors support biobanks while others are more critical towards it. It will allow us to trace why different actor groups support this infrastructure, through investment of money and donation of biomaterials as well as through its use, thereby laying the foundation for a sustainable biobank concept. Yet, understanding values attached to biobanking is also complex as the attribution of value is a process and practice that takes many forms and happens in many different situations and there are very different core values at work for the respective actor group. To identify these core values and show the value dynamics at work in diverse situations will be the aim of this objective.

Objective 2: (Bio)data citizenship

In a second move, our empirical investigations will address **the complex relationship between biological data and being a citizen**. For this purpose, we will develop and explore the notion of **(bio)data-citizenship**. Using the notion of citizenship draws our attention to rights and obligations and it invites to think about ideals and values such as responsibility, solidarity, justice and many more. However, it also reminds us that the very meaning of being a citizen and citizenship is performed differently in different understandings of biobanking. Furthermore, (bio)data-citizenship has to be seen in the wider context of 'big data' becoming an important matter of concern in public debate. The objective is to understand the relation of individual and collective imaginations around the relation of donors and researchers to "their" data. Our focus will thus be on data and how human subjects/donors, regulators, ethicists, industrialists and researchers connect them to human identity. This relates to a number of more recent debates, which we will address in this document. An example of such a debate would be one started by Rose and Novas on "biological citizenship" (Rose and Novas 2005), discussing the individual and collective dimensions of how biological data and understandings of citizenship (rights, possibilities and protections) get connected in new ways; the other, on the growing role of big data for the (self)-understanding of human beings.

Objective 3: The impact of GDPR on biobanking

Across both domains, it will be essential to reflect the current context of the new General Data Protection Regulation (GDPR), which was implemented in spring 2018. In particular for consent processes, donors' access to information about the use of their data and the possibility to reclaim

one's data will create new challenges for all actors involved. But it more generally also points to shifting understandings of the role of biological materials and related data when it comes to questions of ownership, use in research and obligations towards those providing these samples/data.

1.3. Structure of the report

To address the issues outlined in this introduction, this report will proceed in four steps.

In chapter 2 we will address in detail questions of value generation around biobanking. We will do so by starting to elaborate on biobanks as infrastructures and what consequences this has. We will then proceed to reflect on a more general level different practices and settings in which value is generated or values are realised, specifically also pointing to the role of projections, promises and other future making practices.

Chapter 3 will discuss the broad body of writings on biobanking and value(s) as well as on the different modes of governing biobanks.

The focus of chapter 4 will be on citizens and their changing relations to data. It will start by engaging with citizens' understanding of data, the challenges of donating biological samples and related data and identify some of the key issues that arose around public perception of biobanking as an outcome of BBMRI.at#1. We will then move to discussing the bodies of literature related to different forms of citizenship and how biological data and samples relate to people's understanding of their bodies and ways of living.

Chapter 5 will finally explicitly address how the GDPR reshapes both the ways in which biobanking is performed, but also citizens' relations to biological samples and data.

2. Biobanks – Value generation and valuation practices

How is value creation imagined and practiced in the context of biobanks? Who is/can be involved in defining which values count? What orders are generated through the highlighting of specific values? What practices are involved in the generation of value and how do practices perform specific values? How are conflicting values handled? These are the key-question addressed in this chapter. We will ask what makes it worth it to collect, standardise and share biological material and related data for research, but also what "counts as proper conduct in science and health care, what is economically and socially valuable, and what is known and worth knowing" (Dussauge et al. 2015b, 1).

In order to address these questions, we proceed in two steps. First, we discuss infrastructures in the biomedical realm. This is essential because infrastructures create and also stabilise specific orders and allow to do biomedical research in specific ways. They address matters of concern (Latour 2008) in the biological/biomedical sciences, and thus also define what can become a matter of concern. Any biobank puts certain values centre stage while pushing others into the background. As biobanks are designed by communities of practitioners, we also can observe which specific values are realised in and through them and how – we can therefore think biobank infrastructures through the notion of "value(s) by design". Yet, this subchapter also argues that we should not look at biobanks as stable entities or things, but investigate the constant work that needs to be invested when assembling biobanks in such a way as to make them sustainable. We use the notion of infrastructuring to capture these activities.

This then links to the second part of the chapter, which looks at value generation practices and how they matter for biobanks in the making. We then shortly reflect on the relation of values in and through the processes of designing biobanks. Finally, we will look into the role visions and future imaginaries play in bringing biobanks into being.

2.1. Biobanks as infrastructures and the infrastructuring of biomedicine and health

2.1.1 Biobanks as infrastructures

As already underlined in the introduction to this report, in contemporary biomedicine, biobanks have become core infrastructures for collecting, storing and providing a large variety of human[3] materials and data, often combined with clinical information. Such infrastructures are essential for contemporary biomedical research as they allow exchange of biological materials and data over time and space and the pooling of relevant resources to advance knowledge. They make human/animal materials available across a variety of research sites, that are situated in different national contexts, fields or institutions. With their strong future-oriented dimension, biobanks lay the foundation for potential research over decades to come, on a broad variety of topics and across many different sites.

[3] The literature reviewed in this report is mainly concerned with biobanks collecting human samples and data. However, in BBMRI.at we also have one network partner who runs an animal biobank. It will thus be key to reflect the different kinds of challenges these biobanks meet. This is all the more of interest as less reflection has been devoted to studying these biobanks.

What does it mean to understand the collection of biomaterial and respective data as an infrastructure? When thinking about biobanks as infrastructure, we conceptualise a biobank "not so much as a single thing", but rather, as Slota and Bowker underline, "as a bundle of heterogeneous things (standards, technological objects, administrative procedures) […] which involves both organizational work as well as technology" (Slota and Bowker 2017, 531). As outlined in the introduction, we therefore understand infrastructures as assemblages of a broad and diverse set of human and non-human entities, which change over time, adapt to new environments and socio-technical possibilities and need constant work and care in order to remain consistent and coherent. This work has to be done in order, on the one hand, to remain acceptable and useful to research practices and values in place and, on the other hand, to meet societal expectations, values and concerns.

Indeed, with Edwards (2003) we could argue that biomedical sciences and care depend fundamentally on the silent functioning of biobanks as they can contribute to assure regularity, predictability and a certain kind of stability in planning research in these areas. Simultaneously, the practices and values of contemporary research, in academia and beyond, "helped define the purposes, goals, and characteristics of those infrastructures" (Edwards 2003, 191). We thus can observe a moment of co-production: a moment where knowledge orders in the biomedical sciences and social orders, i.e., how human materials but also the allowed work procedures, emerge in close interaction with each other (Jasanoff 2004). Therefore, we aim at carefully exploring how biobanks function as infrastructures for the different actors in the biomedical field at large (including patients and citizens), "both conceptually and practically, as environment, as social setting, and as the invisible, unremarked basis" (Edwards 2003, 186). Looking into *BBMRI.at* from such a perspective then means that our attention needs to be directed towards the socio-technical assemblages in which "technical, political, legal, and/or social innovations link previously separate, heterogeneous systems to form [a] more powerful and far reaching network" (Edwards et al. 2009, 369).

We will thus be attentive to at least five aspects when analysing biobanks as infrastructures.

First, analysts studying infrastructures have pointed out that new infrastructures never "grow de novo". Consequently, we will have to reflect how biobanks have to "wrestle with the 'inertia of the installed base' and inherit strengths and limitations from that base" (Star and Ruhleder 1996, 113). They are built on already existing collections, and their inherent — locally framed and epistemological — logic. They inherit some of the strength and vulnerabilities when it comes to the documentation and/or the classificatory/standardization practices[4] that have been employed. This means paying attention to how and when sample collections were transformed into biobanks or inserted in a network of other such collections (BBMRI.at or BBMRI-ERIC), often becoming much larger and also having a longer time-horizon than initially assumed.

Second, biobanks as infrastructures build on socio-cultural and epistemic routines and regulatory practices. Belonging to a scientific community means having "fluency in its infrastructures" (Edwards

[4] For the importance of standards and classificatory practices in research and beyond see Bowker and Star (1999) and Busch (2011).

2003, 189). In our case such a fluency involves knowing the many tacit features of biobanking, including: knowing and understanding how samples were collected, prepared and stored; which kinds of samples were seen as important; and how roles and responsibilities were distributed in these processes (e.g. how to address donors; quality assurance). In addition, building and maintaining trust relations to actors involved in biobanking is essential, for example, when it comes to the quality of samples and their documentation, or to reflections on the donors who contribute to the biobank, making sure that data are dealt with in a responsible and ethically acceptable manner.

Third, as Larkin (2013, 329) has underlined, infrastructures "also exist as forms separate from their purely technical functioning". We thus have to look at them as "emerge[ing] out of and store[ing] within them forms of desire and fantasy." (ibid., 329) This invites us to investigate the argumentative repertoires and modes of justification used to demand or justify biobank infrastructures, to study the promises that are part and parcel of biobanking, and the futures of health research and care that get imagined through them (see section 2.2). Attention needs to be drawn to narratives different actors produce. Narratives "reflect prevailing institutional structures, express values and reinforce collective aspirations" (Felt et al. 2007, 73) and they "tacitly define the horizons of possible and acceptable action, project and impose classifications", revolve around important values and norms that guide us, "distinguish between relevant issues from non-issues, and central actors from non-actors" (Felt et al. 2007, 73). Key for our research are the stable and often repeated narratives (including visualisations) which collectively shape the ways in which diverse actors make sense of biobanks. We call them "narrative infrastructures" as they form a temporarily stable network of narratives through which shared meanings and values of biobanking can be articulated, circulated and exchanged (Felt 2017). Where are these narratives emerging from and how do they gain traction and travel? What imaginations are expressed through them and can we see tensions around some of them? What role do these narrative infrastructures play in justifying the investments in building, maintaining and improving biobanks as infrastructures?

Fourth, investigating biobanks as infrastructures means looking at them at different scales. To begin with, it will be relevant to reflect the change in time scales biobanks bring about. Biobanking allows to collect samples over time, accumulating the richness of diverse sets of bodily materials and related data through a set of conservation techniques. It permits new kinds of temporal organisation of research work through the availability of samples and data. The second scale regards the social organisation of biobanks, which range from small collections run by individuals to institutional or national biobanks to supranational networks like BBMRI-ERIC. Each scale tells us something about where we stand in biomedical research - epistemologically and socially. They point to existing tensions, which need to be addressed when wanting to understand the development and sustainability of biobanks.

Finally, the analysis of biobanks as infrastructures also invites to take a look into practices and structures which govern biobanks. These questions range from the financial models that sustain biobanks, to who curates, maintains and cares for the biobank, to the (often soft) regulations of who can store samples and who gets access to what kinds of samples. This includes processes like informed consent when providing bodily materials for research, but also more mundane standardised practices of preparation of samples and storage. In and through all these processes values and different visions of value generation find their expression.

2.1.2 Infrastructuring the biosciences

When aiming at understanding biobanks as socio-technical assemblages, it is important to not mainly focus on the more or less stable entity "biobank", but rather investigate the constant work and care needed to build und uphold a biobank. We therefore want to speak of *infrastructuring* as an activity. By using the notion of infrastructuring, and not infrastructure, we draw attention to the processes biobanking needs to engage in and move away from mainly describing and analysing the outcome of the process. This fits well with our understanding of biobanks as heterogeneous assemblages that emerge out of relational networks. It means that biobanks have to be understood as being in a constant mode of 'becoming'. This view is supported by other observations made when it comes to health-related data infrastructures. Grisot and Vassilakopoulou (2017, 8-9), for example, investigating national, public eHealth services show "how the design work to infrastructure is not confined to a delimited design phase but unfolds over long periods, events and design decisions over time and on the rearrangement of sociotechnical interdependencies and relations." Thus, we see the making of a biobank not as a single moment in time, but as a constant process of development.

This also means being attentive to practices of imagining present and future developments, of researching with materials stored and provided in biobanks, of designing processes and procedures to best capture the available materials and data, of constantly adapting to new potential approaches, as well as of using biobanks in new ways. To that end, we need to reflect on the development, implementation and use of biobanks through a process, by which practices and technological elements (hardware and software) form a social and technological –or a socio-technical – network related to biomedical samples, data and their use in research (Grisot and Vassilakopoulou 2017). Yet, infrastructuring biomedical research also means thinking of citizens/patients/donors, individually and collectively, in new ways; they become silent actors in the research practices and processes.

Looking into infrastructuring the biosciences means bringing the research and information practices of a set of actors – ranging from donors to different kinds of researchers, but also including policy makers who support the formation of such infrastructures – into one socio-technical network. This socio-technical network includes many different contexts of use (e.g. pharma industry; application oriented/disease specific research; basic research; personalised treatments, ….). And it stretches over a number of otherwise nationally or locally organised biomedical infrastructures and thus calls for comparative work.

In doing this, infrastructuring is never a fully plannable exercise. We will not know beforehand which connections the infrastructure will stabilise in the future and which one become routinized or not. Neither will we be able to foresee the practical use patterns that might emerge out of new data practices which are in the making. It seems promising to use an approach which emphasises the value and importance of multi-sited and longitudinal studies. For the BBMRI.at context this means looking into different kinds of biobanks, what they share and how they differ, and to follow that up over time trying to capture change and the debates reflecting the need for adaptation.

2.1.3 Standardisation of and through infrastructures

Infrastructuring always goes hand in hand with processes of standardization, which are seen as essential to be able to work across time and space and to assure the quality. Over the past century, we witnessed a variety of attempts to make biodata available across sites in order to get access to samples from different sites, but also to get bigger sample sizes in order to align with the currently dominant imaginary of big data as an answer to many of our (population) health related questions. Yet, in order to achieve this aim, "terminologies and communication routes need to be standardised, and technical standards have to be implemented so that the information systems of all these different parties can communicate smoothly" (Timmermans and Berg 2003, 7). Guidelines on how to produce and store health data have been put in place in different medical institutions and research environments; education in the field of biobanking is being standardised, and so are protocols and procedures.

To engage in the creation of common standards, or a harmonization of standards, on different levels is therefore essential. It is also important to convince different actors to conform to them in order to turn biosamples and data into useful 'goods' that can travel and be used across sites. This requires, and is necessarily preceded by, acts of giving them a specific agreed upon form. This demands what Thévenot (1984) has called an "investment in form," i.e. an agreement on "formats of information". Any such process of standardization always stands in tension between "disciplining uniformity", i.e. achieving the ideal of sameness (objectivity) across very different sites, and the very difficult to "impossible accomplishment in the face of actual practice" (Thévenot 2009, 810).

Busch (2011, 84) has clearly described the fact that "modern science requires that research be accomplished using highly standardised objects. Put differently, science creates its objects of study such that they conform, as much as possible, to the assumptions of probability statistics". Only by defining such common standards and by complying to them can samples and data be used across sites and outcomes be regarded as comparable, at least on a principal level.

2.1.4 Making biobanks sustainable

Much of the ELSI literature on biobanks emerged when biobank initiatives begun to take shape. As a consequence, much attention was paid to the promises and expectations that enabled biobanks, the ethical and social issues and concerns that were triggered by such initiatives, and the ways in which potential participants and publics perceived such initiatives. A smaller portion of the ELSI literature engaged with the issues and challenges that biobanks meet once they are set up and need to be maintained—or to biobanking in action or in practice. Within this body of literature, expectations on the value of biobanking are not only discussed as enabling, but also as constraining challenges. For instance, Aaro Tupasela notes that

> *"[i]n Europe, and elsewhere, [large collective cohort] biobanks have struggled to live up to the political and commercial expectations laid out by policy discourse and to the role given them by social-scientific theocratizations of biotechnological capitalist accumulation." (Tupasela 2017, 189)*

Within this body of literature, **sustainability** has emerged as a topic, reflecting in part discourses within the field of biobanking. In line with this, Don Chalmers and colleagues (2016) have identified "challenges for sustainable biobanking" as a third wave of issues—after governance frameworks and issues of standardization—that biobanks have to address. They concede that at the early "biobank establishment stage", issues of sustainability have not been at the forefront. However, in the meantime and also notably after a major financial crisis, such issues have become quite salient. Sustainability is being described as consisting of several layers, which range from "financial sustainability", over the need to ensure—as well as to prove—that sample/data are used, to "social sustainability" (see figure 2 for our representation of sustainability layers).

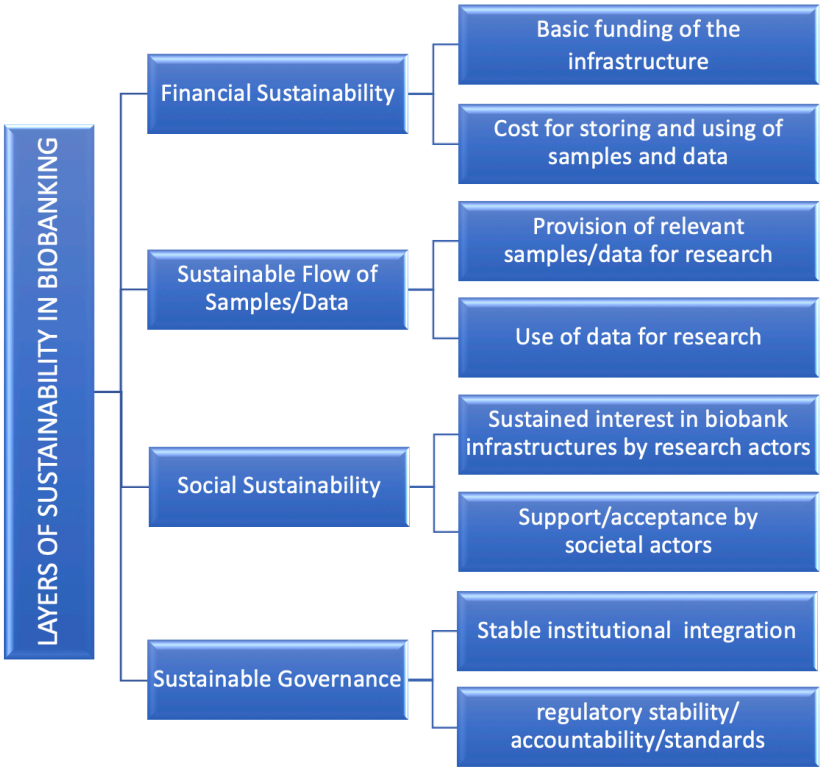

Figure 3: Layers of sustainability

While it will be essential to empirically explore the concrete challenges to sustainable biobanking in the context of the Austrian biobank network and how they potentially differ in diverse institutional settings, we want to capture some lines of the international debates in sustainable biobanking in the following.

Financial sustainability – has been identified as a major problem that many, even if admittedly not all biobanks, seem to meet (Tupasela 2017, 194; Cañada, Tupasela, and Snell 2015; Chalmers et al. 2016). It is discussed along two dimensions: the importance of ensuring funding of the infrastructure as such, as well as the challenge of ensuring financial returns from users, i.e. from both, those who store their samples/data and those who use them.

When it comes to ensuring funding, both Tupasela (2017) as well as Chalmers and colleagues (2016) note that while most biobank initiatives manage to secure funding for the setting up of biobanks, financial concerns start once biobanks are established and need to be maintained. They note that funding is often provided as "start-up funding", with the expectation that biobanks "would eventually be able to generate enough revenue form their own activities to fund their own operation" (Tupasela 2017, 192). Similarly, Cañada and colleagues note that "public administration often funds biobanks as if they were research projects with a clear beginning and end" (Cañada, Tupasela, and Snell 2015, 371). Timmons and Vezyridis (2017, 1250) note that in their case study, an NHS-based biobank in the UK, the manager of the hospital actually expected the biobank to become "financially self-sustaining in the long term in return for their initial investment."

One way for biobanks to generate revenues is charging the costs for services when supplying sample/data to users via the development of "cost-recovery" models (Chalmers et al. 2016, 8). Timmons and Vezyridis (2015, 1250) describe such a "pricing structure", in which local researchers and users could access sample/data free of charge, while academic researchers from elsewhere in the UK were charged a cost, and commercial users were charged market rates.

However, Tupasela notes that biobanks have to navigate between "competing logics" or competing expectations materialised in particular policy discourse, arguing:

> *"On the one hand, biobankers are expected to keep costs [for samples] as low as possible so that university researchers can afford to use the resources—the majority of researchers' grants do not offer the possibility to cover market-based costs of sample handling. On the other hand, biobankers are expected to achieve financial independence and sustainability by selling their samples and services." (Tupasela 2017, 195)*

Thus, he observed a trade-off between "captur[ing] the value and cover[ing] the costs of their activities" and ensuring the use of sample/data. He notes that this trade-off is further aggravated by the emerging discourse of open data (Tupasela 2017, 189). Chalmers and colleagues added that "cost-recovery models" might also endanger cardinal values in biobanking and challenge public trust and support for biobanks (Chalmers et al. 2016, 8–9). Quoting Turner and colleagues (Turner, Dallaire-Fortier, and Murtagh 2013), they noted that:

> *"Biobanks are caught directly between the values and rights of the participants and the potential commercial and scientific value of the samples and data, and, at the same time, have to construct a business model that will ensure the long-term sustainability of the biobank." (quoted in Chalmers et al. 2016, 8)*

Similarly, Timmons and Vezyridis observe "tensions between ethical, scientific and commercial values", when biobanks seek to develop "sustainable business models" (Timmons and Vezyridis 2017, 1242).

Ensuring a sustainable flow of sample/data is another essential dimension of sustainability to be considered. This relates to the need to not only collect, store, and maintain samples/data, but also to ensure—and at times to prove—that these samples/data are actually used in research. While at the early stage of the establishment of biobanks it was taken for granted that samples/data would be used, there is an increasing awareness that the actual uptake has often not met these taken for granted expectations. In particular, smaller biobanks have been reported to have few requests of access (Scudellari 2013; Chalmers et al. 2016, 8). The "underuse" of biobanks has thus become a concern within the biobanking community and in particular of those funding them. Cañada and colleagues note that:

> *"Biobankers are conscious that if their samples remain unused – or even if their use is not visible – the value of biobanks is considerably reduced, with the consequence this can have on their flow of funding." (Cañada, Tupasela, and Snell 2015, 369)*

They note that many biobanks strive for "attracting researchers to their collections", so as to "achieve sustainability" (Cañada, Tupasela, and Snell 2015, 369).

Social sustainability has also been addressed. Tupasela and Cañada and colleagues relate the financial sustainability and the need to avoid underuse to social sustainability of biobanking. Tupasela argued that

> *"biobanks need to engage in a multitude of practices to secure the public funding, political support, and social acceptance that are necessary to ensure long-term sustainability (Tupasela et al. 2015)." (Tupasela 2017, 192)*

Together with colleagues, he stressed that biobanks need to engage with a variety of groups if they wish to achieve social sustainability, including the users of biobanks and in particular from industry (Cañada, Tupasela, and Snell 2015, 367–68) and (academic) researchers. For academic biobanks, the latter are a particularly tricky group. Biobanks within academic institutions have to achieve both, "to convince researchers and universities to use their samples" (Cañada, Tupasela, and Snell 2015, 369), *and* to convince them to store their sample/data in centralised repositories (Cañada, Tupasela, and Snell 2015, 369). They argued that these groups, their expectations, values, and needs, also have to be addressed in biobanking. Tupasela suggested that there was a need to develop more nuanced policy discourses, but also more fine-grained social science theories on economies of values; or in his words:

> *"There is a need to develop more nuanced theory of biobanking politics, where the interests of scientists who control samples and data are better understood and recognized in relation to the more normative political expectations associated with sample- and data-sharing set out in policies. These developments suggest a need to revise both policy discourse and social-scientific theories of the bioeconomy." (Tupasela 2017, 190)*

Cañada and colleagues conclude with the observation that "biobanks as young entities [are] still in formation [and] continuously need to find support in other communities in order to survive" (Cañada, Tupasela, and Snell 2015, 372). Similarly, Stephens and Dimond (2015, 433) write about a "precariousness" of biobanks.

As can be seen in figure 3, there are further dimensions, which need to be explored when it comes to questions of sustainability in the specific Austrian context. One such dimension would be the governance of biobanks, which would need to address issues of regulatory dimensions of biobanking (e.g. the handling of samples and data after the introduction of the GDPR) but also of the institutional embedding of biobanks. We plan to explore these dimensions of sustainability of biobanking throughout the project.

2.2 Value generation practices

2.2.1 Value, values and valuation as practice

As outlined in the introduction to this report, our research wants to contribute to a better understanding of values and value generation practices in the context of biobanking. In this section we want to shortly outline our understanding of and approach to the very notion of value, explain why we use the plural and prefer to speak of values and even more specifically want to focus on better grasping value generation practices. This section thus begins by underlining that we do not want to start from a clear definition of what "a value" is. Indeed, Dussauge and co-authors (2015a) offer interesting insights into the multiplicity of understandings of the very notion of value when seen from the perspective of different subsystems or actors. They point to the impossibility of the task to abstractly define what the very notion of value means. Rather, we often speak of "cultural" values, "biomedical" values or "economic" values. However, each time this would mean that we have to dive deep into a specific system and its understanding of what is at stake when declaring specific objects (such as biological samples in our case), an infrastructure (a biobank) or specific people (with specific know-how and skills) as valuable, as value generating, as realising a specific value, and many more.

Already as early as 1939, John Dewey pointed to the difficulty of the notion "to value". He states that

> *"in ordinary speech the words 'valuing' and 'valuation' are verbally employed to designate both prizing, in the sense of holding precious […] and appraising in the sense of putting a value upon, assigning value to. This is an activity of rating, an act that involves comparison …" (Dewey 1939, 5)*

Dewey reminds us "that praise, prize, and price are all derived from the same latin word" (ibid., 5) and that it is essential to attend to the differences that have emerged over time. Different processes are involved in holding precious and appraising. While "holding precious" points to a personal - he also calls it emotional - reference, the second is "primarily concerned with a relational property", i.e. needs something to be compared to. We are invited to reflect on the relation of these different forms of valuation, asking whether they are to be kept separate, they are complementary or even contradictory. This will be essential to keep in mind when thinking about what makes a biobank valuable (see also Beckert and Aspers 2011).

Therefore, we will not ask what a value is, trying to find a definition and developing a yardstick against which we can measure the degree of "valuability" of objects or collections such as a biobank, the work performed or the people involved in it. Rather we want to move away from looking at value and value generation in the singular to exploring what comes to count as a value or as valuable, which values are put centre stage in which moments, but also how efforts are made to reconcile or at least coordinate divergent values that come to matter in the field we investigate.

Dussauge and co-authors have brought that clearly to the point by stressing that it would be worth to

> *"… not treat values as stable and predefined, but rather as something grappled with, articulated, and made in concrete practices. By looking at dissonances, discordances, and ruptures between values, we find situations of the explicit assembling, articulation, coordination, and negotiation of values. These practices illuminate the various yardsticks, different technologies, and matters of concern that inform these mundane, but fundamental, activities." (Dussauge et al. 2015a, 1-2)*

Therefore, in our work throughout the project we will investigate how different groups of people, from researchers over biobankers to industrial actors, including citizens/donors and policy makers, make value in practice; how different actors in the field of biobanks develop their situated perceptions, explanations, interpretations, and interventions in the biobank and its larger ecosystem. We are thus interested in studying valuation as a social practice, as something that gets done. In this definition valuation is a continuous process that can take many different forms; it may focus on objects, infrastructures, and knowledges, as well as on diverse sets of subjects. At times, we will need to be attentive to the practices that aim at producing value, at others we will be observing how values are assessed; and often we will witness how both happen simultaneously, creating reinforcements, convergences or tensions. We thus want to develop in our research a version of Dussauge et al.'s approach and investigate "articulations, choices, exchanges, hierarchizations, sortings, displacements, and commensurations of values" (Dussauge et al 2015a, 5). This will allow us to grasp how, where, when and by whom values are made. We do not see values "as intrinsic properties of objects, people, or cultures" (Dussauge et al. 2015a, 5) but as expressions of practices. At the same time, we could, in analogy to Baudrillard's (1981) conceptualisation of an "economy of values" in the context of art auctions, argue that we witness the emergence of an economy of values around biobanks, which should be understood as a political economy. Investigating biobanks, we could point to the fact that this economy of values

> *"… goes well beyond economic calculation and concerns all the processes of the transmutation of values, all those socially produced transitions from one value to another, from one logic to another logic of value which may be noted in determinate places and institutions — and so it also concerns the connection and implication of different systems of exchange and modes of production." (Baudrillard 1981, 122)*

A relevant addition to this framing of reflecting values can be found for example in recent work in the domain of data studies. Here, reference is made to the fact that focusing mainly on the work invested in producing data and transforming them in ways that they become valuable research resources is not sufficient, but we also need to consider "the affective and attentive relationships that humans build with data" (Pinel et al. 2020, 175). Studying biobanks from the perspective of valuing, thus invites us to treat samples as well as the related data as relational entities. We will analyse, on the one hand, the multiple practices of care (Puig de la Bellacasa 2017) that researchers and biobankers invest to produce and maintain their sets of samples on a level of quality that meets expectations of related research communities. On the other hand, we will also look into the specific institutional, legal, ethical and financial arrangements within which these *caring* practices take place. Using the notion of care here points to the fact that bringing together a set of samples and their integration into a biobank needs commitments in terms of time, careful reflection, attention to what gets selected and what not. This often also means building and maintaining relationships to the humans that provide these samples and data. This investment in bringing together samples and data, however, does not stop in the moment of getting them from the donor. Essential steps need to be taken in order to prepare, document, store, update and make samples/data accessible in order to transform a biobank into a valuable asset in an institutional setting and for the biomedical community at large.

We will thus engage in what Dussauge and co-authors have aptly labelled a "**valuography**". We will engage with the taken-for-granted and do so by going to places and looking into situations where we will find "values as enacted, ordered, and displaced rather than as fixed and constitutive forces" (Dussauge et al. 2015b, 268). Studying values through practices can happen through multiple engagements with a broad variety of actors and by zooming in on specific issues. These could for example be efforts to define "a successful biobank" or gold standards for biobanking. We will also be attentive when controversies emerge or when ownership issues are being posed, reflect on the underlying economic models in biobanks, study processes of classification and standardization and many more. Or we could observe frictions between efforts to enact what Dussauge and co-authors (2015b, 269) call "biocapitalist values pertaining to 'production, profit, and novelty'" and how they potentially stand in contradiction with other value system such as following specific long-term research interests.

2.2.2 Biobanks – Values by design?

Building an infrastructure, and this also holds true for biomedical infrastructures such as biobanks, is never a value neutral effort. The relation of technological innovation to societal developments has been addressed by numerous analysts over the years. In the 1980s, for example**,** Langdon Winner (1986) convincingly argued that technological innovations are, often in invisible ways, shaped by values and, in turn, impact the ways in which we can live in the world or as in our case do research **in the biomedical field**. Technologies thus can be seen as capable to ''authorize, allow, afford, encourage, permit, suggest, influence, block, render possible, forbid, and so on'' specific human action (Latour 2005, 72) and **through** this also to shape the knowledges that can be generated.

Thus, biobanks as other technological assemblages always build on specific values that are expressed through their design, making certain things possible**, allowing for specific practices to unfold while making others more complex**. And even if we carefully reflect which values we try to realise through

design, Verbeek (2011) reminds us that technologies have mediating effects, shaping behaviour as well as experiences of users. Sometimes they even affect the value frameworks from which we assess the very same technologies. This is of particular importance when it comes to questions of human health and how this will relate to the way samples and data are collected and shared**, how research can be done and where hurdles emerge**.

It is thus on the one hand helpful to reflect on the research, development and design process of such a socio-technical infrastructure using Akrich's concept of a "script". Using the analogy between technologies and the production of a film, Akrich (1992, 208) suggests that "like a film script, technical objects define a framework of action together with the actors and the space in which they are supposed to act." The concept of a script tries to capture how technological objects, such as a biobank, enable, evoke or constrain specific actions and interactions. On the other hand, we have to see how these scripts are "read" by users, reinterpreted and potentially changed, thus shaping relations between donors and research, creating new possibilities for research, imposing some classifications and standardisations or defining questions of ownership and access to samples and data.

Thus, it is essential to carve out the values and valuing practices that are at work in relation to concrete technological innovations and how they are reflected in their practices. Values here can be defined very vaguely as "lasting convictions or matters that people feel should be strived for in general and not just for themselves to be able to lead a good life or realize a good society" (Van de Poel & Royakker 2011, 72). Designers, then, can be seen as materialising morality by building technologies in specific ways and not others. Thus, in the words of Verbeek (2016, 369), they are doing "ethics by other means" or "materialize morality". As technologies mediate between humans, actors and the world around us (here largely focused on biomedical issues), they shape perceptions and expectations, as well as actions and practices and, as a consequence, mediate morality (Swierstra 2015; Swierstra and Waelbers 2012). This demands being specifically attentive to "history and political culture in ethical reasoning about technological futures" (Jasanoff 2016, 27), i.e. developing a sensitivity to the pre-existing value orders which get incorporated into our sociotechnical infrastructures and to the (in)possibilities that need to be considered when building technologies and governing them.

2.2.3 Future making through and for biobanks

As outlined in the beginning of this report, sociotechnical innovation such as biobanks are deeply interrelated with the social arrangements that inspire them and sustain them along their developmental trajectory. They are deeply connected to a large area of expectations, promises, and prospects which are to be realised in the future if related investments would be made in the now. Expectations and promises mobilise, justify and legitimate the activities of scientists, medical professionals, biobankers, policy makers, and regulators around the making of biobanks. When reflecting on and analysing biobanks we thus have to consider the social complexities that matter and ask why attempts to build such infrastructures sometimes work successfully while failing at other moments despite engagement of relevant actors. This also means reflecting on different values attached to biobanks in the making, but also the futures in biomedical research and in the biomedical field that are imagined to be realised through the construction of such an infrastructure.

In investigating the making of biobanks we thus have to carefully consider "the role of performative future-oriented statements, representations, and practices" (Konrad et al. 2017, 466). Under the label of a "sociology of expectations" studies have shown the key role they play in realising technoscientific endeavours (Brown 2005; Brown, Rappert, and Webster 2000; Petersen and Wilkinson 2014). As expectations are never solely tied to individuals, we have to pay specific attention to the often-collective character of expectations, which are carried by a community of practice or a scientific community. In that sense, we will consider that "the main performative roles of expectations in mobilizing, guiding, and coordinating diverse sets of actors involved in technoscientific fields require expectations which are to some degree common, shared reference points" (Konrad et al. 2017, 466). This will be reflected in our study through considering expectations of different actor groups and carefully investigating where they converge and where they differ. Expectations also get expressed through assessing more or less explicitly the potential of a socio-technical assemblage, e.g., when funders, universities or a ministry decides to (not) invest. Investing or not, along with the arguments and justifications delivered for (not) doing so, reveal a specific vision of the future and the related commitment to it. Expectations are never value-free statements about potential options; they are always already a step to guide developments into a specific direction; they can be seen as governing sociotechnical developments.

Investigating the power of visions, projections and promises also invites us to look at the "economics of technoscientific promises" (Felt et al. 2007) or "political economy of hope", as Novas (2006) has put it. In describing the political economy of hope Novas (2006) captured the investment of patients in the establishment of biological data banks and their readiness to enter new contractual arrangements where they make both their bodies and data available to support pharmaceutical innovation in the hope of harvesting promised benefits. The hopes point to the importance of promises when it comes to technoscientific innovations and the need to nurture them to develop their potential. The drawback, however, is that they are often "subjected to short-term return-on-investment requirements". This points to the importance of being attentive to timeframes at work when expectations and promises are assessed. The economics of technoscientific promise also invites us to not simply take promises at face value but to engage with the ambiguities of promises: "promises are by their very nature uncertain, requiring support by believing in them before they exist; but they should not be accepted at face value either" (Felt et al. 2007, 24).

It will also be important to carefully look into justificatory practices of different actors as well as related promises and projections used. These are not solely discursive devices for building a convincing narrative to justify investment in terms of resources, but they have to be simultaneously understood as shaping actions and having implications for conceptions of health, illness and human biomedical condition more generally. They thus represent an important element in shaping what a biobank is. Inspired by Boltanski and Thévenot's (2006) work on "justification", Tamar Sharon (2018) developed an in-depth analysis of stakeholders' argumentative strategies used in the context of data-driven health initiatives and pointed to the moral repertoires of justification. While biobanks are in many ways different to the health data banks Sharon focuses on, it is nevertheless interesting to reflect on her findings. She points to the presence of what she calls a "vitalist repertoire", pointing to the fact that "good health, life and vitality are upheld as the highest values, (human) life and its proliferation is understood as having intrinsic value, the pursuit of the good life is framed in terms of the quest for health" (Sharon 2018, 7). Something similar can be found in arguments for personalised medicine. Other repertoires of justification such as the civic

repertoire then “emphasizes the collective or general will over and above that of the individual” and conceptualises “the common good … as collective well-being” (ibid., 5). This is to be achieved through the research made possible by sample and data provision for research. Or we can identify the project repertoire of justification, which conceptualises the common good “as innovation, specifically innovation that expands networks” (ibid., 7). This repertoire of justification draws, in particular, on the idea that biobanks will support personalised medicine to be aimed for. Identifying these repertoires of justification, and in particular the promises and projections that come with them, will also allow us to see different and partly competing moral repertories that are present.

In order to address visions, ideas, and inspirations that carry projects of biobanking we specifically find Jasanoff’s (2015) concept of “sociotechnical imaginaries” aptly capturing these aspects. Jasanoff defines them as “collectively held, institutionally stabilized, and publicly performed visions of desirable futures, animated by shared understandings of forms of social life and social order attainable through, and supportive of, advances in science and technology” (ibid., 4). In looking for such shared visions, we have to be aware that while sketching attainable futures we also see the prescribing kinds of futures that ought to be attained in a specific context. Imaginaries are thus more than simple visions; they tacitly define the horizons of possible and acceptable action, project and impose classifications, and make certain explanations or choices seem more attractive than others (Felt et al. 2007). In this, they become an influential force in directing research, personal choices, but also societal developments. Yet they do so in a largely invisible manner, which is why we speak of a “tacit governance” (Felt and Fochler 2010), a governance which largely escapes public scrutiny and questions of responsibility. In doing so, “imaginations of desirable and desired futures correlate, tacitly or explicitly, with the obverse—shared fears of harms that might be incurred” (Jasanoff 2015, 4-5). In our case this happens either through not engaging in biobanking and thus not realising certain biomedical innovations or because samples and data potentially might not be used in ways that donors had imagined.

Being attentive to the assemblage and stabilisation of the sociotechnical imaginary around biobanking thus helps us to go beyond the description of biobanks as material assemblages and draws our attention to the role of imagination, projection and promise. It allows us to “engage directly with the ways in which people’s hopes and desires for the future—their sense of self and their passion for how things ought to be—get bound up with the harder stuff of past achievements”. Scientific and technological achievement thus always point “back at past cultural achievements and ahead to attainable futures” (Jasanoff 2015, 22). While being strongly oriented towards the future and containing important promises that lie ahead, they are always rooted in and related to pasts. Biobanks are deeply connected with ideal about past practices of collection and classification and medical traditions to refer to.

3. The value(s) of and in biobanking: insights and spotlights from the literature

A first objective of our empirical research is to engage with how value is produced, diffused, assessed, and institutionalised across a range of settings where biobanks matter, but also whose values come to matter in the building and using of biobanks. As outlined in section 1.2., we want to concretely trace the values which matter when donating, collecting, storing and using biomaterials, funding biobanks, maintaining but also regulating them.

In doing so, we will embrace a **practice oriented approach** and investigate
- when (at what moments, in which kinds of situations),
- where (in which places, institutional contexts),
- how (through which practices) and
- by whom (involving what kinds of actors and institutions)

values are made and how different sets of values come together, get articulate, create tensions or even conflicts.

Box 2: Guiding questions for research objective number 1 – Value(s) in Biobanking

This chapter takes stock of the social studies of biobanking and ELSA/ELSI literature, focusing on work that has engaged with value(s) in and of biobanking. This body of writings has co-emerged with the increasing salience of biobank initiatives at the turn of the 20th to the 21st century, spawning more than two decades by now. The kind of value(s) and the ways in which these were discussed shifted, reflecting both transformations and dynamics in the field of biobanking and also dynamics between the different "ways of knowing" of the various disciplines assembled in the interdisciplinary study of biobanking (Hoeyer 2006).[5] As it would go well beyond this report to capture the details of the different developments, we will focus on the literature that is particularly helpful and valuable to our research at this stage, discussing some research at length, while clustering other work into themes, giving some examples.

We will proceed in two steps. We will first start with a discussion of some "spotlights" of the literature that engages with the "value *of* biobanking". The second part of the chapter will then speak to the history of cardinal values in the governance of biobanking using different examples of biobanks from the Icelandic biobank, over the UK biobank to the commercial genomic databases. We finish this chapter, taking stock of debates in the literature.

[5] Some of this literature is normative and prescriptive, as it either deduces specific requirements and action points from general principles or uses often implicit principles and values to criticise developments. Another part of this literature is more geared towards empirical analysis: it either discusses values that are taken into consideration in the design and setting up of biobanks, their governance, or daily routines in practice, or it uses empirical social science methods, such as interviews, focus groups, or surveys, to explore the opinions, perceptions, and understandings of particular groups or publics. Some studies are *hybrid,* as they both describe and prescribe values, for instance by using empirical findings from focus group studies to argue why some values ought to be taken into consideration rather than others.

3.1. The value(s) of biobanking

In what follows, we engage with discussions in social science literature around the value of biobanking. What kind of expectations are vested into the establishment biobanks? What kind of value(s) are biobanks expected to generate and to produce? How is the value—or the values and goods that biobanks generate and produce—assessed? How do different values enter into conflict or conversation? And what kind of values and norms do biobanks produce in and through practice?

The section is structured along the following lines. First, we begin with social science literature **on promises, expectations, and imaginaries of biobanking.** Second, we continue with research that looks into the **changing meaning and identity of the biological objects** assembled in biobanks. Finally, we will conclude with a short note on what we call **"collateral values"** of biobanks—or the values and norms that co-emerge as unintended "side effects" of biobanks.

3.1.1 The promissory value of biobanking: public health and economic growth

In many ways, biobanks are promissory assemblages. They have been associated with the generation of value from the very inception, which has been described as "inestimable". In 2009, Corrigan and Tutton began their contribution on biobanks in the *Handbook of Genetics and Society* with the following quote from a newspaper report in the *British Observer* of then emerging plans on the establishment of the Icelandic Biobank:

> *"Inside the Reykjavik headquarters of deCODE Genetics, a guard stands on permanent duty outside a small, panelled room containing double locked steel safe … The safe however is no more repository for financial secrets or bonds. They are the genetic records of tens of thousands of Icelanders and their value is inestimable." (MacKie 1997, 14, quoted in Corrigan and Tutton 2009, 302)*

The "inestimable" nature of the value is an instance of what social scientists have referred to as the "promissory" (Kragh-Furbo and Tutton 2017; Martin 2015; Haw 2015) or "speculative" (Birch 2017) value of biobanking.

This refers to a first "form" or "mode" of engagement with the value of biobanking—value in the form of promises, expectations, visions as well as imaginaries, that materialized, for instance, in particular narratives or in actions in the present performed so as to make the promissory value happen (see section 2.2.3). Drawing on the "sociology of expectations" (Brown 2005; Brown, Rappert, and Webster 2000; Petersen and Wilkinson 2014) as well as related work on "socio-technical imaginaries" (Jasanoff and Kim 2009; 2015; Felt 2015), much social science literature has pointed to the salience of promises, expectations, visions, as well as imaginaries in biobanking (Tsai and Lee 2020; Stephens and Dimond 2015; Aarden 2017b; Tutton 2007b; Aarden 2017a). This body of literature has approached biobanks as "'promissory entities' in the sense that financial and personal investment in them is driven by expectations of future benefits of genetic science and technology" (Tutton and Prainsack 2011, 1082).

Scholars have also emphasised that multiple kinds of values are entangled in this "promissory discourse" (Tupasela 2017, 188), including scientific or epistemic values, biomedical or (public) health values, as well as commercial and financial ones. Future values of biobanks have been related to the biomedical therapies they might enable in the future (Aarden 2017a; Busby and Martin 2006). Biobanks have been endorsed as infrastructures that would enable to assemble a sufficient quantity of sample/data so as to enable "genomic" approaches, or "-omic" approaches more generally, or as means to "accelerate" research efforts that would support researchers to avoid wasting time and financial resources for the collection of tissue and data (Chalmers et al. 2016, 1–2).

Scholars have noted that biobanks are also tied to economic, commercial, and financial values. For instance, David Winickoff underlined that much support for deCODE's plans in Iceland (which we will discuss in more detail in section 3.2.2) were tied to the expectation that once materialised they could create new jobs in a then already ailing economy (Winickoff 2006). Similarly, Erik Aarden emphasised that policymakers in Singapore endorsed investments into biobanks as a mode of facilitating and accelerating innovation and, simultaneously, as a mode of taking care of the health of populations (Aarden 2017a, 2017b), underlying that while economic and financial values matter, they are not the only values at stake. Corrigan and Tutton summarise this succinctly, relating biobanks to the "twin goals of health and wealth creation" (Corrigan and Tutton 2009, 312).

But how can these different expectations be aligned and synchronised? Where could conflicting values emerge and how can they be addressed? Much of this body of literature deals with particular biobank initiatives as these emerged—mobilising promises and expectation on future values as a condition of possibility for their emergence. Yet we also encounter studies that draw our attention to expectations and promissory values that failed to materialise (Stephens and Dimond 2015; Aarden 2017b), or biobanks that were closed down. These studies point to the fact that expectations also need to be aligned and synchronised with new situations and constellations.

For instance, in their discussion of a disease-specific biobank, which was closed down, Neil Stephens and Rebecca Dimond (2015) highlighted that expectations vested into tissue were not static; instead, "new sets of expectations and promissory narratives were being formed around its use" (Stephens and Dimond 2015, 9). Erik Aarden (2017a) underlined the importance of synchronising expectations of different groups, so as to make biobank initiatives durable in his discussion of the "Singapore Tissue Network" (STN)—an infrastructure initially designed so as to materialise the imaginary of the bioeconomy in Singapore, which was discontinued in September 2011. Established in 2002 with the help of government funding, the STN was envisioned "as a 'custodian' of samples and 'facilitator' of biomedical research with economic potential" (Aarden 2017a, 168). While a funding agency established the STN as a facility for storing tissues, all biomedical researchers working with national research grants were expected to store their samples at the STN. The stored samples were associated with "basic data" only, such as "age, gender, ethnicity, and minimal medical history" (Aarden 2017a, 168). While policymakers had hope that users of the STN would eventually collaborate with researchers, researchers were reluctant to make additional data available "without already having established a rapport with requesting scientists" (Aarden 2017a, 168). The STN ended up being used only rarely and was shut down. Aarden argued that the closing down of the STN was the effect of different or even competing expectations vested into the STN by different

groups of actors (policymakers on the one hand and researchers on the other) and of the different timeframes of these expectations that were not aligned (Aarden 2017a, 169).

3.1.2 Changing meaning and identity of objects assembled in biobanks

Social studies of biobanks have related the promissory discourse on biobanks to the changing status of objects, such as tissue, and associated data—which we refer to as "sample/data" for now.[6] Sample/data had a long history of secondary use in biomedicine, well before biobanks begun to gauge public attention. However, compared to earlier secondary uses of human body parts (e.g. for transplantation), biobanks are more focused on the "putative future benefits" (Kragh-Furbo and Tutton 2017, 2) of samples. Similarly, Stephens and Dimond (2015, 2) argued that the value inscribed into sample/data is "as much premised upon what the bio-objects [sample/data] could become (and the institutional processes that will afford that) as the status of the bio-object [sample/data] today." (Stephens and Dimond 2015, 2)[7]

Techno-scientific developments and legal/regulatory changes

The expectations vested into sample/data was enabled by the emergence of technology-intensive modes of knowing and ordering life, such as the rise of next generation sequencing (NGS) machineries and bioinformatics. This promised to disenchant the mechanisms ordering disease, health, and life on an unprecedented scale. (Nowadays, we might add "artificial intelligence".) With the emergence of such machineries, sample/data were reframed as entities harboring a wealth of yet unknown "information", or "bioinformation" (Parry 2004), that new tools and methods could help to unravel. Sample/data became reframed as "bioinformational proxies" (Parry 2004), that were deemed to contain a wealth of not yet identified information, which the new machineries would be able to unleash. The promissory informational value of sample/data was entangled with other regimes of value. Bronwyn Parry notes that: "The idea that (…) biological material could (…) yield up genetic or biochemical information that could form the basis of commodifiable products and processes began to animate entirely new approaches to the collection and utilization of biological material that have proven to have serious economic, cultural and ethical consequences." (Parry 2004, 64)

The techno-scientific developments overlapped with a number of regulatory and legal changes. Kragh-Furbo and Tutton (2017) argued that from the 1980s onwards, there were significant legal changes of "the status of bodily and biological matter" (160f), which gave rise to new opportunities to generate commercial value from genetically altered organisms, isolated gene sequences, and immortalized cell lines" (Kragh-Furbo and Tutton 2017, 161). Scientists, clinicians, as well as entrepreneurs could claim intellectual property rights over tissues and data retrieved from human bodies. These were no longer seen as "natural entities", but as "'examples of human ingenuity and inventive effort', altered and improved

[6] As we have seen empirically, the clear distinction between sample and data does not always hold. Samples get datafied, samples without relevant data are seen as less valuable or as not very promising for research. Therefore we use the notion of sample/data.

[7] Drawing on the work of Lena Eriksson (2012) on human embryonic stem cells, they note that „processes of bio-identification and the generative relations they co-produce are as much premised upon what the bio-objects could become (and the institutional processes that will afford that) as the status of the bio-object today." (Stephens and Dimond 2015, 2)

by human labour (Tutton 2004, 25)" (Kragh-Furbo and Tutton 2017, 161). In a context in which sample/data was reframed as embodying promissory scientific and economic value,

> *"hospitals, universities and other institutions with banks of human biological samples found that they were now in possession of what Dorothy Nelkin and Lori Andrews (1998, 31) call a 'capital resource'." (Kragh-Furbo and Tutton 2017, 161)*

Extant collections, that had been assembled as devices for and records of routine diagnostic procedures, were now endorsed as resources or "assets" (French, Miller, and Axler 2019) that could allow hospitals and universities to re-envision their place in a transforming political economy of knowledge production.

From objects with use value to contested things with multiple values

The increasing expectations vested into sample/data also raise the question how sample/data relate to persons, triggering discussions if persons providing samples should have a say in their storage and use (Hoeyer 2002), as well as debates on how biobanks ought to be governed. As we will discuss in more detail in the next section, previously, consent for a secondary use of sample/data collected in, say, hospitals in diagnostic procedures, was not deemed necessary. This long-standing practice was based on the understanding that while retrieving tissues or blood cells from the body of a person was an intervention requiring consent, once tissues or data were disentangled from human bodies, these became mere "objects". Research with them could not harm an individual person, nor infringe on the autonomy of a person, given that this was research on objects—and not on persons.[8]

While such understandings have not disappeared altogether (and actually seem to resurface in the context of discussions on the secondary use of data), over the past two decades, the identity of the objects stored in the basements of pathological archives, blood samples, and clinical records changed. They ceased to be mere research objects, private property, and—perhaps—"epistemic capital" of biomedical professionals. In the context of the rise of genomic approaches, they became potentially valuable and also contested "bio-objects" (Metzler and Webster 2011; Vermeulen, Tamminen, and Webster 2012) instead. They were entangled in multiple value systems (Stephens and Dimond 2015, 6)[9]. What these "objects" were and how they ought to be dealt with accordingly became uncertain and increasingly contested.

[8] The most powerful example of this long-standing practice is, perhaps, the history of the HeLa cell, a cell line that biomedical professionals generated from cancerous tissue retrieved from Henrietta Lacks, a woman who died from cervical cancer in Baltimore in 1951. Generations of biomedical professionals worked on this cell line, without ever asking Henrietta Lacks or her relatives for permission (Skloot 2011). While the story of the HeLa line is also a story of racism and medical paternalism, it seems fair to claim that this research was also largely deemed unproblematic, exactly because it involved the materiality of a cell line—which was seen as distinct to the individual who had provided the initial cells.

[9] More specifically, they note: "Each competing regime articulates a different configuration of the tissue's meaning and most pertinent feature. Moments of contentment between multiple regimes of value can provoke controversies that challenge the co-production of a tissue's value and the socio-technical arrangements that support it. The movement of tissue across both physical and symbolic locations involves 'hierarchizing the values associated with tissue productivity' (Waldby and Mitchell 2006 p. 31), bringing further tension between competing regimes." (Stephens and Dimond 2015, 4)

Biovalue, tissue economies, and assets

Sample/data and their value have been discussed particularly intensively in the body of social science literature on "tissue economies" (Waldby and Mitchell 2006) or the "bio-economy".[10] As this is by now a rather complex field of research, we point only to those aspects that promise to be helpful for our empirical research.

The work of Catherine Waldby and colleagues was particularly generative for this field and provides a helpful starting point (Waldby 2002; Waldby and Mitchell 2006; Mitchell and Waldby 2010; Waldby and Cooper 2008). They developed a number of concepts, including "biovalue" (Waldby 2002), "tissue economy" (Waldby and Mitchell 2006), and "clinical labour" (Mitchell and Waldby 2010).[11]

Waldby and Mitchell described the "tissue economy" as an emerging "system for maximizing productivity, through strategies of circulation, leverage, diversification, and recuperation" of tissue (quoted in Stephens and Dimond 2015, 3). In tissue economies, tissue is constantly dis-entangled (e.g., from patients' bodies) and re-entangled (e.g., into biobanks) into different socio-cultural contexts (cf. Stephens and Dimond 2015, 3). In these processes, tissue transitions from the category of "waste" (e.g., a surplus IVF embryo) to the category of potentially "profitable object" (cf. Stephens and Dimond 2015, 4) or sources of "biovalue", that is "new and unexpected forms of value" (Waldby and Mitchell 2006, 108). Building on these ideas, Stephens and Dimond note that biobanks "exist to maximize the opportunity of this speculative biology by cataloguing and making visible otherwise locally collected and invisible tissue to broader demand from research professionals" (2015, 4).

While many of the "bio" concepts were taken up in numerous studies, we also see critical debates around how to conceptualise and research them. For example, Birch (2017) and colleagues criticised that the emphasis on the "bio" silences other aspects at work, including "the knowledge and knowledge labor required to transform these fragments into commodities that are valuable" (Birch and Tyfield 2013, 308). He argued that the value of sample/data should not be seen as intrinsic to a piece of biological material, but as the effect of an assemblage of work, devices, and other elements, in which sample/data are entangled in the process of becoming part of a biobank.

The point that tissue/data is not intrinsically valuable, but becomes valuable through human work and care has also been emphasised in empirical studies on biobanks. For instance, Stephens and Dimond underlined that the transition of tissue from "a position of valueless to valued" (Stephens and Dimond 2015, 1) in a tissue bank was made possible through connecting "the value of the bio and the non-bio" (Stephens and Dimond 2015, 6). The "non-bio" included: the need for sample/data to be "logged within standardized forms of bureaucratic accountability" (ibid., 6), the "physical work of ordering the tissues",

[11] By now, the repertoire of terms to name and conceptualise disentangled sample/data is however much broader. It includes terms such as "life as surplus" (Cooper 2008), "lively capital" (Rajan 2012), or "biocapital" (Rajan 2006; Helmreich 2008).

and "networking, and bureaucratic and promissory work" (ibid., 6).[12] French and colleagues pointed to the data practices needed to make tissue valuable, noting that in the hospital biobank they studied, "patient material[s] is made valuable through its linkage to, its correlation with, clinical information" (French, Miller, and Axler 2019, 146). Referring to insights gained from interviews, they noted:

> *"Although possession and accumulation of tissue may be a defining characteristic of biobanks, many of our informants were careful to specify that, without the capacity to understand tissue in relation to patient records, personal health histories, collective geo-demographic information, risk exposure, treatment regimes, future patients, and the like, the biobanking enterprise would add limited value to health research." (French, Miller, and Axler 2019, 146)*

Therefore, to fully capture the worth of biobanking means to investigate the practices, the work and the investments that are needed to turn collected samples/data into valuable entities.

In this context, it is also relevant to engage with Kean Birch's concepts of "assets" and "assetization" (Chiappetta and Birch 2018; Birch and Muniesa 2020). This concept was introduced to analyse the processes through which "things"– in our case sample/data – are transformed into assets, and not (necessarily) into commodities. It entails, first, carefully unpacking the coming together of specific interests, work, skills, organisational environments involved in creating an asset. Chiappetta and Birch invite social scientists to study how "value is understood and managed, and by whom, and how these social practices are carried out" (Chiapetta and Birch 2018, 66). Second, they also underlined that the promissory value of sample/data is not only the result of a specific assemblage of work, data, organisations, and many more that transform sample/data into assets; but also stabilised by the valuation practices of others, such as funding agencies or industrial collaborators. Moreover, third, they observed that "assets" can serve as "mediating devices", drawing groups of people together, and thus being generative of collaborative relations (Chiappetta and Birch 2018, 66).

Finally, coming back to French and colleagues' article it is also important to see that the value regimes that shape and are reshaped by the transformation of tissue/data into assets are always multiple. Drawing on a case study on the biobank of an "entrepreneurial hospital" in Canada, they argue that this hospital mobilises their "means of care beyond care itself" (French, Miller, and Axler 2019, 134) making research possible. Both patients and the available care infrastructure are conceptualised "as distinctive assets in pursuit of entrepreneurial aims" (147) while the hospital also "positions its entrepreneurial aims as a decisive element in the service of care" (147). However, they argue that the relationship between care and research is not uni-, but bidirectional. In their analysis, the hospital also positions "their research and entrepreneurial aims as decisive elements in the service of care" (ibid., 133). Accumulating sample/data and brokering access to industry is their way of contributing to hopes for therapies, helping patients in

[12] Similarly, Timmons and Vezyridis (2017, 1243), argued that the value of a sample is neither intrinsic to it nor "guaranteed from the outset. It is rather through various socio-technical arrangements as well as the continuous intellectual, affective and technological work of (human and non-human) actors that value will be produced" (ibid., 1243).

the hospital to imagine themselves as part of a community that contributes to – hopefully – more health in the future. This can then be described as an "attempted virtuous cycle in which care feeds into research and research feeds into care, all the while functioning in a way that aims to be respectful of patient interests" (ibid., 147). In the end, biobanks are not only sites were different "regimes of value" enter into conflict; these can also be sites were such regimes are brought into conversation. Biobanks can thus become "access brokers" (ibid., 144) for some users, including those working in the private sector, as access to tissue is made legitimate through the governance and oversight processes well established in hospitals.

Biobanks and collateral values and norms

While much of what we have discussed in this part of chapter 3 could be read as focused on actions to realise specific values, we also have to carefully consider that biobanks could also bring about what we would like to label "collateral values and norms", loosely drawing on John Law's work on "collateral realities" (Law 2011). These are values and norms that biobanks help to generate, incidentally and in form of (unintended) side effects of the visions projected, the dominant kinds of practices as well as the institutional and regulatory framings. Among these collateral values and norms are for example the ideas about health and illness biobanks produce and project, or the way biobanks understand good research that can be done with their support. However, incidentally they potentially also shape the identities of individual and collective subjects, such as research participants, populations, and publics at large. We will discuss them in more detail in chapter 4, below.

Erik Aarden, to give one example, has pointed out that biobanks tend to reify biomedical understandings of health and disease, narrowing down visions of how states ought to take care of the health of their populations to biomedical understandings of health and disease. Drawing on insights from a cross-country comparison, he concluded that "value emerging from biomedical research collections in the form of benefits for a population can take various—financial and non-financial—forms, while simultaneously imposing values—in their normative sense—on populations" (Aarden 2017a, 162). When it comes to research practices in the life sciences and how they get transformed through biobanking, we can take as example Aaro Tupaela's work on large prospective cohort (LPC) biobanks, where he notes that they have "served as a platform to develop sharing practices among researchers" (Tupasela 2017, 189).

Both examples, but also the chapter at large, thus invite us to look beyond the more narrow scope of what biobanks do and the value(s) they can create and also reflect the many different, larger or smaller, visible or invisible, transformations these infrastructures can bring about.

3.2. A short history of cardinal value(s) in biobank governance

3.2.1 Introduction

As already underlined, biobanks have been endorsed as infrastructures with the expectation that they would help to generate benefits and values, such as new insights, better health, innovation, and economic growth in the future. While these expectations on the value *of* biobanking have enabled and justified the assembling of resources, there is also a shared sense that there are some values, goods, and norms that need to be taken care of when designing, organising, maintaining, and governing biobanks. In other words, there is a shared understanding that there are some cardinal values *in* biobanking that ought to be

protected (see chapter 2); however, what these values are, how they ought to be protected, and why they matter, is often less clear.

The proliferation of biobank initiatives from the late 1990s on, has "open[ed] up a normative space" (Tallacchini 2015, 105), in which a variety of actors joined forces to reflect on what these values are, how they ought to be protected, and why they matter. Ethics, both in the form of practices, procedures, and institutions and in the form of a professional discourse or expertise, occupied a particularly prominent place in this debate (Hoeyer 2008, 430). Reflecting trends that cut across many developments in the life sciences, ethics was expected to identify and elucidate those "individual rights and fundamental societal values" (Tallacchini 2015, 101) that would help make biobanks governable.

The debates neither started from scratch, nor did they take place in an empty space. They built on moments of consensus from past national and international debates on bioethical values and legal norms in biomedical research. Values cardinal in clinical and medical ethics such as the value "autonomy", as well as practices and procedures, such as asking participants for consent or involving institutional review boards (IRBs), were also central in debates on biobanking. And yet, biobanks and the new kind of (often) population-wide genetic, genomic, or "-omic" research that these symbolised and also infrastructurised were nonetheless significant technoscientific innovations. They thus could not be straight-forwardly framed in traditional terms of research ethics and governance, which came into being in relation to medical research on humans. Understandings of the values in biobanking co-emerged with understandings of the identity of the objects, i.e. samples/data assembled in biobanks, the subjects that would be affected by these developments, and the value that these would help to generate.

For instance, while there was a shared understanding on the ethical values and legal norms that needed to be respected in human subject research, it was less clear what these norms should mean when research was not conducted on the bodies of fully-fledged persons, but on blood or tissue samples that had been disentangled from them or on data collections. To use Hoeyers concept, body parts become "persons by proxy" (Hoeyer 2014, 11).

Numerous questions had to be posed: *What was the status of these objects? And how did these relate to individuals? Did individuals have a right to have a say on the use of their "tissue" and "data selves"? And, if yes, how much control should they have on them? Was their right limited to disagree on the banking of their tissue/data selves? Should they also be involved in envisioning how and for which purposes their data/samples ought to be used?*

Such questions became all the more challenging in the context of biobanks, as these assembled tissues and data from subgroups or even entire populations, and thus not from a handful of distinct individuals. *Who would have the right to authorise and who could oversee research on such "populations by-proxy"? Who had a right to have a say?*

Moreover, as we have argued in the previous section (3.1), biobanks also emerged at a moment in time in which the "political economy" of biomedical research was reimagined. The boundary between publicly funded research and privately funded research became increasingly blurred and the "influence of

corporate business in the management of biological and medical data" (Gibbon and Prainsack 2018, 181) became ever more salient (Sharon 2016; Jasanoff 2019). Biobanks emerged at a moment in time in which a variety of actors—including a lot of policymakers and research funders—joined forces to puzzle through how "public-private partnerships" ought to be organised so as to enable the generation of desirable knowledge, while understandings of what exactly desirable or good knowledge were, also increasingly narrowed down to actionable knowledge, therapies or, in short: innovations (Mazzucato 2015; Felt 2018). Biobanks were one of the sites in which a new political economy of the life sciences was both played out and materialised. This also generated a wealth of questions about the values at stake, and added to the "ethical anxiety" (Hoeyer 2008) and complexity: *What would such collaborations mean in terms of "intellectual property rights", "ownership" and "social justice"? What would be an appropriate form of collaboration? And who should be involved and have a say in stipulating such agreements?*

While engaging with such questions, ethical debates meandered in between the two poles of "normalization" and "experimental normative trends" (Tallacchini 2015). While "normalization" comes with the expectation that all relevant normative questions can be "preidentified and listed in order to neutralize and control the potential unknows of innovation" (Tallacchini 2015, 101), "experimental normative trends" take a much more procedural and generative shape. When reflecting on biobanking, it is thus essential to also consider the experimentality when it comes to normative questions.

To address this body of questions we outline here, we build in what follows on some findings of the large body of literature on the "ethical, legal, and social aspects" (ELSA) of biobanking, focusing in particular on literature that engages with values in biobank *governance* and discussing this in a historical order. This focus helps us to substantiate two points. First, taking a historical approach to values in biobanking, helps us to show that understanding on the kind of values, goods and norms at stake in biobanking are not predefined context variables or stable factors, that can be defined and settled once for all. They are rather tied to understandings of the identities of objects assembled in biobanks, the subjects that these might affect, and of the promises and properties of biobanks. Just as biobanks, so their values are both historically contingent and geographically situated. Biobanks and values are mutually supportive or "coproduced" (Jasanoff 2004).

Moreover, second, the focus on governance also helps us to show that such debates on values in biobanking are not abstract, but tied to particular practices and procedures, tools and devices, and instruments of governance, that translate normative visions into specific practices, arrangements, and architectures, and, while doing so, also materialise, institutionalise, and perform them. In this section, we take stock of this debate, so as to convert it into a methodological stepping stone for our field work. It directs us to approaching practices, tools, and institutions of governance as sites where values crystallise in practice.

3.2.2 After Iceland: consent as an obligatory passage point for biobanks

ELSI debates on values in biobanking begun to gain salience at the turn of the 20th to the 21st century, when the company deCODE Genetics planned to combine three databases, in order to unravel the genetic factors of common diseases. This plan never materialised as initially envisioned (Hoeyer 2004; 2008). Nonetheless, the Icelandic example set the stage for debates on biobank governance (Corrigan and Tutton

2009, 302).[13] In the words of David Winickoff, the "Iceland Health Sector Database case has as much a globally important normative legacy, as a technological one" (Winickoff 2006, 98), with the "database" becoming an "experimental site not only for genomics, but for genomic governance" (Winickoff 2006, 98). The controversies the Icelandic biobank caused indeed precipitated "the development of global norms governing the relationship between citizens, medical information, makers, and the state" (Winickoff 2006, 80). And further: "in its failure as much as its success, the [Icelandic case] became an important channel through which key aspects of bioethics, individual rights, and global governance were clarified and reframed in relation to genomics and the new life sciences" (Winickoff 2006, 81). Similarly, Klaus Hoeyer notes that the "debate about deCODE Genetics, more than any other event, put [such collections] on the international agenda" (Hoeyer 2004, 7) of bioethicists, policy makers – and also of social scientists.

The Icelandic experiment began in 1996, when Kari Stefansson and Jeff Gulcher established the company deCODE Genetics with the plan to establish three databases: a database assembling the genealogical data of the Icelandic population; a "Health Sector Database" (HSD) with electronic health records and medical data; and a database with genetic data of the population of Iceland (Hoeyer 2008, 432). In these days, "genetics" begun to transition to "genomics" and an understanding emerged that large datasets were needed to make such a transition happen. Stefansson and colleagues envisioned the population of Iceland as a particularly appropriate resource for mining data to unravel the genetic factors of common diseases, and they also underlined that this would help an already ailing national economy.[14] They managed to convince the Icelandic government and a majority of the Icelandic Parliament of the value of this vision. In 1998, the Icelandic Parliament passed the "Health Sector Database (HSD Act)". The Act authorised granting access to the fairly detailed health records of the population of Iceland (dating back to the 1920) to a company through a license (Winickoff 2006, 82).

The HSD Act included provisions on values deemed to be in need of being protected. First, it linked the license to a series of architectural requirements that should protect the privacy of all enrolled individuals (Winickoff 2006, 82).[15] Second, it also authorised the transfer of the medical records to the database to happen on the basis of a "presumed consent" (Winickoff 2006, 82), allowing (living) Icelandic citizens to opt-out (Corrigan and Tutton 2009, 308).

Corrigan and Tutton note that such a "presumed consent" was not unusual. Before deCODE and the debates that this experiment engendered, it seemed to be a widespread practice to "reuse" materials and

[13] The company eventually built a repository of DNA samples with associated information, asking participants for consent for use of data for research purposes (Winickoff 2006, 96).

[14] They argued that the genetic homogeneity of the Icelandic population and the wealth of medical records and genealogical data made this population particularly valuable for uncovering the genetic factors of common diseases (Winickoff 2006; Palsson 2008). Similar understandings of "genetic uniqueness" of particular populations have also been articulated in other examples of biobanks. See Tarkkala and Tupasela (2018).

[15] Winickoff provides more details on this: "First, the licensee could not grant direct access to the database or information it contained to third parties. Second, it would have to process the information itself in ways that could not be linked to identifiable individuals. The act provided that the licensee could be civilly liable for neglecting disclosure of information, and the act authorized other penalties, including fines, imprisonment, and possible revocation of the license for violations of the act" (Winickoff 2006, 82).

data collected in clinical practices or clinical studies without asking those, from whom these materials were retrieved, for permission or consent (Corrigan and Tutton 2009, 306). However, for the envisioned reuse of clinical records in a biobank, "presumed consent" proved to be an Achilles heel (Palsson 2008; Winickoff 2006; Corrigan and Tutton 2009).

The absence of informed consent made these plans vulnerable to critique that was articulated in and outside of Iceland. In Iceland, the Icelandic Medical Association and biomedical professionals invoked concerns about the inappropriate protection of privacy and the lack of appropriate consent procedures and argued that the project infringed upon national constitutional rights to privacy and international human rights (Palsson 2008; Winickoff 2006, 89).[16] The Icelandic controversy also triggered "a small explosion of international scrutiny and criticism" (Winickoff 2006, 90). David Winickoff observed that this debate "helped to precipitate and emerging global consensus that the 'technological fix' of a thick encryption architecture [to protect the privacy of presumed donors] would not replace affirmative consent from individuals prior to their enrolment in population genomic projects" (Winickoff 2006, 98). A consensus began to emerge, that gravitated around the understanding, "that a priori consent of patients should be indispensable for engaging in this type of research in all but the rarest exceptions" (Winickoff 2006, 96). Informed consent became a first layer in biobank governance—indeed, an "obligatory passage point" (Hoeyer 2008, 435).

Asking individuals (donor or participants) for their consent, so as to respect their autonomy and/or their right to self-determination, became a cardinal value in biobanking and also a requirement in the setting up of biobanks (Hoeyer 2008), even if the debate on the scope of this requirement, the means to implement it never stopped. Many emphasised that a full-blown "informed" consent was impossible to achieve in practice, given that biobanks assemble materials, information, and data so as to enable research in the future, the details of which are not yet known (Chalmers et al. 2016, 6). Others underlined that requirements for individual consent would impose insurmountable burdens in particular on those biobanks, which did not collect materials and data of often healthy citizens in a prospective way, but sought to reorganise their tissue collections from routine clinical procedures—such as cancer tissue used for staging after surgeries—in a retrospective way. Many warned that "too strict" regulations for consent might possibly "hinder progress" (Hansson et al. 2006, 266). Various forms of consent were discussed, which ranged from "specific", over "broad" (Hansson et al. 2006; Maschke 2006; Hofmann 2009; Caulfield and Kaye 2009), to "open" consent. As the debate on the appropriate form of consent progressed, and digital infrastructures and platforms became more salient (see section 3.2.4 below), more "dynamic" forms of consent were proposed, which would allow individuals to keep control over their tissue and data (Budin-Ljøsne et al. 2017; Kaye et al. 2015), while also "exerting influence on the precise use of their data and tissue in a biobank" (Stranger and Kaye 2016, position 500).

Debates on appropriate shape of consent continue and were also revitalised, once the GDPR entered into force (see below, chapter 5). They are also shaped by differences in binding legislation (that are amenable

[16] Gisli Palsson has conceptualised their opposition as a "biopolitics of the dispossessed" (Palsson 2008, 52). Feeling "deprived of the control and security that they had enjoyed in the past" (ibid., 42), biomedical professionals positioned themselves as the custodians of the health records of the Icelandic population and used a language of ethical values and legal norms to substantiate their critique.

to be enforced via sanctions) across different countries, as well as interpretations of soft laws, such as recommendations or guidelines by professional societies, requirements from publishers, as well as expectations raised by users, such as researchers and industries. **However, while before Iceland the absence of consent of donors might have been the rule, "after Iceland" its absence needed to be explained and (very well) justified.**

3.2.3 UK Biobank: support, trust, and public engagement

Debates on the values in biobanking began to diversify at the beginning of the 21st century, as other countries ventured into setting up other "population-wide" biobanks (Gottweis and Petersen 2008) or "genetic databases" (Corrigan and Tutton 2004), and various groups of actors puzzled through how they ought to be set up in practice. While consent of *individual* donors or participants continued to be an important value in these debates, consent procedures alone were no longer deemed sufficient in terms of the governance of biobanks (Corrigan and Tutton 2009, 306). Values such as the support and trust of publics, as well as practices and procedures such as participation, deliberation, and public engagement became salient. After individual donors, collective publics became agents deemed to be affected by biobanking; their involvement began to form a second layer of values in biobank governance.

As the first period of debates (on consent of individual donors), which crystallised around the Icelandic case, this second period (on the engagement of publics) was also shaped by a particular biobank: UK Biobank. Funded by the Medical Research Council (MRC), the private charitable organization "Wellcome Trust", and by the British government via its Department of Health, the Scottish Government, and the North West Development Agency, UK Biobank was designed as a longitudinal prospective population study, consisting of a collection of samples (blood and urine), and biometric, healthcare and lifestyle information from 500,000 UK adults aged between 45 and 69. Recruitment commenced in April 2007 and was completed in July 2010 (Winickoff 2006; Tutton 2007a; Tutton and Prainsack 2011). Today, UK Biobank is deemed the world's biggest "large-scale, publicly funded, population biobank" (Chalmers et al. 2016, 4).

The design of UK Biobank differed from the planned databases in Iceland. While deCODE Genetics sought to capitalise on genealogical and health records, capitalising on the datafication of the Icelandic population in the past, UK Biobank was built from scratch, recruiting often healthy citizens on a population-wide scale. Therewith, new categories of individual and collective subjects began to be assembled in biobanking: the individual category of often (healthy) "research participant", on whose willingness to "participate" in research biobanks had begun to depend (Tutton 2007a, 176); as well as the collective category of the "public".

At a time in which "publics" were also salient in other (controversial) fields of science governance (Barry 2001; Laurent 2017; Felt et al. 2013), "publics" became important agents in biobank governance (Stranger and Kaye 2016, position 406). Publics, Oonagh Corrigan and Richard Tutton observed, or "the public", were now "understood to have the capacity to undermine or jeopardize a [biobank] project" (Corrigan and Tutton 2009, 307). An understanding emerged, that "in order for the future development of biobank projects to be secured such enterprises must be accorded legitimacy and trusted, not only by the donor but by the public at large" (Corrigan and Tutton 2009, 307). Therewith biobank governance became a

matter of ensuring the support and trust of public with the help of "public engagement" or "participatory democracy" (Papaioannou 2012; Petersen 2005).

The emergence of this second layer of biobank governance was facilitated by the organisers of UK Biobank, that were visibly at pains to learn from the Icelandic example. They "stressed the voluntary, opt-in nature of enrolment into their biobanks" (Corrigan and Tutton 2009, 308).[17] Moreover, they also sought to ensure public legitimacy and trust, by consulting the public (Corrigan and Tutton 2009, 308). They commissioned market research organizations to explore public attitudes towards providing tissue samples to biomedical research (Tutton and Prainsack 2011, 1085–86). They also developed a comprehensive "Ethics and Governance Framework"—that is "a 20-page document that lays out details of the resource and outlines the ethical principle UK Biobank are to follow" (Corrigan and Tutton 2009, 310). Moreover, a dedicated "Ethics and Governance Council" was established, taking up several tasks, including the commissioning of research, the tracking of concerns of participants, as well as providing ethical advice to UK Biobank (Stranger and Kaye 2016, position 611-612).

While it might not be a surprise that the value of trust and practices of engaging the public begun to emerge in the UK (which is by now well known for its empirical "political culture" and its effort to reason through "common sense" involving publics (Jasanoff 2005; Jasanoff and Metzler 2020; Hauskeller 2004), once these values and practices were assembled in the field of biobanking, they began to travel to other sites were biobanks were established and/or discussed. After consent, public engagement became a second "obligatory passage point" in biobank governance. For instance, in 2006, the OECD enshrined public engagement as an essential requirement for biobanking, noting that "public engagement in the development of such databases is essential for ensuring their viability, as well as community support for and participation in such undertakings" (quoted in Cañada, Tupasela, and Snell 2015, 355–56). Six years later, in 2012, Edward Dove and colleagues, noted that "[p]articipatory democracy, deliberative democracy and related models of inclusive, public engagement (…) gained a formidable foothold in biobank, genetics and science-and-society literature" (Dove, Joly, and Knoppers 2012, 1). They insisted that "meaningful engagement with tax-paying citizens is critical to build and sustain public trust and involvement" (Dove, Joly, and Knoppers 2012, 1)[18].

While "public engagement" became a second important value and practice in biobank governance and perhaps also a "buzzword" (Bensaude Vincent 2014), what it ought to mean in practice was not always agreed upon. Just as "consent", "public engagement" became an "essentially contested concept" (Gallie 1955). While pretty much all stakeholders and shareholders in biobank governance agreed on the worth and desirability of participation and public engagement in principle, they disagreed on its desirable form, scope, and function. Social scientists and ethicists were also involved in this debate. They helped to stage

[17] UK biobank opted for a system of "broad consent", in which participants agreed to "support all future 'health-related research' and delegate subsequent decision making to proxies such as Local Research Ethics Committees, which will approve research applications to use the biobank, and are charged to protect both participants and the public" (Tutton and Prainsack 2011, 1087).

[18] Similarly, Kay and Stranger observed the acknowledgement of links between "donor participation, public trust and public consultation", noting that "public engagement has been embraced as a necessary step in establishing a biobank" (Stranger and Kaye 2016, position 429).

participatory arrangements (see the section on PUS below for more details), questioned and criticised them (Petersen 2007), or envisioned particular procedures that would allow publics to have a say (Dove et al. 2012).

Debates on participation gravitated around three sets of questions. First, the question of the desirable design of instruments for public participation was opened up. Specific practices ranged from "public communication" or "science communication" events, in which publics were a passive audience listening to and learning from experts; over experiments conducted to understand the "public understanding of biobanks" of various "mini-publics" (Gottweis, Chen, and Starkbaum 2011; Gaskell et al. 2013; Haimes and Whong-Barr 2004); to "public consultation" events, and full blown "public engagement" experiments, where publics were actively involved in decision-making on the governance of biobanks. Second, a related set of questions centred on what it was that publics should participate in, and why. While some framed participation as a means to increase the public understanding of biobanks and as an instrument to ensure public trust in biobanking, others insisted that participation should not be interpreted in such an instrumental way. They argued that participation was a value in its own right, and that meaningful participation ought to mean that publics should not only passively learn what a biobank is, but also be entitled to actively contribute to its design, organization, and governance (Tallacchini 2015; Saha and Hurlbut 2011; Dove, Joly, and Knoppers 2012). A third set of questions regarded the nature and composition of the public (or in the United States "communities" (Haldeman et al. 2014)) that ought to be involved or engaged. A particular prominent public were patient groups, in particular groups organised around rare diseases.[19] Cañada and colleagues note that "having laypeople and donors inside the biobanks's governance structure" emerged as a recurring engagement strategy (Cañada, Tupasela, and Snell 2015, 361), in particular in disease-specific biobanks. Others envisioned mechanisms that would allow a much more dispersed public to have its say (Dove, Joly, and Knoppers 2012, 6).

Thus, just as consent, the values of "trust", "public engagement", and "participation" were contested goods. How participants and publics ought to be involved in biobanking in practice as well as who these publics were or ought to be continues to be an object of often intense debates. However, using some forms of consultation and participation became a requirement for good biobank governance.

3.2.4 Commercial genomic databases: participation 2.0, reciprocity, and social justice

A third important moment for engagements with cardinal value(s) in the governance of biobanks was the emergence of "direct-to-consumer" genomic companies from 2006 on. These were founded by "sociotechnical vanguards" (Hilgartner 2015) in particular in the United States, who were often located outside of the fields of biobanking and also biomedicine. Nonetheless, such initiatives had an important impact on the debates on cardinal values in biobanking and on the tools and devices needed for realising them. While perhaps only a tiny minority of the global population choose to "buy into" direct-to-consumer genomics—also in light of bans on the provision of genetic tests outside of the health care systems in

[19] For instance, the "Telethon Network of Genetic Biobanks", a network of 11 Italian non-profit biobanks for rare diseases, engaged with patient organisations (POs) for rare diseases, via meetings, roundtables, and inclusion of representatives from POs, actively involving POs "in drafting biobank policies and procedures, including those concerning ethical issues" (Baldo et al. 2016).

several countries (Curnutte 2017; Hogarth and Saukko 2017; Dijck, Poell, and Waal 2018)—these commercial vanguards had a deep impact on the "narrative infrastructures" (Felt 2017) at work in the field of biobanking. Moreover, drawing together "practices of predictive genetic testing, the science of genetic association studies, and Web 2.0 techniques" (Kragh-Furbo and Tutton 2017, 159), they also introduced new digital devices and tools, spearheading the use of IT "platforms" (Dijck, Poell, and Waal 2018; Van Dijck and Poell 2016) to collect data and to mediate relationships with research participants, and the rise of "big data" in biomedicine.

In particular the visions and practices of "23andMe" (Sunnyvale, California), one of Silicon Valley's "unicorns" (Hogarth and Saukko 2017), gauged a lot of attention. These concerned the way in which biomedical care or genomic medicine ought to be delivered and to be produced. In terms of delivery of genomic medicine, 23andMe set on to provide genetic information directly to paying customers. These could order a "spit kit" online, fill it with saliva, and send it back to the company, which subcontracted laboratories for the "genotyping" of the saliva (Kragh-Furbo and Tutton 2017). Customers were notified about the results via an online account on a platform, which enabled them to access "personalized risk information", which 23andMe continuously updated in light of new research results (Tutton and Prainsack 2011, 1086; Stoeklé et al. 2016, 3).

While the status, value, and utility of this risk information was at the centre of fierce debates on the desirability and permissibility of this service (Bloss et al. 2011; Curnutte and Testa 2012), from 2009 on, 23andMe also invited their customers to participate in research, providing their genetic information, web behaviour information, as well as additional self-reported (phenotypic) information collected via surveys (Stoeklé et al. 2016, 3). In so doing, 23andMe claimed to contribute to the generation of public health in a way, that—as the CEO of 23andMe was at pains to underlay—would generate health and innovation that overly bureaucratic public research sectors failed to deliver (personal observations at an event on 23andMe in the United States in 2013). Venturing into re-envisioning genomic research, 23andMe framed this as a "Do-it-yourself Revolution in Disease Research" (Tutton and Prainsack 2011, 1088) or a "'participant-led' research methodology" (Harris, Wyatt, and Kelly 2013, 236).

The genetic database that 23andMe managed to assemble is deemed to range among the biggest ones on the globe;[20] yet, the impact of 23andMe on the field of biobanking is perhaps less a matter of numbers or scale than a matter of how its language, practices, and tools affected the "narrative infrastructures" or "economy of values" of the field of biobanking.

[20] In 2011, Saha and Hurlbut (2011,313) noted that "23andMe (..) holds biosamples and genomic data from in excess of 120,000 individuals, more than 97% of whom have opted to participate in research", sample/data had grown over 1,000,000 (Stoeklé et al. 2016), most likely forming the largest (non-forensic) available collection of DNA samples that exist on the globe today. Thus, 23andMe, as well as "other American biotech companies", became "essential intermediaries between researchers and their research subjects, through the generation of DNA banks and biobanks containing hundreds of thousands of different samples provided for DTC genetic testing" (Stoeklé et al. 2016, 2).

Specifically, first, 23andMe used a language of participation and democracy (Dijck, Poell, and Waal 2018, 102). There is a bit of an overlap between the entrepreneurial approach to participation and the language of public engagement of UK Biobank. However, while public engagement envisioned by initiative such as UK Biobank was tied to an understanding of giving a public some say on how biobanks ought to be organised and governed (leaving the science to experts alone), participation in the 2.0 version of 23andMe also included participation in knowledge production. In so doing, companies such as 23andMe began to spearhead a "participatory turn" in scientific research (Kaye et al. 2012). Anna Harris and colleagues underlined that they did so with the help of new tools and devices, underlying a "digital dimension of participation, where online platforms, large data sets and computational abilities allow new kinds of participation in research" (Harris, Wyatt, and Kelly 2013, 238). They observed, that 23andMe "celebrates what it promotes as the emancipatory aspect of participating in the genetic research revolution. (…) 23andMe claims to provide a platform for users to have a voice and to have greater input in genetic research. In so doing, 23andMe utilizes two complimentary discourses concerning the democratizing and empowering potential of the internet and the democratizing and empowering potential of personal genomics" (Harris, Wyatt, and Kelly 2013, 243).

Bringing these innovations to the field of biobanking, they also began to spearhead the ongoing revolution of the "digitalization of health" and "googlization of health research" (Sharon 2016), as well as "big data" (Saukko 2017) approaches (on which we will say more in chapter 4).

Second, another innovation to the field of biobanking was that paying customers of 23andMe got something in return. Unlike the "donors" or "participants" in other biobank initiatives, who were deemed to donate tissue/data as gifts for the benefit of present and future societies (Tutton and Prainsack 2011), paying customers of 23andMe received personalised risk information. They were given a right to access information that the company held on them, in the name of what Anne Wojcicki claimed to be a "'fundamental right' of biobank donors to access their own genetic information (Wojcicki 2009)" (Tutton and Prainsack 2011, 1082). Therewith, 23andMe brought the value of "reciprocity" to the field of biobanking, and also helped to trigger a debate on whether participants should be entitled to have access to "individually relevant [research] results" (Chalmers et al. 2016; Knoppers, Zawati, and Sénécal 2015) and/or to "incidental findings" (Black et al. 2013) from research conducted on their tissue/data.

A third effect of DTC-genomic initiatives was more indirect, as the visibility of full-blown commercial actors drew new attention to issues such as "intellectual property rights", "ownership", "benefit sharing" (Stranger and Kaye 2016, position 452), and "social justice". These values became newly salient once the visibility of commercial companies like 23andMe highlighted that the emergence of biobanking paralleled a political economy of research that was in rapid transformation. Questions such as who could get access to the tissue/data assembled in biobanks, as well as on what terms and for which purposes, became newly salient (Huzair and Papaioannou 2012; Capps 2013).

3.2.5 Taking stock

The emergence of biobanking as publicly supported infrastructures engendered debates, which helped to crystallise a set of cardinal values deemed to be in need of being protected and taken care of in the governance of biobanks. In particular, much-discussed and often large-scale biobank initiatives, such as

deCode Genetics' plans to build and combine three databases, the public-private initiative UK Biobank, and the building of a commercial genetic database by the US-American company 23andMe, engendered debates that helped to elucidate a set of cardinal values deemed in need of being appropriately taken care of and a range of practices, tools, and institutions for doing so. Among the cardinal values was the protection of the privacy of research participants, that cut across the entire debate (Kaye 2015; Chalmers et al. 2016, 6), and was also revitalised with the GDPR (see chapter 5 for further details). Moreover, the cardinal values included the need to respect and safeguard the "autonomy" of individual donors or research participants via consent procedures; the need to safeguard the support and "trust" of publics, via public engagement instruments; as well as issues of "reciprocity" and "benefit sharing" (see Table 1 for a summary).

Cardinal (ethical and social) values in biobanking and means for protecting them		
Example	Cardinal values	Governance
	Privacy	architecture of IT systems; consent procedures
DeCode Genetics	Autonomy of donors	Consent procedures
UK Biobank	Support and trust of public	public engagement
23andMe	Reciprocity and participation	IT platforms

Table 1: Cardinal (ethical and social) values in biobanking and means for protecting them

While these values emerged at specific moments and in particular geographical spaces, once these entered the field of biobanking, they began to travel to other sites, where these were often adopted and adapted differently. The values travelled via various routes. Only some of them, such as the requirement to ensure consent for the storage of tissue and/or data in biobanks, or the need to protect the privacy of research participant, was enshrined in legally binding national legislation in a limited number of countries. Most values travelled not via law, but via other routes, such as debates in scientific journals or trade journals, as well as via "soft regulation", such as recommendations or guidelines.

3.2.6 Networks of biobanks

To close this chapter, we will shortly touch on the emergence of networks of biobanks that have been observed to be particularly important hubs for the realisation of values in the literature on biobanks. These networks include initiatives such as the "Public Population Project in Genomics", which sought to "harmonize and enhance the interoperability of 43 large, longitudinal studies" (Knoppers and Hudson 2011, 329), or the "BioBanking and Biomolecular Resource Research Infrastructure" (BBMRI) (Tupasela 2017; Cañada, Tupasela, and Snell 2015). Considerable public funding has been invested into the establishment of such networks, both on a national and an international level, with the expectation that the "research power of biobank data sets" could be "considerably strengthened if they are combined with equivalent data sets from other biobanks and data repositories" (Chalmers et al. 2016, 2). Cañada and colleagues note that many biomedical professionals and stakeholders saw such networks as an opportunity to "[add] value to (..) individual [biobank] organizations", providing new contacts, while also "add[ing] extra value to sample collections through the establishment of shared databases that, through

the development of digitalization technologies, allows researchers to access data remotely." (Cañada, Tupasela, and Snell 2015, 364).

In terms of governance, these networks were both a challenge and a means. On the one hand, collaboration often made visible the contingency of specific local governance arrangements (Mascalzoni et al. 2015) and showed differences in national regulations (Larsson 2017). They also increased concerns on "ownership and custodianship" (Cañada, Tupasela, and Snell 2015, 364), in particular if these networks spawned across national boundaries. Collaborations and exchange of tissue/data across biobanks triggered a considerable amount of "uncertainty", given that requirements and practices for handling consent, intellectual property rights, data management, but also the quality of samples were deemed to vary broadly (Knoppers and Hudson 2011, 330).

On the other hand, however, cross-border collaborations were also observed to give rise to self-governing practices of biobanks via "soft regulations" (Mayrhofer and Prainsack 2009). Networks were sites where "standards" emerged (Cañada, Tupasela, and Snell 2015, 365) and were often locally contingent practices began to be "harmonized" (Larsson 2017). Notably, harmonization also regarded more technical or epistemic values. For instance, these helped to harmonise "quality management and standards in sample collection, storage, and data management" (Chalmers et al. 2016, 6).[21] Networks such as BBMRI-ERIC have become "an important infrastructure that supports [the] activities [of biobanks] through providing a forum" (Tupasela 2017, 196) in which specific issues and challenges are discussed. Thus, local, regional, and national biobanks began to be "governed through" cross-country infrastructures, such as BBMRI-ERIC (Rial-Sebbag and Cambon-Thomsen 2015).[22]

[21] Chalmers and colleagues saw these developments as significant enough to refer to them as a "second wave" of engagements with biobanks. While a "first wave" of engagements with biobanks focused on "governance frameworks" that sought to ensure that "the particular ELSI of biobanking were appropriately addressed", this new "second wave" focused on "harmonization to facilitate combination and sharing of biobank datasets" (Chalmers et al. 2016, 2).

[22] Chalmers and colleagues also point to professional organisations, such as the "International Society of Biological Environmental Repositories" (ISBER), which "has taken a leading international role in standardizing preservation and storage of biological material" (Chalmers et al. 2016, 7). Moreover, several authors point to the salience of the OECD in shaping biobanks via "soft law".

4. (Bio)data-citizenship

4.1. Introducing (bio)data-citizenship

A second objective of our empirical research is to engage with changing understandings of "citizenship" in the context of the rising salience of "data", "big data", and "datafication" in biomedicine—or with what we aim to conceptualise as "(bio)data-citizenship" for short.

More specifically, we seek to

- understand how various actors frame and envision the relationship between biological data and identities of different groups of individuals including their own; and
- distil normative elements and values that are mobilised when actors frame (discursively and in practice) or envision this relationship. We are thus attentive to encoded rights and legal norms (such as data protection regulations) and obligations and duties. In addition, we will carefully consider values expressed as expectations (e.g., on the distributions of responsibilities) or as narratives (e.g., on solidarity and/or justice).

We use "citizenship" in a broad sense, to underline the relational and patterned (or "discursive") nature of human identity formations. Citizenship is more of a heuristic concept that points to our focus of analysis on identity formation, on participation and who should get voice, on empowerment and exclusion, on new forms of responsibility relationships, and on the tensions between individual rights and freedoms and the public interest. Citizenship has to be embedded in wider transformations (such as the withdrawal of the state from certain arenas, the decline of social cohesion, privatisation, individualisation, and more), which are also tied to a re-envisioning of subjects as calculating (based on an increasing set of information gathered about themselves and their environment), responsible for their own lives, and as acting autonomously.

Citizenship is thus a relational, fluid, and also contested concept. Citizenship in a (very) narrow sense would limit our attention to a set of individuals who have passports of particular countries. Such a narrow understanding of citizenship would exclude a considerable number of patients and research participants and arguably also researchers, which are essential to include in our reflections. Moreover, it would also presume that a narrow set of authorities, such as, say, a central set of institutions making up the "government" of nation-states, define citizenship. Embracing citizenship in a broad sense acknowledges that central state authorities are merely one among several actors that are involved in the definition of rights and entitlements (Sorensen 2014).

In studying the emergence of a new kind of citizenship, we build on those social science theories that underline, first, that individuals envision and imagine their selves in relation to others, including collectives and communities; and, second, that when individuals make sense of and act upon their selves, they assemble elements of "discursive repertoires" (Silverman 2011) or "moral repertoires" (Sharon 2018), thus tacitly reinforcing and stabilising these repertoires. In our research we are specifically interested in mapping the "moral repertoires" that mediate the relations between selves, particular collectives, as well as (bio)data, and in exploring how these enter into conflict and conversation. Qualifying citizenship with

"(bio)data" directs us to exploring how "(bio)data" mediate the relationship between particular agents and the collectives they are part of or related to.

We keep the "bio" in (bio)data in brackets, so as to remind ourselves to not grant these kinds of data neither an exceptional status. After more than a decade of discussions on what health data or genetic data are and how they ought to be protected, we know that health relevance of data is not an intrinsic property of data. Rather their relevance for health-related issues depends on the ways in which data are assembled and by whom, and where and how these are interpreted. Rather than an intrinsic property of data, health relevance is a relational and emerging quality (Marelli, Lievevrouw, und Hoyweghen 2020).

In short, the notion of "(bio)data citizenship" focuses our attention on the complex relationship between the following dimensions (see Figure 4):

(1) the ways in which individuals understand (bio)data and their relationship to them ("selves and data");
(2) the ways in which individuals understand and envision the relationships between their selves and the collectives or communities they imagine to be part of/relate to ("selves and collectives");
(3) the range of values and norms ("moral repertoires") that individuals mobilise when framing and imagining the relationship between "selves", "data", and "collectives."

Box 3: "(Bio)data-citizenship" at a glance – Objective 2

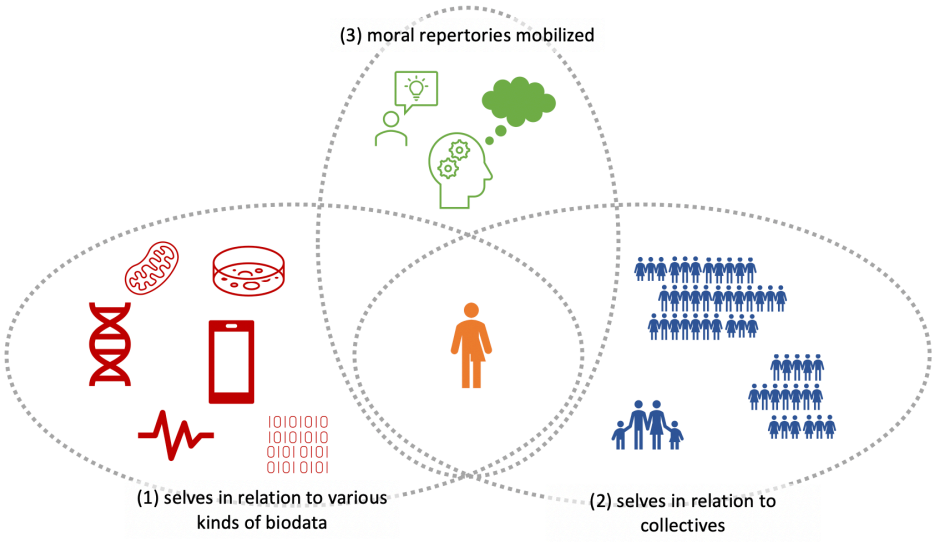

Figure 4: Dimensions of (bio)data-citizenship

In what follows we will start (section 4.2) by exploring the notion of (bio)data-citizenship and outline what such a concept can do for understanding the relation of human actors to biobanks. In the second part of this chapter (section 4.3) we will then look into the different ways of imagining citizens/donors within the biobank context and offer a typology. We will then discuss perspectives from the literature on citizens' perception, understanding and visions of biobanks, data use and data donation. To close this section we

will draw together some of the key-findings from the work done in BBMRI.at#1, where a series of citizen group discussions allowed insights into their conceptualisation of biobanks and their imagination of biological data and related research.

4.2. Exploring (bio)data-citizenship: approach and sensitising concepts

4.2.1 (Bio)data-citizenship

Using the notion of "citizenship", we build on research from STS and related fields that has associated transformations in the standing of techno-science in Western societies in general, and bio-medicine in particular, with transformations in the understandings of the range of rights, entitlements, and duties of individuals vis-à-vis the authorities involved in their governance. By way of examples, Andrew Barry directed our attention to the ways in which members of techno-scientific societies are increasingly expected to be knowledgeable about technoscience (Barry 2001), and to become "scientific citizens". Others have underlined how advances in genetic knowledge have reconfigured individual and collective identities, rights and entitlements, and reconfigured responsibilities for health and illness (Erikainen et al. 2019), at times summing up such transformations with "genetic citizenship".

Before the background of a shift of patienthood and participation, due in part to socio-technical transformations and the intertwined phenomena of big data and datafication, Erikainen et al. (2019) look at how conceptualizations of 'patients', 'participants', and health 'consumers' merge. Citizens are no longer conceptualised - by themselves, healthcare providers, researchers, policy-makers - as passive recipients, but as both patients and active and engaged participants in biomedicine and healthcare. One example of this development is the trend towards participatory medicine and healthcare – for example personalised medicine, genomics, or direct-to-consumer testing. Individuals are involved in the production of their own biomedical and health data, which should enable them to take responsibility for their own health. The 'activation' and 'responsibilisation' of patients and citizens is on the one hand described as empowering and democratic, while on the other hand it is seen critically in terms of medical surveillance and an ethically questionable transfer of responsibility from the healthcare services to the individual. "Patient-participant-consumers are both subjects and agents of biomedical practices, bringing to the fore that we must not only account for the multiple roles and experiences that co-emerge through digital technologies, but also ethically re-assess the rights and responsibilities of individuals in the digital era" (Erikainen et al. 2019, 2). Further, due to developments such as lifestyle data being aggregated, the authors make a case for new populations and subgroups emerging out of big data analytics. These groups/groupings do not emerge out of a vacuum, but are rather embedded in cultural assumptions.

Another particularly influential notion is the notion of "biological citizenship", which has been developed among others by Nikolas Rose and Carlos Novas (2005). They highlighted the productive and generative powers of biomedical knowledge in generating new individual and collective identities, and linked changing identities to citizenship. They noted that scope of rights, that citizens were vested with, were in a process of being extended from civic, political, and social rights and duties to somatic and biological rights. Drawing on examples from health advocacy groups, they underlined that this extension of the range of rights was a process that did not only occur in a "top-down" way, but also in a "bottom-up" way,

given that an increasing number of citizens mobilised their bodies and biologies speaking on behalf of their "'vital' rights as citizens" (Rose and Novas 2005, 441).

Using the neologism of (bio)data-citizenship, then, we wish to pay attention to how understandings of citizenship are transformed, challenged, and, perhaps also, reified in the context of the emergence of "big data" and the "datafication" of biomedicine and societies. Adding "(bio)data" to citizenship sensitises us to the ways in which the emerging salience of "data" and related practices of "datafication" transform the patterned relationship between individuals and collectives in practice, as much as it shifts our relation to our bodies and perceptions of health. What we observe in the context of biobanks and the ways in which sample/data are conceptualised and dealt with, however, has to be understood in a much wider movement of collecting personal health related data. A large segment of society has started to use a myriad of tracking devices and health related apps, producing, storing and sharing (bio)data—"(bio)datafying" experiences of health and illness. Data and the related infrastructures and platforms that support citizens in collecting, storing and sharing them, mediate the relation between citizens and their bodies and perceptions of health. "(Bio)datafication" thus shapes how citizens understand and act on themselves, their bodies and health. Assembling data and having them available therefore changes how citizens perceive their bodies and their health, and also transforms how researchers engage with questions of health. "(Bio)datafication" organises new ways of how we can "see" our human bodies.

While there is little literature on how donors/providers of biological samples for biobanking understand their relations to samples and data, a parallel strand of literature on the "quantified self" and self-tracking practices provides insights on how citizens understand themselves in relation to data (e.g. Lupton 2016). While aspects of agency and community may differ, the ways in which big data, new technologies and infrastructures shape the relationship of data, bodies and selves might be similar. Indeed, studies on the quantified self have shown how data starts to participate in sense-making about how citizens feel and how they are in the world. Simultaneously, through a growing "trust in numbers" (Porter 1995), data gain power in guiding individual actions and informing choices. Together, this data-mediated vision of health and body brings along new kinds of practices of engaging with body and health – both in the everyday life as citizens but also as researchers – (re)shaping understandings of responsible (bio)data-citizenship.

This datafication of bodies and health, however, also creates a number of quite essential questions, which are omnipresent in the discussions around biobanks. Who owns health related data? What counts as health related data? How important have data become to understand the relation of bodies of data and data bodies (Mager & Mayer 2019)?

4.2.2 Making up identities: envisioning participants, citizens, populations and publics – Operationalising (bio)data-citizenship

In order to grasp the different meanings of (bio)data-citizenship we need to be attentive to the ways in which individual and collective identities can be and potentially are formed, and to the ways in which individuals are envisioned and can envision themselves in multiple ways.

Several studies have underlined the ways in which particular biobanks participate in the making of collective identities of groups, such as whole populations and specific publics. For instance, Bühler, Barazzetti, and Kaufmann (2019), looked at participation of populations as donors and supporters of biobanking in the case of two Swiss biobanks (a cohort biobank and a general biobank). They showed how discourses around these biobanking endeavours supported the shaping of

> *"an ideal figure of participant as morally attuned, caring for future generations, concerned by the common good, and engaging democratically in public debates. In other words, being a good citizen means participating in biobanking both as a bioprovider and as part of the public. This ideal figure is very much aligned with the need for health-related and genomic data, solidarity and trust, necessary to the development of PH [personalized health]." (ibid., 126)*

The authors thus describe how identities and biobanks are co-produced in participation processes. Others, studying the emergence of national or regional biobanks, noted that they contributed to the creation "imagined national communities" as a collateral effect of their enrolment strategies (Busby and Martin 2006; Corrigan and Tutton 2009). Drawing on the example of Iceland, David Winickoff argued that "science and technology have become, or are at least widely seen to be, constitutive of modern nationhood itself" (Winickoff 2006, 99).

Moreover, scholars have also directed attention to the ways in which individual identities of "donors" or "research participants" are constructed, envisioned, or "made up" (Hacking 2000), e.g. in particular arrangements for governing specific biobanks (see section 4.3.1 for details), or how identities are discursively imagined in bioethical literature. This scholarship highlights that human beings always have multiple identities and that some parts of these identities are also shaped by expectations and legal rights, freedoms, obligations and responsibilities that are often envisioned by others "from above". The philosopher of science Ian Hacking refers to such processes of envisioning identities from above as "making up" people (Hacking 2000; Tutton and Prainsack 2011, 1083). Being aware of such top-down identity constructions is important. We will exemplify in the next section (specifically section 4.3.1) how different governance arrangement coproduce identities of subjects and their rights, freedoms, responsibilities, and obligations—and of biobanks entrusted with taking care of these rights.

However, top-down understandings can also have "looping effects" (Hacking 2000) and shape the ways in which individuals understand themselves, by providing them with identity constructs that they use as a resource to make sense of their selves (Silverman 2011). Public discourses around biobanking thus become part of the wider "narrative infrastructure" (Felt 2017), that individuals can draw upon to envision and express their selves in relation to biobanks or more specifically in relation to (bio)data. While the large majority of studies has engaged with the ways in which individual and collective subjects are conceptualised and envisioned by others, very often by those in power, we know much less about how individuals make sense of their individual and collective identities and their selves (see also Beltrame and Hauskeller 2018). This will be key in our research in BBMRI.at#2.

4.3. Putting citizens/patients at the centre

In what follows we will engage with the place and role of citizens or patients in the wider context of biobanking. We start by reflecting on the body of literature which analyses how the relationship between citizens and their samples/data is performed in discourses and practices of biobanking. Here we will identify five ideal types and reflect on what they entail for our concept of (bio)data-citizenship (section 4.3.1). In the second part (section 4.3.2), we will bring together some key-aspects from studies on how citizens and patients actually understand the meaning of biobanking, data use and providing their data for research – often labelled as "donation". In the third and last part (section 4.3.3), we will shortly report on a first set of findings which were drawn from regular engagement exercises with Austrian citizens in the context BBMRI.at#1.

4.3.1 "Making up" citizens and their relationship to sample/data in biobank governance

In this section, we discuss five different ways of "imagining citizens" and their relationship to tissue/data in biobanks and biobank governance, thus, exemplifying the conceptual discussion on the "making up" of identities made above (in section 4.2.2). We draw on social science literature that has engaged with this question in an explicit way (e.g., Tutton 2007a; Tutton and Prainsack 2011), and on the ELSA literature, that has articulated visions of how donors or providers ought to be conceptualised in explicit and more implicit ways.

The five types – or "modes" of imagining citizens in biobanks – described below are "ideal types"; in the practices assembled in biobanks, they are often less pure and more enmeshed.

Mode 1: Individuals as autonomous citizens

A first imagination constructs the identities of individuals as autonomous citizens with a set of rights and freedoms. Such a framing is usually associated with the understanding that autonomous human beings have a set of rights and freedoms, such as the right to be informed about plans to conduct research on sample/data, and the freedom to disagree with such plans—in light of their autonomy. It is the prevalent framing of citizenship not only in biobanking but also in liberal democracies. It is also an extension of provisions for ethical rules enshrined for clinical research on fully-fledged subjects to practices of biobanking. This liberal understanding is entrenched in the practice of asking donors for consent in biobanks. And it is also enshrined into a range of regulations that apply to biobanking, including the GDPR (see chapter 5).

Within this imagination of citizenship, there are debates on the nature and scope of the rights and freedoms that individuals ought to be vested with and on the appropriate practices, procedures, and architectures for enacting them. Some limit the rights and freedoms of individual donors to the freedom from coercion, and thus to the right to be asked for consent before data/samples are included into a collection (Aicardi et al. 2016, 208).

Others argue that individuals should also have a say in how data/samples are used. They insist that individuals should not be seen as individual "donors", but as "partners" or "participants" in research (Saha and Hurlbut 2011; Tutton 2007a; Haimes and Whong-Barr 2004). Here, "participation" has a double meaning, referring not merely to the right to agree or disagree with the act of providing data/samples to research, but also to the right to have a say in how these data/samples ought to be used. Tutton argued that framing individuals as "participants" in biobanks implied that they should be seen not merely "as the sources of blood samples and data but also as potential co-decision makers" (Tutton 2007a, 177).

Exemplifying such an extension of the scope of rights that autonomous citizens should be vested with, Kris Saha and Benjamin Hurlbut suggested:

> *"Current practices in managing biobanks tend to see the public as little more than a resource for mining data and materials, and as a potential source of resistance. Participants provide information or tissue with little or no knowledge of the researchers' priorities, goals or expected outcomes. Barriers are erected. Materials and information are 'de-identified' to protect people's identities. Participants neither see how their donations are used, nor what the research produces." (Saha and Hurlbut 2011, 312)*

They underlined that "[m]ost people prefer to have a say in how their donations are used" (Saha and Hurlbut 2011, 312), and called for "an alternative approach, in which donors are made partners by staying connected to research" (Saha and Hurlbut 2011, 312). Specifically, they warn against construing the bioethical principle of autonomy to the narrow "right to sign a consent form." Rather,

> *" 'respect for persons' […] should also entail a respect of the ability, willingness and right of participants to share in imagining the futures to which research aspires. If human subjects are asked to give material from their bodies for research, they should also be treated as competent to govern the material's future uses." (Saha and Hurlbut 2011, 313)*

Saha and Hurlbut therefore encourage the building of "infrastructures" that would allow individuals to remain involved with/connected to research. This could mean getting insights regarding the kinds of studies their donation was used for, choosing the level of privacy protection they want, deciding whether to be informed of incidental findings, or being able to contribute additional information for selected areas of research.

Arguing in a similar direction, Edward Dove and colleagues envisioned a "wiki-governance model for biobanks" (Dove, Joly, and Knoppers 2012, 1), which would give "[p]ower to the people" (Dove, Joly, and Knoppers 2012, 1) and also facilitate bottom up approaches to the governance of biobanks, "by citizens rightfully envisioning themselves as co-creators of genomic science and policy" (Dove, Joly, and Knoppers 2012, 6).

Thus, the nature and scope of rights and freedoms of autonomous citizens is contested. However, the shared assumption of this first mode of imagining subjecthood in biobanks is that these are autonomous citizens with individual rights and freedoms, such as an "individual" right to control which data/samples are stored or to have a say on how biobanks ought to be governed (cf. Prainsack 2019; Sharon and Lucivero 2019).

Mode 2: Individuals as relational subjects

A second mode envisions the identities of citizens in biobanking in relational rather than autonomous terms (Gibbon and Prainsack 2018). This understanding conceptualises individual subjects as always entangled in a web of relations to others and thus as members of groups, such as a family, a group of patients, a community, or also of bigger abstractions such as the "imagined community of the Icelandic population" (Winickoff 2006) or "humanity". Scholars approaching providers of sample/data with relational terms, do not stop at the relationship between disentangled individuals, their materials and data, and biobanks, when puzzling through the values that matter in the ordering of biobanks. They underline that the ways in which individual providers—or research participants—imagine to be related to other participants and members of a community through the biobank need to be taken into consideration. And they underline that relational subjects have rights and freedoms, but also moral duties and obligations towards other subjects to which these are related via solidarity or altruism.

Such relational understandings can be found in the communication of biobanks, which tend to emphasise the collective value of biobanking, very often in terms of a benefit to public health. Individuals are invited to "donate" to biobanks so as to help their fellow citizens or humanity via an imagined "gift relationship". For instance, Busby and Martin (2006) underlined how a language of solidarity was used in the British context, stressing the "pooling and sharing [of] risks" which was seen as "evok[ing] a post-war ethos" (ibid.) – an unusual move in the current UK policy climate, "which tends rather towards a stress on the limits of the responsibilities of the state towards its citizens" (ibid., 245). Similarly, Tutton and Prainsack observed that "policy guidelines" on the use of human tissue in the UK draw upon "the notion of the 'gift relationship' […] to emphasize that participation in medical research should be motivated by social solidarity and personal altruism" (Tutton and Prainsack 2011, 1084). In so doing, biobanks continue practices of solidarity found in other health related fields (Felt et al. 2009).

Such a relational understanding of the identity of providers has also been elaborated in ELSA scholarship. In explaining what they refer to as a "solidarity-based approach to the governance of research biobanks", Prainsack and Buyx (2013, 75) argue that people are willing "to carry costs (financial, social, emotional and otherwise) to assist others" and identify this "willingness" as the defining property of "solidarity," suggesting that "solidarity should underpin the relationship between participants and biobanks, alongside autonomy" (ibid., 77).

The practical consequences that scholars deduce from a relational conceptualization of individuals differs. Prainsack and Buyx (2013) take their assumption that individuals are willing to pay the price for the sake of the benefit of others as providing justification for broad rather than specific consent. Thus, they limit the rights and entitlements that individuals have in their control over their samples, information, and

data, once they decide to donate them to a research biobank. However, they also emphasise the need to establish mechanisms of "collective control" in biobank governance, such as the establishment of governing bodies that oversee the use of sample/data. Others have argued for a soft obligation of individuals to donate sample/data to a community, from which they benefit. For instance, Ruth Chadwick and Kare Berg (2001, 321) argued that there might be "moral considerations in favour of sharing information that could benefit the whole group." While they make this argument in relation to the family as a collective, it also pertains to donation as possibly facilitating research from which future generations could benefit. In this way, "participation [in biobanking] becomes framed as an act of solidarity similar to providing blood for transfusion or organs for transplantations" (Tutton and Prainsack 2011, 1084).

Mode 3: Sovereign customers

Another mode of envisioning citizens in biobanks is to frame them as sovereign customers, who can choose to consume a set of rights and to participate in research, and, in so doing also work on their "empowerment through self-knowledge" (Kragh-Furbo and Tutton 2017, 168) or their self-fulfilment and freedom (Lee 2013).

Such a way of envisioning citizenship is particularly prominent in personal genomics companies such as 23andMe—and thus in settings outside of public health care. Customers are invited to consume services, such as access to personalised risk information. Moreover, customers can also choose to "donate" data to research, and therewith "participate" in an imagined epistemic community. While the language of "participation" used by companies such as 23andMe evokes elements of an "altruistic" "gift relationship" (central to mode 2 described above), the sovereign customer also gets tangible and intangible gifts in return, such as "returned results, acknowledgements and badges" (Harris, Wyatt, and Kelly 2013, 244).

Richard Tutton and Barbara Prainsack (2011) have examined how "23andMe, in promoting a particular model of research participation, is creating a certain form of 'research subject' that contrasts with that constituted by the practices of population-based biobanks" (1082). They compared "different subjectivities produced through their discursive and material practices of recruitment and conditions of participation", which they called "enterprising" selves for 23andMe and "altruistic" selves for UK Biobank (Tutton and Prainsack 2011, 1082). They argue that while UK Biobank constructed participants as an "'altruistic self' who is addressed through a discourse of communitarianism, and who enrols in the biobank, freely giving of themselves with no expectation of anything in return", 23andMe constructed an "'enterprising self' who is addressed through a language of democratization and empowerment, and who has the right to information as a value in itself. This 'enterprising self' is willing to pay for information about personal genetic risks while, at the same time, will also actively contribute towards new research. Rather than being an altruistic 'gift giver', this participant is engaged in a consumer transaction by which she both purchases and provides information about herself (Prainsack 2010)." (Tutton and Prainsack 2018, 1090)

Mode 4: individuals as unpaid workers performing clinical labour

Another mode of framing individuals in biobanking is to see them as "producers" or "workers".

Such a framing has been proposed by Robert Mitchell and Catherine Waldby (2010), who have pioneered work on the role of biobanks in the global bioeconomy. They reconceptualised donation or participation in biobanks as "clinical labour" – defining it as a „regularized, embodied work that members of the national population are expected to perform in their role as research participants" (ibid., 334). Building on their work, Beltrame and Hauskeller (2018) interpreted participants in biobanks as "the first ring in a value chain, which transforms donated tissue and the related bioinformation into commodities" (5-6).

Scholars have argued that such a fourth mode of framing individual providers helps to see dimension that are made invisible by other modes of envisioning them. For instance, Beltrame and Hauskeller (2018) also problematised the language of civic rights, freedoms, and duties, as well as the imaginary of the "gift relationship", to think about contributions of individuals to biobanks, arguing that this language made economic dimensions of biobanking invisible. Similarly, Anna Harris and colleagues questioned the language used by 23andMe, arguing that their framing of research participation in terms of an altruistic "gift exchange" was used "to draw attention away from the free, clinical labour which drives the profitability of 23andMe" (Harris, Wyatt, and Kelly 2013, 236).

Mode 5: Individuals as bioentrepreneurs – an emerging type

We are not aware of biobank initiatives that frame individuals as workers. However, what we can observe is the emergence of a number of initiatives, in particular in the US, that seek to capitalise on personal genomics and blockchain technologies, so as to empower individuals to share their data, keep control of them, and also get revenues from them (Buhr 2018; Cohen 2018). This might be an emerging fifth mode of imagining individuals, but perhaps not so much in "biobanking". Indeed, such a way of storing and sharing data would elide the role of biobanks as custodians or intermediaries of sample/data.

Together, the five modes of imagining subjecthood in biobanking point us to sites and practices in which the identities of the subjects involved in biobanking are discursively imagined (e.g., on the website of a biobank), or performed or produced via specific practices of governing biobanks (e.g., consent practices). These are sites where identities of sample/data providers are imagined, where the balancing of value(s) of biobanking crystallised in practice, and where (bio)data-citizenship takes shape. Thus, in our project the questions of how individuals are imagined and enacted in specific biobanks in practice, how individuals imagine their own identity, as well as how these imaginations enter into conflict or conversation, will be key.

4.3.2 Citizens perceptions, understandings, and visions: Public Understanding of Biobanking, Data Use, and Donation

Scholars have also engaged with the ways in which providers of sample/data understand biobanks and particular practices, such as data use, consent and donation, often using quantitative methods, such as surveys, to "measure" citizens' opinions of and trust in biobanking. These studies give us some insights on wider trends but do not produce insights into the why and how of citizens' positioning work and thus do not really allow to move forward in engaging with citizens around biobanking. However, for the purpose of our study this corpus of literature invites us to reflect on the aim of these case studies and on how the relation of 'the public' and biobanking is thought about and contextualised.

Various studies explored the **public perception and understanding of biobanks**. The majority of these studies have looked at the conditions and reasons that shape decisions to participate in biobanking, at times with the implicit aim to identify challenges for achieving public support and trust. For example, Hoeyer et al. (2004) gained interesting insights of public attitudes concerning tissue use for research via a quantitative questionnaire. The study was performed in a region in Sweden and found that while there was a general acceptance of biobank material being used for genetic research, most of the participants did not grant access to their healthcare records without specific consent. Sharing medical records and clinical data seemed to be of greater concern to the participants than sharing their genetic information. This can be supported by a qualitative study of Austrian patients providing tissue to research after surgery where we saw nearly 100% consenting, while we witnessed a broad discussion on the willingness to share basic health data collected in the electronic health record (Felt et al. 2009).

Tupasela et al. (2010) conducted a survey with the aim of finding out how Finnish citizens perceived the setting up of a national biobank, the use of existing samples, and different types of informed consent. They reported that over 80% of the respondents indicated they had little or no knowledge of biobanks, while most of the same respondents were also in favour of establishing a national biobank. The majority, however, wanted to be able to control how their sample/data was used.

Using a multi-method approach, including focus groups and surveys, Gaskell et al. (2013) looked at public perceptions of biobanks across Europe. Their findings showed that public perceptions of biobanks are heterogeneous and unequally distributed across Europe. Public support and willingness to participate seems to be lower in southern and eastern Europe than in northern Europe. Support for biobanks is further contingent upon people's engagement with biobanks - engagement is thus seen as relating to willingness to participate in biobank research. Further, "[t]hose hesitating to participate in biobanks have lower trust in key actors and have greater concerns about data privacy and security. Such concerns will only be allayed by building trust and transparency and by engaging the public as partners in the biobank project" (ibid., 19).

Domaradzki and Pawlikowski (2019) give an overview of the existing studies on attitudes towards biobanking. The authors found that many people lack knowledge of biobanking, but are generally positive towards donating samples and data and establishing biobanks. Most potential donors are driven by motives of a common good, and are concerned that their biological sample is linked with their personal data and can be used to their disadvantage by the government, their employer, or insurance companies. "This review also shows that the public trust public and national biobanking institutions rather than commercial and foreign institutions; trust toward biobanks links positively with willingness to donate, preference for broad consent, and links negatively with concerns about privacy protection and being a member of ethnic minorities. Biobankers who establish and manage their biobanks should take into account socio-cultural circumstances and care about a culture of trust towards biobanks, research, and scientists" (ibid., 7).

Critchley, Nicol, and McWhirter (2017, 617) reason that human biobanks are dependent on public support and trust, and therefore understand public expectations of biobanks as crucial "to maximise the scientific

utility and economic efficiency of biobanks". They set out to identify how people thought biobanks should behave towards donors, society in general, and the research community. The participants of the study, which consisted of a sample of 800 Australians, were asked to rate 13 different biobank behaviours or responsibilities along their perceived importance. The authors found that most importance was placed on the protection of privacy, ethical conduct, and generating new healthcare benefits (in this order). Less importance was attributed for example to obtaining specific consent, benefit sharing with donors, and collaborating and sharing data with other researchers. Analysing their quantitative data further, the authors found that the answers could be grouped in two groups, one which thought behaviours that respect the donor are more important, and a smaller group, which placed more importance on accelerating science. Concluding their study, Critchley, Nicol, and McWhirter (2017) surmise that "privacy, ethics and scientific utility are valued above all else in relation to biobanks [...] [which] suggests that potentially controversial issues such as broad consent, collaboration and the return of research results could be neutralised if biobanks communicate to the public that they will successfully lead to medical discoveries, ensure their practices are ethical and above all else maintain donors' privacy" (ibid., 684).

Scholars have also performed qualitative studies, engaging with specific biobanks and related publics. In what follow we will shorty point to three perspectives which seem relevant to our research in the project: the meaning of the very notion of participation, citizens understanding of data use and their perception of donation.

The meaning of participation in biobanks

Richard Tutton (2007a, 172) drew on data from focus groups to explore how people "constructed and contested two different kinds of participation in UK Biobank": their participation through the provision of sample/data and their participation as "co-decision makers".

He also referred to a study conducted by Erica Haimes and Michael Whong-Barr (2004) on participants in the „North Cumbria Community Genetics Project". They distilled different ways in which individuals imagined their participation: "there is the ‚active participant,' who stresses his or her willingness to help; the ‚cost/benefit participant,' who talks in terms of weighing up personal risks against greater collective goods; the ‚passive participant,' who can see no reason not to provide the samples and/or personal data; and the ‚reluctant participant,' who regrets having done so." (Tutton 2007a, 176)

Building on their work, Tutton explored various "subject positions" that participants construed while envisioning their role in a biobank and its governance. He noted that such visions were shaped by "ambivalence about the choices that they or others may make, and about the role of institutions and scientific experts associated with UK Biobank" (Tutton 2007a, 178). He noted that the "language of active citizenship and community involvement" was only one of several "discursive repertoires" on which people draw to imagine their subject position vis-à-vis UK Biobank, concluding that the complexity and contingency found in people's perceptions is "rarely acknowledged in institutional discourses" (Tutton 2007a, 189).

Understanding data use

Next to literature on the public understanding of biobanking, there are many studies that focus on understandings of and attitudes towards data and sample use.

Skovgaard, Wadmann, and Hoeyer (2019) composed a literature review on how people living in the EU viewed the reuse of health data. The authors found that the majority of studies were conducted in Britain and stressed the importance of future studies with different local backgrounds. Further, "[a]cross the reviewed studies, it was striking that many respondents did not know which health data were being shared and how they were being used. Hence, when interpreting the findings of the studies, it is important to bear in mind that patients expressed more generally formed attitudes without knowing the specificities of the practices involved" (ibid., 569). In general, the majority of people were positive towards reuse of health data for other purposes than treatment. This attitude was often linked to an understanding that the use of data would lead to a common good. Major concerns were expressed in the case of privacy and when it came to commercialisation of data or a use of data that could potentially disadvantage patients.

Before the background of the research exemption in the GDPR, Richter et al. (2019) conducted a quantitative study with 700 outpatients at a German university hospital to find out whether consent for secondary data use is seen as necessary or not. The authors found that there was a strong willingness to give broad consent and an acceptance of abolishing patient consent for secondary use.

Grasping the meaning of donation

Another aspect researchers have looked more closely on is the concept and practice of donation in the context of biomedical research, biobanking, and changing data practices.

Boylan et al. (2019) tackle the concept of donation in health research by conducting narrative interviews with people who have been invited to donate biosamples and other forms of samples to research. The authors find that the concept of donation can encompass many things. In the context of biomedical research, the term 'donation' most often denotes the giving of biosamples, such as bodily fluids or tissue. Often however, participants are also asked for personal health or lifestyle data. Also other contributions, such as time and effort, taking part in surveys or interview, or agreeing to experimental treatments can be viewed as donations. The authors thus conclude that a conceptualization of 'research donation' has to take all these different contributions into account.

Lee et al. (2019) conducted focus groups to investigate whether citizens distinguish between biospecimens and electronic health records, when they consider participating in research and donating their samples and data. While many of their participants did not distinguish between those two types, a subset of participants did have concerns about the donation, use, and storage of samples. For example, in their focus groups Lee et al. encountered heterogeneous views on the relationship between biospecimens to the human body and personal identity - "some participants asserted that the physical nature of biospecimens retains an individual's essence even after samples are collected, stored and distributed for research. For several focus group participants, this durable connection created a heightened sense of vulnerability and required special care and consideration that do not extend to digital forms of patient data" (2019, 110). The authors encourage further research in how understandings of research participation differ regarding which information or sample is transferred. Further, it should be

looked at how cultural and religious beliefs, as well as a historical underrepresentation of a population in biomedical research may influence these understandings and attitudes.

In a book chapter on the ethics of medical data donation, Nickel (2019) argues, that modern mass data collection and analysis contain many uncertainties. This paper focuses on the changing relations and uncertainties between data and data subjects. 'Data subjects', people whose data is collected and processed, are hindered in their decision-making by the uncertainties surrounding emerging technologies and data practices in two ways: regarding the trust they put in the institutions that manage data, and knowing their own moral obligation to share their data. Nickel explains, among other things, that whether a data transfer really counts as a donation is in itself an uncertainty - as without knowing the specifics of how and by whom the data will be used for what, it could also be conceptualised as "the price of a service, or as a shared burden - a sort of tax - imposed for the sake of fairness and solidarity" (ibid., 65). There are therefore numerous uncertainties about the duties and responsibilities of data subjects. Nickel especially argues that "these uncertainties are an ethical problem for data subjects" (70). For Nickel it seems these uncertainties only exist or effect data subjects, or "ordinary people" (ibid., 70). At one point he draws a divide between data subjects as ordinary people and experts which should be trusted. It could also be worthwhile to see if uncertainties also exist for other parties involved in collecting or handling data.

Lipworth, Forsyth, and Kerridge (2011) review and analyse qualitative studies on how lay people conceptualise and experience the process of donation to biobanks. A first observation is that there is no universal theory suitable to look at the process of donation. "Rather, any 'sociology of biobanking' would need to be nuanced and to draw upon a variety of social theories in order to account for the donor population (e.g. people with a serious illness vs. healthy donors vs.an ethnic group), the type of tissue being donated (e.g. tumour vs. blood vs. DNA), and the context of the donation (e.g., recruiting patients in a medical clinic in a welfare state vs. a public drive for a commercially-owned biobank)" (ibid., 806). Second, the concerns of tissue donors and of sociologists studying them are not necessarily congruent. For example, many potential donors do not feel strong ownership of their tissue and are not in general against commercially funded research, as long as it contributes to a common good. A third observation concludes about governance that "there is general agreement that it is important to take seriously the results of research which consistently reveals high levels of trust; a desire for, or expectation of, reciprocity and an expectation of public involvement and benefit-sharing" (ibid., 806).

Finally, authors such as Locock and Boyland (2015) point to the importance of how to denominate the act of providing samples for biobanking. They critically discussed that "conceptualizing donation as altruistic downplays the role of reciprocity and personal or family benefit" (ibid., 805) and point to the use of partly contradictory terms in the context of biobanking. They report that while "the term 'gift' was considered appropriate by some, […] it also evoked puzzlement, especially in relation to 'waste' material" (ibid., 805). From their research they could observe that "for donors (and researchers), value is attached to the information derived from the sample, rather than the sample itself". Therefore they suggest to "avoid using the term 'gift'" and acknowledge, when asking people for biosamples, that "the value of participation and the information the sample holds may mean more to potential donors" (ibid., 805). This points to the importance of using language when debating biobanking, but also to observe citizens' own framings in terms of narratives and key notions they relate to.

4.3.3 Public understanding of biobanking – learning from BBMRI.at#1 about the Austrian context

Our work in BBMRI.at#2 builds on research done by colleagues in the previous period of BBMRI.at, in which group discussions across Austria were used to identify potential donors' (citizens') concerns and understandings. The aim of the social science work in BBMRI.at#1 was to understand how citizens make sense of biobanking activities in the Austrian context. To gain an understanding of this, in-depth qualitative engagement methods were chosen[23]. These discussions covered a broad range of topics concerning biobanking activities, such as consent, public-private-partnerships, commercialization, ownership and sharing of data and samples.

A total of twelve discussion groups were carried out from 2014-2017 in Austria, which generated some key insights and suggestions for further study (see Deliverables of BBMRI.at#1, i.e. Felt et al. 2018; 2019):

- When participants talked about the consent process, often the discussion turned to data protection and privacy. Public discourses about data, also beyond the biomedical context, shape how citizens discuss and reflect on consent processes. A next step would therefore be to look further into how societal debates on big data and data ownership play a part in how citizens relate to biobanks as a (potential) donor, and to their own data.
- Citizens did not understand giving informed consent as a singular act, but as the start of a relationship of responsibility and trust that goes beyond the situation of giving consent. The relationship between donors and biobanks was not conceptualised as unidirectional information, but as needing mutual engagement further down the line (for example in case of future incidental findings). The understanding of informed consent and its role in how citizens relate to biobanks (and to their data) needs to be looked at attentively.
- Participants' future scenarios - the expectations that were formulated about the progress of research and technology, as well as the concerns about what this might mean for the use and accessibility of data, and how a changing social or political climate may impact the protection of donors - affected citizens' present choices and opinions. A closer look at how citizens imagine a sustainable future for biobanking and how responsibilities are distributed in this future, would offer further insights.
- A central question in the discussions was the accessibility of data before the background of cooperation and data sharing, which was often linked to the question of trust. Participants' concerns and positions differed depending on whether cooperation takes place in public-private collaborations and if data are shared with national, EU-wide, or international partners. Beyond tracing these concerns, there was no clear outcome regarding where precisely these boundaries are drawn. These questions gain even more importance in the light of the GDPR.
- While some participants did not want to engage further with their data after donating, quite a number of participants wished for some form of oversight over where their data go and how they are used, thus wanting to track their data.

[23] Different methodological approaches were used over time, from using input from experts (researchers and professionals with experience and expertise in biology, medicine, ethics, and/or law) to performing card-based discussion methods to discuss biobank related questions in groups of different size and across different sites (Graz, Innsbruck and Vienna).

- Citizens had difficulties to differentiate between samples and data in the discussions, and frequently interpreted samples as carriers of (genetic) data. There was also no clear conceptualization of what 'data' are and do in biobanking activities.
- In general, a collective preference for broad consent came out of the discussions. However, individual positions regarding consent remained much more diverse. The consensus reached within the group might thus be better conceptualised as a compromise. For developing sustainable consent models, it would be important to look further into these dynamics and try to understand how citizens' values and experiences play a role in reaching a compromise or voicing disagreements.
- Discussion participants were aware that data have become a valuable resource for biomedical research. Citizens wanted their samples/data to benefit the common good, but were not supportive of private companies making a profit from their data. How citizens conceptualize value generation in biobanking influences their position on biobanking in general and on donating samples. It is therefore important to look at what is understood as a resource, who can contribute, and how benefits are distributed.
- The experts taking part in some of the discussions had different understandings of their role in this format, which influenced their input to the discussion (while some wanted to convince citizens, others opened up the discussion for collective reflection). This observation makes a case for trying to better understand how different actors conceptualise their role in the relation between biobanks and citizens or donors.

As seen in the description of the main method and the short overview of the results, the focus of BBMRI.at#1 was mainly on the understandings and conceptions of citizens themselves. Many of the questions asked and opened up for further inquiry in the context of BBMRI.at#1, can also be looked at in relation to other stakeholders. For example one could assume that the understanding and practice of informed consent (and related to this the GDPR) not only shapes how citizens relate to their sample/data, but also how biobankers, clinicians, and researchers think about ownership of sample/data. Similarly, while citizens' future scenarios played a part in the analysis, in a next step, also the future scenarios of other stakeholders, such as biobankers, university management, and the ministry, should be investigated, so as to gain a better understanding of the different dimensions of sustainability in play in the context of biobanking.

Finally, we will focus our attention to the concrete valuation practices of citizens and donors (with a stronger focus on donors and donation processes), to how they created their future visions for this domain of biomedical research and treatment, with specific attention to the kinds of resources and moral arguments they use to do so, to their understanding of biobanking more broadly speaking, with specific focus on the journey sample/data can take, but also to how they relate biomedical data to themselves, their bodies and lives as well as to the collectives they are part of.

5. Impact of the General Data Protection Regulation

5.1. Introduction: Impact of the GDPR on biobanking

In this last chapter of the report, we want to reflect on the third focus of our research: the General Data Protection Regulation (GDPR) (that entered into force in May 2018) and the differences that it makes in biobank assemblages.

The GDPR replaced the previous European directive on data protection of 1995, which member states had implemented differently. With the GDPR, policymakers sought to "harmonize" data protection in the EU so as to facilitate the flow of data across national boundaries in Europe (Marelli, Lievevrouw, and Hoyweghen 2020, 2). This should be achieved by entitling European citizens with comprehensive rights to "control" their personal data, stipulating a number of organizational and technical principles that public and private bodies must implement when processing personal data of identified or identifiable natural persons, and imposing harsh financial penalties for infringements on these rights and principles.

Governing **data protection and privacy**, the GDPR addresses values that accompanied debates on biobanks since their emergence at the turn of the century. Both the lengthy and contested negotiations of the GDPR and the enactment of the GDPR have been watched and witnessed with much attention by actors from the biobank arena. Some of them were also actively involved in the lengthy negotiation process (Starkbaum and Felt 2019). The eventual enactment of the GDPR has also given rise to a small yet controversial debate on the meaning and desirability of the regulation and its provisions.

Thus, there is a shared agreement *that* the GDPR matters for biobanks. In WP4, we seek to **explore *how* the GDPR matters** and what difference the GDPR makes for the collection, storage, use, and sharing of samples and data, as well as for the practice of donating or providing samples and data. Approaching law as a technology, we seek to engage with the GDPR "in action", focusing on how the GDPR is made to matter and on its practical consequences.

We use qualitative methods to explore:

- how the blueprint of the GDPR is interpreted, materialised, and translated into assemblages of practices, procedures, and IT architectures in specific situations; as well as
- how elements enshrined into this blueprint are discursively appropriated as a "moral repertoire" (Sharon 2018) by a range of actors, including citizens.

Specifically, we ask
(1) How does the GDPR reconfigure extant elements, including practices and procedures, of biobank assemblages, and the "value economies" at work in the biobank arena? **– the GDPR as an element in biobank assemblages**
(2) How do various actors, including citizens, appropriate the GDPR or some of its major tenets when articulating visions of what (bio)data is and how and by whom it ought to be taken care of? – **the GDPR as a moral repertoire**

Box 4: Guiding questions for research objective number 3 – the impact of the GDPR

Both questions are related to the first two research objectives. Question 1 singles out the GDPR as a new and therefore particularly relevant element of biobank assemblages, zooming in on the agency of this element in biobank assemblages and the related value economies at work in the biobank arena. Question 2 focuses on the GDPR and some of its major tenets as potential elements in the moral repertoires that actors might use to justify particular practices, to criticize procedures, or to envision alternative futures, when envisioning and enacting "(bio)data-citizenship".

Chapter 5 is structured in two parts: we start by unpacking our approach to the GDPR. Subsequently, we discuss spotlights from the emerging body of literature on the GDPR and how it impacts research.

5.2. Our approach to the GDPR: a pragmatist approach to law as a technology

Law is among the most ancient technologies that authorities use to govern and shape societies, directing them towards desirable ends (Jasanoff 2011). Similar to other and more modern technologies, the technology of law can be assessed at various stages in its life. These include (1) the moments of its design or ***enactment***, (2) the travails of law to spaces in which law is adopted or ***implemented***, as well as (3) moments in which law is appropriated by actors and ***gets a social life*** of its own.

The enactment of law: law as blueprints

The enactment of the GDPR was a generative—or perhaps indeed "constitutional" (Jasanoff 2011)—moment for "(bio)data-citizenship" in Europe, as it envisioned a particular identity of data and of how and by whom it ought to be governed. The GDPR envisioned data as a resource that could drive innovation in Europe, while also entitling citizens to comparatively comprehensive rights to control their personal data.

In more abstract terms, then, the enactment of the GDPR can be compared to the composition of a blueprint for a technology. Engaging with the envisioning and making of such blueprints provides a privileged moment to unpack visions and values inscribed into it (see section 2.1). This can be done in a descriptive, an interpretative way (for instance, when legal experts seek to translate the often complex wording of laws to more accessible language), and/or in a normative way, critically assessing whether the visions inscribed into a law are desirable or "fit for purpose" (Marelli, Lievevrouw, and Hoyweghen 2020).

The implementation of law: from blueprints to assemblages

A complementary approach to law is to follow it around to spaces where it is adopted and implemented, and thus translated from a blueprint with worded definitions, visions, and provisions, into an assemblage of practices, institutions, technical devices and architectures, or a sociotechnical arrangement for governing data or a full blown data protection regime. Such an approach studies *law in action*.

Law is always worded in abstract and general ways, so as to make provisions broad enough to accommodate a range of specific situations, making them amenable to travel to specific spaces and situations, including situations that might emerge in the future. When the blueprint is adopted or implemented in specific situations, the wordings need to be interpreted and materialised. Rephrasing an argument made by Klaus Hoeyer and colleagues for accountability, we can say that we cannot understand the working of law "without engaging with the material practices through which [it] emerges and come[s] to have effects" (Hoeyer, Bauer, and Pickersgill 2019, 460) in specific situations.

In the terms introduced earlier in this report (see section 1.1.) the provisions of a law are new elements that are added to existing assemblages, which in turn need to be reconfigured so as to accommodate this new element. At the same time, the meaning of this new element is aligned with and stabilised through its relation to other elements in the assemblage. Thus, an additional approach to law is to explore how law reconfigures extant assemblages of actors, practices, and technical devices, and to explore how the meaning of law is stabilised in the very same process. Such an approach does not deny the importance of words and inscribed visions. But it underlines that it is important to be attentive to the practical effects on the grounds to fully assess these words. Moreover, it also acknowledges that actors have to balance at times competing values and norms. Hoeyer and colleagues refer to this as "ethics work", underlying the importance of paying attention to "what people do, rather than what they think they ought to do" (Hoeyer, Tupasela, und Rasmussen 2016, 388).

While this argument can be made for all laws, it seems to be all the more relevant for the GDPR which made a comprehensive effort to govern the processing of personal data. The GDPR named a number of bodies and means, entrusting them with the implementation of the GDPR.

First, as a European regulation, the GDPR entered into force in all member states. Unlike *directives*, which need to be translated into national laws of member states, *regulations* are immediately effective. And, yet, the GDPR included several dozens of so called "facilitation mechanisms" (*Öffnungsklausel*), giving member states some discretion to enact national laws on specific areas. Marelli and colleagues note that

> *"the GDPR also contains facilitation mechanisms provided with regard to scientific research or processing of statistical purposes (see Portmeister 2017); these, among other things, enable to bypass altogether the purpose and storage limitation requirement (cf. Art. 5(b) and 5(e), (…) effectively enabling continuous re-use and repurposing of previously collected data" (Marelli, Lievevrouw, and Hoyweghen 2020, 8).*

Moreover, Article 6 (4) also enabled nation-specific provisions on the processing of genetic, health and biometric data (Marelli, Lievevrouw, and Hoyweghen 2020, 8).

Notably, the Austrian Parliament made ample use of these "facilitation mechanisms" when it enacted the "Datenschutz-Anpassungsgesetz 2018 – Wissenschaft und Forschung" (WFSDAG 2018) (*Data Protection Amendment Act 2018 - Science and Research*), which — among others — amended the "Forschungsorganisationsgesetz" (*Research Organization Act*). Notably, the WFSDAG was the first law in Austria that mentioned "biobanks".

Second, next to carving out specific areas and entitling member states with some discretion on providing legal grounds for the processing of personal data in these areas, the GDPR also envisioned a decentralised approach for its implementation. It made so-called "data controllers" accountable for taking "context-specific" and "risk-based" approaches to data protection (Shabani and Marelli 2019, 1). These must take "organizational" and "technical measures" to "ensure that appropriate protection measures are designed and implemented throughout all data processing activities" (Shabani and Marelli 2019, 4).

Third, while the GDPR took an "omnibus approach", stipulating provisions on data protection that ought to be respected and implemented by all bodies processing personal data of identified or identifiable natural persons, it made space for "codes of conduct" for specific areas. Marelli and Testa underline the importance of "the ongoing effort lead by BBMRI-ERIC (…), involving major research organizations, patient advocacy groups, and industrial representatives, to develop a comprehensive code of conduct for the processing of personal data in health research", noting that the code of conduct might eventually "enabl[e] international harmonization in the EU and possibly beyond" (Marelli and Testa 2018, 497).

When law get a social life of its own: law as moral resource

A third mode of engaging with law is to be attentive to those moments in which actors appropriate some of its visions or elements as a "moral repertoire" to justify particular practices (or to underline their worth and value), or to question the practices of others, that is, drawing on the words of Sheila Jasanoff, when law gets a "social life" of its own. Jasanoff writes:

> *"For rights to have social meaning, they must become embedded in people's imaginations and understandings and worked out in their practical dealings with one another, with the products and processes of technoscience, and with governing institutions. A right in practice emerges not only at the moment when a court declares it, but also when people (and institutions) assume that they or others own the right and can assert it through their actions." (Jasanoff 2011, 15)*

The GDPR entered into force only two years ago, continuing to puzzle many in their daily activities. It might be too young to have such a social life of its own. Nonetheless, when thinking about the GDPR in action, we also wish to be attentive to when, say, commercial companies appropriate it and literally capitalise on it, providing other actors with technical solutions that help them comply with demands of

the GDPR. Similarly, citizens might appropriate some of the provisions of the GDPR when making sense of their selves vis-à-vis bodies that process their data.

5.3. Spotlights from the literature

The GDPR is currently in the process of transitioning from a "blueprint" to an assemblage of actors responsible for its implementation, practices, procedures, and institutions, as well as technical devices, that help to materialise this blueprint. While it entered into force two years ago and is thus amenable to be enforced (and sanctioned), there is still some ongoing tinkering to make the GDPR work in practice, balancing individual rights to control and facilitating the flow of data.

This is reflected in the properties of the emerging body of literature on the impact of the GDPR on biomedicine in general and biobanks in particularly, which tends to focus on the wording of the blueprint of the GDPR (but see Cool's (2019) observations described below). Some articles take a descriptive and interpretive approach, seeking to describe the major tenets of the GDPR, and to help readers understand how these came into being. However, much of the literature discussed below deals with potential effects of the regulation and seeks to identify potential challenges to research practices. It addresses tensions that the GDPR sought to overcome, often reaching different conclusions. It is also (unusually) antagonistic, with some articles arguing explicitly against the interpretation of other ones, and at times also questioning the expertise of other authors.

Protecting rights of citizens and enabling scientific innovation

One of the themes discussed in the literature is the balance that the GDPR seeks to strike between the protection of the rights of individuals and the processing of data for scientific purposes.

The emerging body of literature on the GDPR emphasises that policymakers sought to balance two goods. First, they sought to harmonise the patchwork of data protection in Europe, so as to enable the circulation of and travails of data (Marelli and Testa 2018; Marelli, Lievevrouw, and Hoyweghen 2020), and to facilitate a "full-fledged Digital Single Market" (Marelli and Testa 2018, 496). Rephrasing an argument introduced earlier by Andrew Barry (2001), we can argue that European policymaker endorsed "data" as one of those goods that should circulate in the "technological zone" of Europe, so as to constitute Europe. Second, the GDPR also sought to achieve this aim, by envisioning or "making up" European (bio)data-citizenship, entitling citizens with comprehensive rights to control their data. These included previously established rights, including a right to control, to consent, to information, and transparency, but also enshrined new ones, such as the "right to be forgotten" and "data portability".[24] Next to entitling

[24] While this individualistic vision of citizens has been applauded by many, it has also engendered some criticism. For instance, Marelli and colleagues discuss the GDPR as a rehearsal of the "liberal" approach to personhood, which we have discussed before (in section 4.3.1). This approach, they argue, embraces "the idea that individuals should be endowed with adequate means to exercise their autonomy and individual choice over processing concerning their personal data" (Marelli, Lievevrouw, and Hoyweghen 2020, 10). While they see these means as essential for exercising self-determination, they argue that self-determination "should not only be regarded as the expression of choice with respect to the diffusion of personal information, but also as an instrument to negotiate the latter's economic value as the data subject engages in digital transactions (Mantelero 2014, 649)" (ibid., 10).

individuals with a range of rights to control their personal data, the GDPR also established a number of principles that bodies must implement, when processing personal data. These include the principle of "transparency" (Art. 5 (1)(a)), "purpose limitation" (Art. 5(1)(b)), "data minimization" (Art. 5 (1) (c)), and "storage limitation" (Art. 5 (1)(e)) (Marelli, Lievevrouw, and Hoyweghen 2020, 7–8).

Starkbaum and Felt (2019) engaged with how this particular balance came into being. They explored how actors from data intensive fields of science, including biobanks, but also patient organisations for rare diseases intervened in the policy-process. Institutional actors such as the biobank network BBMRI-ERIC warned that demanding *specific* consent for data use in science and health research, with only few exceptions, would harm statistical, scientific, and historical research and healthcare. The importance of achieving high-quality research outcomes and the reproducibility of results were put forward as arguments to underline the need from the research side. They clearly called for patients having "the option to donate their data and biomaterials to biobanks and research entities without restricting their consent to a specific study" (BBMRI-ERIC event, cited in Starkbaum and Felt 2019, 8). Probably one of the most important moves was to shift "the discourse from its key topic 'data protection', to a paradigmatic focus on 'protecting the health' of individuals and societies at large". This effort can be seen as part of a wider "epistemic transition, where Big Data approaches are increasingly framed as necessary innovative modes for knowledge generation to serve the public good" (ibid., 2).

A range of other articles discuss whether the GDPR achieved the balance between the protection of rights of individuals and the enabling of scientific research, reaching different conclusions. For instance, Staunton and colleagues (2019) argued that the GDPR failed to strike an adequate balance between individual rights and research freedoms, noting that implementing the GDPR "can simultaneously be challenging in light of the ethical requirements and well established standards in biobanking that have been set forth in various research-related soft legal tools, international treaties and other legal instruments" (ibid., 1159). The GDPR grants a lot of rights to data subjects, "and simultaneously takes them away for research purposes" (ibid., 1162). They related this gap to research exemptions envisioned in the GDPR as well as further discretion given to Member States and suggested that other legal instruments could offer some guidance and additional safeguards.

Indeed, it is important to note that some of the regulations introduced by the GDPR were also experienced as challenges by researchers working with patient sample/data. Cool (2019) investigated this with Swedish researchers working with population data. She reported that the "implicit faith in the certainty of the law in a broader sense seemed to coexist with a strong sense of uncertainty about data law" (ibid., 5). The GDPR and other data regulations that strive for flexibility and adaptability to new technological possibilities by building on accountability principles, can evoke anxiety in researchers due to their perceived uncertainty and unknowability. Besides more ordinary uncertainty, about where data should be stored and how access should be regulated, researchers reported feeling responsible and accountable for the people behind the data. Encountering these people only through their data, researchers then tried to guess these people's intentions, so as to do right by them. Wanting to stop having to interpret the law and "cast off the ethical weight of personal data" (ibid., 18), some researchers turned to anonymisation as the solution. Cool (2019, 21) argued "that the continuing appeal of anonymization for researchers –

despite their knowledge that the theory of anonymization did not bear out in practice – is in its promise to relieve them of the burdens of accountability".

Also other research underlined the challenges of the GDPR in practice. For instance, Hulsen et al. (2019) described a dilemma requiring a balancing act from clinicians and scientists, between the opportunities Big Data provides for health care and the rights of patients and donors to control their own data. Snell (2019) described a similar dilemma between a "moral principle of health" in the case of data-driven medicine in Finland and the due protection of the privacy and autonomy of individuals.

More recently, however, Peloquin and colleagues argued against this interpretation, and underlined that such articles tend to underestimate the potentially "disruptive" and "avoidable" effects that the GDPR puts on the secondary uses of data and associated biospecimens (Peloquin et al. 2020).

Harmonisation: enabler or hurdle?

A second prominently addressed theme is whether the GDPR is likely to achieve one of its visions, namely to enable the flow of data across national boundaries. Similarly as in the case of the balance between the protection of individual rights and enabling the processing of personal data for scientific purposes, the literature on harmonisation is not conclusive.

Basing their argument on a comparison of national regulatory frameworks of biobanks in Mediterranean and Eastern European, Penasa and colleagues (2018) argued that the implementation of the GDPR might work as a "catalyst for adoptive harmonization of biobanks regulation in the European framework" (242) and lead to a common regulatory framework throughout the EU, so that shared definitions and standards may emerge. This harmonisation is seen as being needed due to the constant flow of data and samples between member states. Penasa et al. (2018) see the GDPR overall as very positive, but are hesitant about one aspect and urge caution in the last paragraph of their paper stressing that

> *"[…] one of the main challenges will arise from Article 9(4) of the Regulation allowing Member States to 'maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health'. Time will tell whether and how Member States will take advantage of this clause, altering the equilibrium struck by the GDPR" (Penasa et al. 2018, 255).*

Others address the ways in which the GDPR might challenge the sharing of data between members of the EU and other countries. In their article Slokenberga et al. (2019) questioned how realistic data exchange between the EU and African countries might be. They looked at data protection laws of African countries to see whether they are up to par with the GDPR. Their main takeaway is the importance of raising the data protection bar in the receiving countries to protect data subjects' privacy. Similarly, van Deursen and Kummeling (2019, 1) identified sharing personal data with China as "challenging at a minimum".

Donnelly and McDonagh (2019) saw the GDPR before a background of rights protected by the Charter of Fundamental Rights of the EU (CFEU) – rights for respect for private life and data protection on the one

hand, and on the other there's the right to healthcare and the freedom of arts and science. The research exemption in the GDPR gives an option to balance data protection against facilitating research – both of which are of societal interest. Thus the authors described the GDPR as a "mixed blessing" (ibid., 97) for health researchers. While data gained for scientific research is exempted from some obligations, the GDPR leaves the details of the exemption to be decided by the Member States – which might result in a continued fragmentation of frameworks. This hinders the existence of a harmonised regulatory framework across the EU and impedes data sharing or research projects across borders – two goals which should have been solved by the implementation of the GDPR. The authors see a not easily achieved solution for this, namely the Member States developing a harmonised framework for the research exemption of the GDPR.

Similarly, Testa and Marelli (2018) noted that whether the GDPR will help to facilitate or hamper harmonisation depends on ongoing and future actions. They underlined the importance of an ongoing initiative spearheaded by BBMRI-ERIC to develop a comprehensive code of conduct for the processing of personal data in health research. Envisioned as "the reference standard in the field", such a code – and thus an instrument of soft governance – could enable "international harmonization in the EU and possibly beyond" (Marelli and Testa 2018, 497).

5.4. Exploring law in action

What, then, can we take away from the literature?

The brief engagement with some spotlights from the emerging body of literature on the impact of the GDPR on biobanks demonstrates that the GDPR governs issues and goods that are highly contentious. Debates on the appropriate balance of values and rights that ought to be taken into consideration in biobanks that have accompanied the emergence of biobanks from their inception seem to continue in often normative and also opinionated engagements with the GDPR.

The inconsistent claims made in the literature also underline that it might be rash to jump to conclusions and to speculate on what the GDPR is, means, or might mean for citizens and biobanks. This point was also underlined by Phillips and Knoppers (2019), who argued that how the GDPR will take form will depend on various interactions, such as the interpretation of courts and national legislations. They see an opportunity and a responsibility for the research community to influence interpretations of the GDPR in a way that balances the right of individuals to control their own data with data sharing and open science.

Building on the insight that the GDPR set on to enshrine a balance between highly contentious values into a blueprint, formulating a number of stepping stones, we will explore how the GDPR is interpreted and materialised in practice. Rather than assuming what the GDPR is, we will explore which differences the GDPR makes in practice, exploring its consequences in the arena of biobanks (Timmermans und Buchbinder 2013).

In so doing, we will take a bottom-up approach, commencing our engagement at local biobanks. We will explore, on the one hand, how the GDPR and the Austrian FOG are interpreted and made to matter at

these specific sites, and how they reconfigure biobank assemblages. On the other hand, it will be essential to better understand how donors conceptualise data protection and the GDPR framing.

In addition, we will be attentive to sites where old and new actors in the biobank arena appropriate elements of the GDPR, foregrounding particular visions of what data and citizenship are and how they ought to be protected.

Last but not the least, we also plan to explore the enactment of the WFSDAG in Austria, as this was a moment in which various actors articulated views on biobanks, the work that they could perform, and how they ought to be governed as a consequence.

6. References

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