Managing access to health data for research and innovation in the EU: is a better regulatory approach possible?

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Abstract

Data, personal data, and health data are critical in developing new technologies and health interventions, but accessing this data is fraught with ethical concerns. The European Union's General Data Protection Regulation (GDPR) and the proposed European Health Data Space (EHDS) regulation seek to provide protection of personal data while enabling access to this data for health research. However, it is questionable whether the current and proposed framework (including the exceptions and derogations within these) adequately balance and protect the breadth of rights, including under Articles 8 and 14 of the European Convention on Human Rights, and interests at stake. This chapter reflects on the competing rights and interests of the differing stakeholders involved in the use of health data for health research purposes. We argue that regulatory frameworks need to account for and engage with these competing motivations and interests, and must also ensure that benefits arising are accessible to stakeholders in an equitable manner. We set out some of these competing interests before considering the GDPR and possible role of the EHDS for the governance of data in the health research context given these considerations. We argue that privacy and re-identifiability are not the only concerns relevant here, and make the case that both regulations fail to fully consider the wider social and ethical concerns in this space. The chapter concludes by reflecting on the limits of both regulations, with proposals for reframing of the system from one primarily focused on individual risk to a system that considers both the individual and collective risks and benefits at stake.

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Introduction

The digital era has led to an unprecedented proliferation of information by and about individual people: we are generating vast amounts of data through our everyday online interactions (from emails to social media activities to our browsing histories) and consumer transactions. Such activities can reveal information about our individual behaviours and preferences, and from this, in some instances, inferences can be drawn about society, or certain groups within a society. Alongside this, third parties (including professional service providers) may need to collect, generate, and store significant digital information about individuals, including sensitive personal data. More specifically, in the health context, data is being generated in a range of digital interactions, including in the context of people's electronic health records, public health prevention, treatment programs, and as part of health research. Such health data can be used for research into human behaviours as well as to uncover insights around the genetic basis of disease. This research has the potential to develop predictive models that improve healthcare decision-making, to develop and improve treatment interventions, as well as drive innovation around developing new health-technologies, such as medicines, diagnostics, medical devices, and other health interventions.[2]

Such research involves significant levels of processing (i.e. collection and various uses) of health data. The collection, use, and sharing of health data is, however, fraught with ethical and legal issues.[3] This includes issues related to the protection of: individual data subjects human rights, including their right to privacy, private family life, and confidentiality, as protected under Article 8 of European Convention of Human Rights (hereafter ECHR), which entails the need for data subjects to be informed about how such data is used and for what purpose to vindicate their broader autonomy interests, and in turn links with concerns related to data protection; and issues of transparency around data use.[4] Moreover, and relatedly, there are risks of data harms for individual health research participants and third parties arising from such research. Such risks have been discussed in detail elsewhere, but include risks of data breaches, data leaks (raising issues under Article 8 ECHR), and individual and group discrimination which also engages rights to non-discrimination under Article 14 ECHR.[5]

Accordingly, new mechanisms have been adopted which seek to deter data uses which could lead to harms and to protect data subjects' rights and interests at stake. This includes oversight bodies such as data access committees (DACs),[6] proposed data trusts,[7] and legal frameworks on the use of data.[8] In the health context, health data that is not anonymous is not only personal data, as defined under the European Union's General Data Protection Regulation (GDPR); it is also considered to be special category (i.e. sensitive) personal data under the law. As such, processing of health data is subject to stricter rules and extra protections must be met.[9] Moreover, since coming into force in 2018, the GDPR has strengthened the protection of personal data in the European Union (EU) and provided rules and procedures that must be followed in the processing of personal data, including the rights of data subjects that must be respected.[10] Like other data protection regulations, the GDPR is a general legal framework and not sector specific (i.e. it is not tailored to the health context). However, due to the importance of research in society, and the concerns that new data protection requirements could have adverse impacts on research, certain exceptions to some of the strict processing requirements were put in place for research contexts. The exceptions and derogations contained in the GDPR have been considered elsewhere in detail,[11] but what is also important to note in the health research context is that there has been a fragmented application to the GDPR in the context of health research across EU Member States. Thus, accessing personal data often requires a complex navigation of differing national approaches.[12] Furthermore, uncertainty in the application of some of the provisions in the health research context, and concerns about potential fines,

has resulted in (some instances) an overly cautious approach to data protection, leading to claims that it is hindering the sharing of personal data for health research purposes.[13] Herein lies a key tension around data within the health research context: although individual rights and interests can be implicated by data breaches and data harms, health research may be hindered by lack of access to relevant health data. Moreover, a lack of data can impact diversity in available datasets,[14] our understanding of health, and the types of health-technologies (including medicines, vaccines, etc.) that may be developed, with knock-on effects for individual people's health which can also impact individual human rights, up to and including, in some cases the right to life (Article 2 ECHR), and collective societal interests in maximizing health benefits and understandings.

To address some of the problems with the GDPR and to improve the European digital environment, including to balance interests of individual data subjects with collective interests of society in making relevant data available for health research, a number of legislative initiatives have been introduced as part of the European Strategy for Data. This is a strategy that is aiming to make Europe a leading player in the data economy.[15] This includes the Data Governance Act, which seeks to increase trust in data sharing, increase data availability, and overcome technical obstacles to data sharing.[16] The Data Governance Act is focused on facilitating the reuse of data held by the public sector, but it is not just public sector data that can be accessed for research and innovation, with the European Parliament estimating that 80% of industrial data is not used, due to low trust in data sharing, conflicting economic incentives, and technological obstacles.[17]

To encourage data sharing in the health space, a draft regulation for a European Health Data Space (EHDS) was introduced by the European Commission in May 2022. The EHDS is part of the Commission's ambition to build a strong European Health Union through realizing the potential that electronic health data holds for the economy and for the realization of healthcare benefits.[18] In part to address some of the problems that have arisen from the fragmented application of the GDPR at a national level in the context of research and innovation, the EHDS proposes to introduce one legal framework across the EU to enable access to electronic health data for eight specified purposes. These are purposes that have been identified as benefiting society: "such as research, innovation, policy-making, patient safety, personalised medicine, official statistics or regulatory activities" (Recital 1). The ambition of the EHDS is that by introducing one legal framework applicable to all Member States, it will address some of the elements of the GDPR that were perceived as hampering data sharing.

A framework that provides a harmonized approach to accessing personal data is undoubtedly needed, and depending on its final form, should improve Europe's competitiveness in data-driven research and innovation. However, the evolving regulatory landscape requires frameworks that enable research and innovation in a manner that adequately protects personal data, while also considering some of the other important individual and collective rights and interests at stake. This includes the rights to privacy, autonomy, and non-discrimination, and the collective/individual interests in the right to health, and societal interests in enabling access to any downstream benefits of the research developed. As we argue in this chapter, data governance in the health research context should be grounded in processes that consider and balance all the relevant rights and interests at stake. This requires a careful balance to be struck between individual and collective interests, and consideration of the interests of a range of different stakeholders.

Given the emerging nature of the EDHS at the time of writing,[19] and ongoing advances within the digital health space in Europe, it is useful at this juncture to assess the GDPR and the proposed EHDS to determine whether and to what extent they are adequately engaging with and balancing the competing rights and interests that are at stake in the collection, use, and sharing of data for health research and innovation purposes. This chapter focuses on these issues, examining specifically whether and to what extent the current and proposed data regulatory frameworks in Europe for the use of health data for research and innovation adequately engages with and balances the range of key rights and interests at stake.

In what follows, we set the scene by providing an overview of the key rights and interests in health research with reference to five key (in some instances overlapping) actors or stakeholders involved bearing rights and interests, namely research participants, patients, researchers, national governments, and industry. It argues that there are a range of competing interests at stake which will impact parties' views and interests in how data is accessed, shared, and used downstream. Following this, we provide an overview of the current GDPR framework and the key elements of the proposed EHDS. Although the Data Governance Act will impact access to data, due to constraints of space, and due to their more specific impact on the use of data in the health space, we confine our focus here to the GDPR and the proposed EHDS. We then critiques the current and proposed framework under the GDPR and proposed EHDS, arguing that the current risk-based approach to data sharing underpinning the GDPR and EHDS fails to fully engage with the range of interests at stake that have been outlined in the chapter, and in particular, with the broader collective interests at stake. We then conclude by arguing that a new data sharing framework is needed, but there needs to be greater engagement with the breadth of competing rights and interests at stake in this context if we are to deliver a sustainable and functional landscape for health research in the digital age.

Rights and interests relevant to personal data uses in health research contexts

Health research is critical in society. It can offer insights which improve diagnosis, treatment, and prevention of illness. It can also contribute to and improve health innovation around the development of new health technologies. Relatedly, fostering health research sectors can play a key role in contributing to employment, industry, and the broader economy. Thus, health research and research-enabling processes can be an important feature of a bioeconomy. As such, there are a considerable number of stakeholders involved in health research, including: patients, research participants, researchers, academic institutions, research centres, healthcare professionals, regulators, policy makers, industry, employees, and the wider public. These stakeholders have a range of (often) competing rights, interests, and motivations around data access, use, and sharing. For example, research participants may make their data available for research due to altruism and the desire for health technologies to be developed that will improve health outcomes for all;[20] patients may be motivated so that therapies can be developed to benefit their individual health or others; researchers can be motivated by a range of factors, including with the aim of contributing to science and public good, contributing to the improvement of health, and also to advance their own career via published research, patents or funding, etc.[21] For industry, employees, and government, alongside potential public interest motivations in terms of generating better health outcomes, they may also have commercially orientated motivations including leveraging health research in particular areas as a means to maximize profitable activities, for example via its use in the development of new health technologies, which in turn can result in patents and other intellectual property rights,

generating increased profits, increased tax revenues, and new industries, and to contribute to a lower unemployment rate.

Considered in this light, it is thus unsurprising that it is often claimed that health research is needed to facilitate the "public interest" given the range of health benefits, societal benefits, and private sectors benefits that can arise. However, "public interest" as a concept is undefined and arguably confuses the discourse in discussions of health data, as "public interest" is a legal basis on which to process personal data within the European data protection frameworks. Nonetheless, while not advocating for the use of the term, if we take public interest—in terms of its broader general conception—as something that could improve individual and public health while also improving the overall economy, it quickly becomes clear that there are a range of competing interests and aims at stake in the health research context that may be in tension with each other. Indeed, broad claims that research is in general in "the public interests" is contested and fraught with challenges, no less in defining what is meant by the "public" or what the "public" interest is.[22] Not only are there are different groups within society at a national and regional level that we have pointed out, but also at a global level who have different (at times competing) interests or priorities in the development of, and downstream access to, health data, health research, and/or new technologies developed via health research.[23] Given such issues, there has been a shift away from considering "the public" as a separate entity to an understanding that "the public" is composed of many "publics".[24] Knowing "the public" to whom the research pertains to is critical, as it is a key factor to determine the risk and benefits of any potential health research activities.[25] In short, differing publics have diverse needs and interests, and these needs and interests can compete against those of other publics.[26] We further expand on some of the publics in health research to demonstrate our point.[27]

In the health research context, at least five key "publics" can be identified with their own rights and interests which need to be carefully considered and balanced in any effective system for the regulation of health data for health research purposes. This section takes each of these five categories in turn in order to highlight the key rights and interests at stake which must be balanced. In doing so, we also see the ongoing tension between parties who may favour data sharing and openness in use of data, and those who may not favour data sharing (for a range of reasons) or secondary uses, and differing considerations which may apply depending on the context for individual and societal interests.

First, there are the research participants who may provide data and/or biospecimens for health research and whose Article 8 ECHR rights are engaged in providing health data and in participating in health research.[28] By participating in health research, a range of individual participant rights are implicated, including participants' rights to autonomy in being provided with adequate information about the research and their ability to give informed consent, right to privacy around use of their data and biospecimens, and right to data protection around use of data collected or derived related to their health and person can be engaged—rights that as noted are protected under Article 8 ECHR. Such participants will likely be concerned with the mitigation of any potential data harms in the use of their health data in research which in some instances may lean in favour of restrictive uses of data, but also that their contribution is given maximum effect via the use and sharing of such data (within the confines of the permission they give) in the health research context.[29] Second, and relatedly, patients may have an interest in the development of new health technologies arising from health research (whether they participate in this research or not), but they will also have an interest in ensuring such technologies, once developed, are accessible and available to them and others.[30] Research participants may in some cases also be patients or may have family members who are patients. Thus, such participants may have an interest in both how their personal

data are used (Article 8 rights), and in how any downstream knowledge or technologies, if developed via such research, are accessed and made accessible.[31] Patient interests in access to health-technologies may also engage the right to health, and right to life (Article 2 ECHR), such as where a patient is suffering from a terminal condition and requires access to life-sustained or curative healthcare. Again, for such patients, their interests will be around supporting the maximization of data use (in a safe manner) within the health research context, while ensuring accessibility of the downstream benefits such as technology and scientific knowledge developed.

Third, national governments have an interest in supporting health research that improves the public health of its population, thereby improving overall societal wellbeing and reducing economic burdens on the national state. Governments also have an interest in supporting strong health research systems by encouraging innovation with potential knock-on benefits for the national economy, employment, and so on. The realization of these aims will require crafting policies that provide for data openness and incentives for industry involvement in research and development. However, governments also have an interest and duty to protect individual citizens and to mitigate against individual and group data harms which may arise in the health research context,[32] and which can impact trust in the health data sharing landscape with knock-on effects for societal trust and participation in health research more generally. Thus, governments must take a nuanced and balanced approach to data sharing and data use and ensure that regulatory frameworks embed systems that manage risks of data harms when promoting data sharing as far as possible while also enabling the system to be workable for health researchers, and alongside this maintaining equity of benefits.

Fourth, researchers have an interest in research to develop healthcare benefits which many scientists may be intrinsically motivated by. Successful health research outcomes may also further their career, either for example, via publications or being named as an inventor on patent applications, which may arise from technologies developed and contributed to by such research. Being awarded and attaining patents (or being named as inventor on such patents) and publications are key facets within many academic promotion systems and can enable better employment prospects in industry contexts. Moreover, depending on the context where new technologies from health research are developed—and the applicable intellectual property rights (IPRs) and employment policy in place (see below)—researchers may in some instances share the potential IPRs over technologies developed, and profits arising. In such cases, researchers will often have an interest in obtaining access to secondary data to further develop their own research. However, the originality of insights for academic publishing and the "novelty" of an invention is a requirement for a patent applications; hence, researchers may also in some instances have an interest in not openly sharing data until the point of publication or prior to patent grant/application. If they share data with other researchers for a secondary use or otherwise for other projects, they may be concerned that others could achieve the outcome they are working on first. Hence, a range of competing interests around data sharing and openness are at stake and must be carefully mediated.

Fifth, in terms of the role of industry, currently health research is often conducted within a private industry context or within public-private partnership settings. Industry has an important role to play in research in the current health innovation landscape, particularly in the translation of research to therapies. In many cases the early-stage research may be conducted within a university context or a university-company partnership, while the translational stage, given in part the high costs and resources needed, often takes place within industry settings. In such cases, generally companies will hold IPRs over health technologies developed, as employment contracts usually provide—unless modified by prior negotiation—that any IPRs

created in the course of employment will be held by the employer (e.g. the relevant company or university). Such IPRs allow the rightsholders to exclude others from use of an IP-protected technology, unless that third party obtains a licence from the rightsholders. Hence, rightsholders (including companies and industry more generally) can use IPRs to develop an income stream from technologies developed and have a strong financial interest in investing in health research where it is likely to lead to a new health technology. Such entities may also have a preference to gain access to data under secondary uses where this would assist their researchers to develop new technologies, but they may prefer not to share data with other groups where to do so would enable such groups to achieve outcomes they may also be working on. For such reasons, again within the industry context, a complex picture emerges and there are likely a range of competing interests or concerns around secondary use of data, around data sharing, and around sharing or openness in the knowledge produced via such health research.

All the forgoing rights and interests are important and in vibrant bioeconomy, but it is critical that they are balanced with each other so that one does that supersede another. As research evolves, so regulations must evolve, ensuring balance between these competing rights and interests must be maintained. Changes to regulatory structures are necessary at times. For example, the emergence of biobanks, genomics, and data-driven medicine has resulted in changes to consent models and oversight mechanisms, such as DACs.[33] Artificial intelligence (AI) and its application to health is now requiring ethical and legal reflection, and the proposed Artificial Intelligence Act will impact this space.

The advent of other new technologies will likely lead to a continued need for our research regulatory processes to adapt and evolve. Indeed, it is critical that the regulation of research is dynamic, evolving in line with developments in science and technology, and aims to balance the competing interests that arise in research. With this in mind, and the impact of the GDPR and likely impact of the EHDS on the regulation of research, we now consider the GDPR and the EHDS in the context of health research, prior to critiquing these regulatory initiatives in light of the foregoing observations below to assess the extent to which the current and proposed frameworks adequately balance the range of stakeholders interests and rights we have observed in this section.

The GDPR and EHDS: key principles and processes

The GDPR sets out the six principles that must be met in the processing of personal data: lawfulness, fairness, and transparency; purpose limitation; data minimization; accuracy; and storage limitation. It sets out the rights of data subjects in the processing of personal data and other procedures that must be followed in the processing. Overall, the GDPR takes a risk-based approach to the processing of personal data with tools contained within it to mitigate against that risk.[34] The purpose of the GDPR was to provide a harmonized framework to the processing of personal data. Due to concerns about the impact some of these strict processing requirements would have on research, certain derogations and exemptions are provided for either by directing invoking the provisions of the GDPR, or through Member State law.[35]

These derogations for research are critical, particularly in data-driven research that is reliant on accessing and using vast quantities of data and data sharing. Despite this, we share the concerns expressed by many others about the potential impact that the derogations have had on research participants' rights and on research. These issues have been covered in depth elsewhere,[36] but the main concerns are worth summarizing here.

First, the provisions enabling Member States to provide for derogations to research has resulted in well-documented criticisms of the fragmented application of the GDPR for research. This has resulted in a multitude of differing approaches to the protection of personal data for research across the EU Member States, a situation that is making data sharing even more challenging.[37]

Second, the GDPR provides considerable rights for data subjects, which includes rights to being informed when their data is processed, having a right to object, or a right to restrict the processing of their personal data. These rights are essential for a participant to exercise their autonomous choices on how their data are used (and fulfil their Article 8 ECHR rights), particularly when consent is not the lawful basis for processing. Without these rights, a data subject will be left in the dark as to when and for what purpose their data is being used. The GDPR provides that a data controller can exempt themselves from upholding these rights if the processing is for research purposes.[38] Importantly, if the personal data is not being collected from the data subject directly, a data controller can be exempted from the right to information (Article 14(5)(b)). As a result, in such instances, a data subject will be unaware that their data has been collected and is being used for research, irrespective of whether the personal data was collected for research or some other purpose at the time of initial collection. Without knowing that their personal data is being processed, a data subject cannot exercise any of their rights under the GDPR. This right to information is thus essential to the exercise of their other rights.[39]

Third, although the GDPR is not a research regulatory framework, it is *de facto* treated as such. It has come to be a key framework and shaped how data is processed, used, and shared not only for research within the EU, but also for researchers outside the EU who work with the EU framework and EU-based data.

EHDS – Proposals on Secondary Use of Data

Alongside these existing criticisms of the GDPR, significant changes have been proposed to the secondary use of electronic health data under Chapter IV of the EHDS, which also give rise to concerns. If the EHDS is passed in the form currently proposed, it will create a legal obligation to share electronic health data if certain conditions have been met. Slokenberga has comprehensively critiqued the proposed legal framework,[40] and Staunton et al. have critiqued the proposed framework from a bioethical perspective,[41] but certain key points are worth mentioning here. Under the proposed new framework, any natural or legal person can apply for access to the electronic health data (called a "data user") from a data holder ("any natural or legal person, which is an entity or a body in the health or care sector or performing research in relation to these sectors"). Electronic health data is broadly defined and includes electronic health records, genetic data, and population-based health data. This electronic health data may be personal data (and thus fall under the GDPR) or anonymous data (and thus outside of the GDPR). Interestingly, considering that governance mechanisms that have been adopted by biobanks and databanks (such as DACs discussed above to decide on access) have been *communicated* to their participants, the proposal takes the decision on assessment and access to the electronic health data from the data controller (as would likely be the case under the GDPR) or data holder, and places it in a new independent body called a Health Data Access Body (HDAB), with a HDAB to be established in each Member State.

The draft EHDS sets out the criteria to be met in an access request to the HDAB: an application must detail the purpose of the data use; description of the requested data; a justification if pseudonymized data is requested; (undefined) safeguards to prevent unauthorized use and the rights and interests of the data holder and natural persons; an estimated time period the data is required; and details on a secure

processing environment. If the application requires access to personal data, applicants must provide details on how the processing complies with the GDPR. Article 44 of the draft EHDS also makes it clear the importance of data minimization and purpose limitation in the HDAB's assessment. Finally, an applicant should also provide information on any applicable ethical aspects. These ethical aspects are undefined but most likely relate to national ethical requirements.

The draft EHDS requires the HDAB must make an assessment within two months of receiving an application, a time limit that can be extended by two months for complex applications. Once an application is approved by a HDAB, a data permit is issued specifying the terms and conditions of the data use. The data holder must make the data available to the data user within two months through a secure processing environment.

The draft EHDS aims to streamline access to electronic health data for many purposes by introducing one legal framework with the same rules and processes to be followed in accessing electronic health data. As discussed, under the GDPR the right to information (and the resulting impact on other rights) can be derogated from if the processing is for research purposes. Under the EHDS the derogation of this right to information has been extended to the other purposes for which electronic health data can be accessed for the secondary use of data. The extension of this derogation (and other issues) has been criticized by the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS). Their joint opinion on the EHDS states that the extension is unjustified, and this and many proposals under the draft EHDS that do not conform with the GDPR.[42] More recently, the European Parliament in its report on the draft EHDS recommends the introduction of an opt-out for natural persons so that they can decide to opt out of the use of their electronic health data for any secondary purpose that they did not want their data processed.

Balancing rights and interests: a critique

Having briefly set up the legal framework for the GDPR and the proposed EHDS, we now turn to consider these frameworks, examining the extent to which they adequately balance the risks of data harms and individual privacy interests with collective and individual interests in data sharing for health research. For a range of reasons discussed above, data sharing is critical for data-driven research methods and for the provision of health care. Data sharing promotes transparency and reproducibility, optimizes the use of a valuable resources, and enables meta-analyses.[43] Moreover, it is well recognized that there are biases in datasets.[44] It is critical that data from unrepresented populations are shared to begin to correct bias in our current datasets, to enhance the generalizability of research findings across populations, and to begin to address health disparities. If we do not have regulatory frameworks in place that enable data sharing, downstream products may only be applicable to populations coming from research regulatory environments that provide for data sharing. It is not, however, enough for regulatory frameworks to enable data sharing; instead, such frameworks must embed ethical, legal, equitable, and socially and culturally appropriate data sharing. By this we mean data sharing that responds to ethical concerns, is appropriate to the specific cultural contexts, and that there is equitable access to the data, and to the use of the data, and reasonable and appropriate equitable access to downstream technologies arising from uses of data.

However, a key concern in this context is that as the GDPR and the EDHS were developed distinct from research regulatory frameworks; they do not necessarily engage with or appropriately balance the competing rights and interests between the individuals and collective rights and interests in the health

research context. This is particularly problematic as the GDPR (and likely that the same will arise for the EHDS) has become a *de facto* research regulatory framework. In particular, we highlight three key concerns in relation to how the GDPR and proposed EDHS frameworks will impact the rights or interests of stakeholders in health research: i) there is a focus on data protection and risk-based protections for individual data subjects against data harms, but limited consideration of other rights such as individual's right to autonomy over how their data are used, and individual interests and rights in data sharing to secure health benefits; ii) there is limited focus on the rights or interests of the *collective*, such as groups within society, around how data may be used or risks of discrimination to such groups; iii) there is also a limited engagement in relation to how industry or other data users may use or share data, and relatedly, limited focus on how resulting knowledge or findings generated may be accessible and shared with the public, due to the competing interests at stake in these contexts.

A risk-based legal framework primarily concerned with data protection: need to consider data subjects' broader rights and interests

The GDPR, and indeed data protection regulations generally, take a risk-based approach to the protection of personal data that are framed around anticipating and seeking to minimize data harms for the individual data subject.[45] Individual data subjects, as distinct from groups or communities, are provided with legal protection. The EHDS continues with this approach in that the focus is on the protection of the individual, and the individuals' data protection rights. They do not consider data harms that can occur beyond data protection, nor do they account for the data harms to groups and communities. The GDPR and the EHDS also do not account for the context in which data is used. In other words, who is using the data, for what purpose, the application of AI to the data use, or the linking of data. Frameworks that seek to provide protection from data harms must consider potential data harms broadly, the potential for harm beyond the individual, and the fact that data harms are often context dependent.

This chapter is not seeking to diminish or detract from the important rights and processes introduced by the GDPR, but in the health research context, this individualistic risk-based framing is problematic, particularly considering the GDPR's (and other data protection regulations') influence on the regulation of health research. The focus within the GDPR is on the protection of personal data and not the other rights and interests at stake. Under the GDPR, the further processing of personal data can be permitted without informing the data subject, under the derogations provided by the GDPR, if personal data is not collected directly from the data subject and it is to be used for scientific research and subject to appropriate safeguards. This is justified due to the important value of research in society and that the use of personal data for research is subject to safeguards under Article 89 GDPR.[46] A data subject's right to autonomy is limited in this context, but it is considered justified, proportionate, and subject to safeguards.

Similarly, under the proposed EHDS, the focus is on ensuring that electronic health data is accessed in a manner that ensures that it meets data protection standards. The proposed opt-out of data uses is critical for providing natural persons with some control over the use of their electronic health data, particularly as electronic health data may be used for a purpose and by an entity beyond which they have provided their consent.[47] For example, would a patient in a public health system expect that their data be accessed and used by a commercial for-profit company to develop and train AI? Without an opt-out, the balance of interests in the proposed legislative framework is arguably too heavily weighted towards providing access to the data, without due consideration of the individual autonomy rights (including those under Article 8

ECHR) and interests around how their data will be used and by whom. An opt-out would go towards rebalancing these competing interests.

This is important as attitudes towards data sharing vary according to the context in which the data takes place: the purpose for which data is being used and who is using the data.[48] For example, there is evidence that members of the public can be wary of commercial involvement in health research.[49] We cannot simply ignore these differing perspectives and seek to address it by introducing a legal framework that creates an obligation to share data. Experience elsewhere has shown us that legal legitimacy alone is never enough.[50] Legal legitimacy does not equate to a trusted governance. Thus, in addition to legal frameworks, there must be mechanisms, such as accountable and transparent procedures on data use, public and community engagement, and other initiatives that can promote the integrity of the data lifecycle and strengthen the social licence for the use of the data.

Yet in making this point, we acknowledge that if all individuals who provide health data for research purposes are given a right to autonomy over how data is used, depending on scope of such rights, and how they choose to exercise these, this could hinder health research. For example, if following the collection of personal data from a person which is subsequently included within and processed as part of a larger dataset, and that individual at a later stage requests removal of all data: a) depending on the context removal of data may be impracticable; and/or b) may impact the usability of the other data in the dataset (which may affect other data subjects' autonomy and other interests over how their data is used). Hence, a balanced approach must be adopted, with proportionate restrictions which may need to provide for derogations on the right to autonomy, for the benefit of collective interests. A narrow individualistic view could be to the detriment of the collective interests, as if too many individuals refuse to share their data, this could introduce bias into the dataset, or the data may lose its value. On the other hand, if we require the sharing of the data due to the public value or collective interests in sharing the data, without respecting the autonomous decision of an individual, this could damage trust in the governance. A nuanced consideration of such issues is needed to adopt an appropriate balance of the rights and interests at stake here.

Need to consider collective risks of discrimination of certain groups which may arise due to secondary use and data sharing

Beyond the right to autonomy, data use also brings the risk of discrimination and stigmatization of certain groups. Such risks can pertain to the individual but are also a risk for the collective community from which the data comes. However, under the GDPR and proposed EHDS, there is no focus on the collective interests at stake. Data access oversight mechanisms, such as DACs, do often take these collective rights and interests into account as they can consider the importance of the research to the community, and the risk to discrimination and stigmatization. But what future do they have under the proposed EHDS? It is the HDAB that sets out the rules for data access, determines access, processes applications, issues data permits, and makes the data available to a data user in a secure processing environment. The HDAB will be made available and the results or outcomes of projects that arise from the secondary use of electronic health data under the EHDS (Article 38(1)). Should the HDAB be made aware by a data user of a finding that may impact the health of an individual, they *may* (but are not obliged to) inform the natural person. The HDAB are also required to publish an annual report under Article 39, and this will include the "number of digital health products and services, including AI applications, developed using data accessed via EHDS". Thus, many of the responsibilities of a DAC now fall under the HDAB. More importantly, there seems no

scope for a DAC to be involved in decisions on access. If a HDAB will soon have this power, it is critical that interests other than the individual data subject's data protection rights are considered and at a minimum, we need to consider the risk of discrimination and stigmatization. Staunton et al. have previously called for an integrated bioethics approach to data protection.[51] Considering the potential power of the HDAB on data access, it is a call that we would reiterate and apply to the EHDS as well.

Limited oversight around how other legal protections may impact sharing of data: the competing interests at stake?

Moreover, as noted, one of the rationales around the proposed EHDS is to enable increased ease of data sharing to maximize health research benefits that may arise from this. For instance, the EHDS imposes obligations around secondary use and access to data; however, it is not clear how this will interact with other legal protections in place, including with various intellectual property rights (IPRs) which may be applicable over relevant datasets or compilations developed from individuals' data. For instance, in some cases, the value of data will be the knowledge or insights gained by the collation of datasets gathered together. Moreover, while there is no IP in data per se,[52] compilations or collections of data, knowledge generated using data from multiple participants, or certain aspects of findings resulting from the processing of people's data may be protected by IPRs. It is plausible that IPRs could be in tension with current discussions around mandating obligations for entities to share data under secondary uses of data provisions within the proposed EHDS. Accordingly, it is questionable how the EHDS's right to information will apply to this area, or whether entities will be able to exert their IPRs to refuse to share this data and in what contexts. The role of IPRs in this and related contexts may also have a very real impact on individuals' autonomy interests over how data they provide, or which relate to them are used and for what purposes, and over downstream access they (and others) may have over knowledge and other benefits that may arise from health research.

For example, a *sui generis* database right exists in Europe which offers certain protections to collections of data collated from multiple sources in a database (such as potentially in the genetic database context); the exercise of this right may potentially conflict with requests to share certain data to third parties.[53] Other IP rights may also apply; for example, trade secrets may be applicable over insights or knowledge gleaned via use of data which are kept confidential by the entity processing the data. It is not clear how potential tensions between entities holding IPRs over such knowledge or related aspects to such data, and the discussions around secondary uses of data, will be resolved under the EHDS. There is already criticism from industry around proposals for the general right to information for third parties and how this may impact their IPRs and other commercial interests related to data.[54]

Indeed, Article 33(4) of the EHDS anticipates such tensions and currently states that:

> **Electronic health data** entailing protected intellectual property and trade secrets from private enterprises shall be made available for secondary use. Where such data is made available for secondary use, all measures necessary **to preserve the confidentiality of IP rights** and trade secrets shall be taken. (emphasis added)

The first line of this article appears to suggest that even where IPRs apply, companies will have an obligation to disclose such health data for secondary uses. However, it is not clear how this provision would operate in practice. Moreover, if the intention is that IPRs could not impede sharing of data, there is potential that the last sentence could undermine this aim as it suggests confidentiality will be preserved.

In practice, depending on how a provision like this were to be adopted or interpreted, it could water down the potential benefit of the provision in terms of open sharing of information for secondary uses in the health research context. For example, it could lead to data being shared but only when redacted in some contexts, and this could limit the usefulness of secondary use provisions.

Moreover, a related but separate issue in term of IPRs and use of data for health research is that IPRs, including patents, will often arise over health technologies such as new medicines which may be contributed to by data provided for health research purposes. Such IPRs over medicines (and other health technologies) give rightsholders the ability to exclude third parties from use of the technology under patent (e.g. medicines) for the duration of the patent term, which is generally 20 years. Patents allow rightsholders to decide how patented technologies can be used and by whom during this term, and this in turn can impact how the publics can access and use such technologies,[55] with implications for right to life and health in some cases.

Moreover, the role of IPRs over technologies contributed to by health research can create tensions. For example, as one of us has discussed elsewhere, even where individuals provide data and biospecimens for use for health research purposes in an altruistic manner to publicly funded biobanks, where their motivation in provide such samples or data may be to contribution to public health, there are no binding European legal obligations mandating that downstream technologies that may be developed are publicly accessible, or that such individuals be informed of the potential impacts IPRs could have on access to technologies that may be developed downstream. This can give rise to a range of bioethical implications.[56] Within such data governance frameworks, there is often a lack of engagement with how benefits generated via research using participants data (or contributed to by such data) will be accessed by such participants and the broader publics. The result can be that although current data protection frameworks seek to ensure that individuals are protected from data harms that may arise at an individual level, there is limited consideration around the interests and rights of individuals have in being able to share in the technological benefits generated by the knowledge gleaned from use of their (and other publics') data. This warrants deeper consideration in terms of how we can best balance private and public interests in such contexts. Such issues also impact broader collective interests, including various publics' right to access the benefits from scientific knowledge, with knock-on effects on population health needs, and for public health systems more generally. Moreover, while a balance must be delivered which engages with various publics interests, needs, or rights and commercial incentives to participate in and conduct health research in such contexts, the lack of engagement with such issues in the health research context, including in the current EDHS discussions around data use and sharing and secondary use of data, should be revisited.

Concluding thoughts: a pathway towards a European Health Data Framework to balance the competing interests at stake?

A new data sharing framework approach is needed for health research in the digital data driven age. It is essential for the promotion of science, but also to meet individual and public health needs. A new regulatory framework, however, must strive to balance the competing rights and interests of the range of different stakeholders within the health innovation and research landscape. This is a complex task given the range of stakeholders and publics implicated in such contexts, and requires a nuanced approach. The draft EHDS is attempting to push the data sharing agenda forward. However, the current proposal is doing

so with a focus primarily on data protection and re-identification as the key concerns. Similar to the GDPR, it is primarily a risk-based approach which focuses on privacy and data protection concerns—one that does not sufficiently account for the need to ensure we also engage with other interests at stake, including the right to autonomy of data subjects in how data may be used for secondary purposes, within what contexts, and by whom. This also connects with the collective interests in ensuring and maintaining trust within the data governance context. Moreover, the current GPDR and proposed EDHS frameworks also do not sufficiently engage with the equity of benefit in downstream access to therapies and knowledge generated or contributed to by health research and participants' data.

A more holistic approach is needed—one that is underpinned by transparency and by respect for individuals and a broader range of communities and publics involved—which seeks to maximize the benefits from health research that may arise, without disproportionately affecting or harming individuals and the collective interests at stake.

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[2] For an overview of some of the potential benefits that data has in the health context, see Charles Auffray and others, "Making Sense of Big Data in Health Research: Towards an EU Action Plan" (2016) 71 Genomic Medicine 1, 3; Javier Andreu-Perez and others, "Big Data for Health" (2015) 19 IEEE Journal of Biomedical and Health Informatics 1193, section II; Aisling McMahon, Alena Buyx, and Barbara Prainsack, "Big Data Governance Needs More Collective Responsibility: The Role of Harm Mitigation in the Governance of Data Use in Medicine and Beyond" (2020) 28 Medical Law Review 155, 158-159; Roberta Pastorino and others, "Benefits and challenges of Big Data in healthcare: an overview of the European initiatives" (2019) 29 European Journal of Public Health 23; Israel Júnior Borges do Nascimento, "Impact of Big Data Analytics on People's Health: Overview of Systematic Reviews and Recommendations for Future Studies" (2021) 23 Journal of Medical Internet Research e27275; Xiaoming Wang and others, "Big Data Management Challenges in Health Research—a Literature Review" (2019) 20 Briefings in Bioinformatics 156; Mark Walport and Paul Brest, "Sharing Research Data to Improve Public Health" (2011) 377 The Lancet 537.
[3] Evelyn Anane-Sarpong and others, "Application of Ethical Principles to Research Using Public Health Data in The Global South: Perspectives from Africa" (2018) 18 Developing World Bioethics 98; Angela Ballantyne and G Owen

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[4] Laura J Damschroder and others, "Patients, Privacy and Trust: Patients' Willingness to Allow Researchers to Access Their Medical Records" (2007) 64 Social Science & Medicine 223.

[5] Forzano and others, n 3; Yann Joly and others, "The Genetic Discrimination Observatory: Confronting Novel Issues in Genetic Discrimination" (2021) 37 Trends in Genetics 951. For a discussion of potential harms that may arise via uses of data within algorithmic systems, see Joanna Reddan and Jessica Brand, "Data Harm Record" available at: https://datajusticelab.org/data-harm-record/; McMahon and others, n 2, 158-160.

[6] Cheah and Piasecki, n 3.

[7] Sylvie Delacroix and Neil D Lawrence, "Bottom-up Data Trusts: Disturbing the 'One Size Fits All' Approach to Data Governance" (2019) 9 International Data Privacy Law 236.

[8] Santa Slokenberga, "Scientific Research Regime 2.0? Transformations of the Research Regime and the Protection of the Data Subject That the Proposed EHDS Regulation Promises to Bring Along" (2022) 2022 Technology and Regulation 135; Staunton and others, n 3.

[9] Ciara Staunton, "Individual Rights in Biobank Research Under the GDPR", in Santa Slokenberga, Olga Tzortzatou, and Jane Reichel (eds.), *GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe* (Springer 2021), 91-104.

[10] ibid.

[11] Santa Slokenberga, Olga Tzortzatou, and Jane Reichel (eds.), *GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe* (Springer 2021); Luca Marelli, Elisa Lievevrouw, and Ine Van Hoyweghen, "Fit for Purpose? The GDPR and the Governance of European Digital Health" (2020) 41 Policy Studies 447; Kärt Pormeister, "Genetic Data and the Research Exemption: Is the GDPR Going Too Far?" (2017) 7 International Data Privacy Law 137; David Peloquin and others, "Disruptive and Avoidable: GDPR Challenges to Secondary Research Uses of Data" (2020) 28 European Journal of Human Genetics 697; Ciara Staunton, Santa Slokenberga, and Deborah Mascalzoni, "The GDPR and the Research Exemption: Considerations on the Necessary Safeguards for Research Biobanks" (2019) 27 European Journal of Human Genetics 1159.

[12] Slokenberga and others, n 11.

[13] Peloquin and others, n 11; Marelli and others, n 11.

[14] Segun Fatumo and others, "A Roadmap to Increase Diversity in Genomic Studies" (2022) 28 Nature Medicine 243.

[15] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – A European strategy for data' (COM(2020) 66 final), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0066.

[16] Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) (Text with EEA relevance), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0868.

[17] European Parliament, "Boosting data sharing in the EU: what are the benefits?" (6 April 2022), available at: https://www.europarl.europa.eu/topics/en/article/20220331STO26411/boosting-data-sharing-in-the-eu-what-are-the-benefits.

[18] The explanatory memorandum to the EHDS states: "The EHDS will create a legal and technical environment that will support the development of innovative medicinal products and vaccines, and of medical devices and in vitro diagnostics. This will help to prevent, detect, and rapidly respond to health emergencies. In addition, the EHDS will help to improve understanding, prevention, early detection, diagnosis, treatment and monitoring of cancer, through the EU cross-border secure access and sharing between healthcare providers of health, including cancer related data of natural persons. Therefore, by providing secure access to a wide range of electronic health data, the EHDS will open new opportunities for diseases prevention and treatment of natural persons."

[19] February 2024.
[20] By "health-technologies", we are referring to a wide range of technologies, including medicines, diagnostics, medical devices, and vaccines.
[21] David Carr and Katherine Littler, "Sharing Research Data to Improve Public Health: A Funder Perspective" (2015) 10 Journal of Empirical Research on Human Research Ethics 314; Winner Dominic Chawinga and Sandy Zinn, "Global Perspectives of Research Data Sharing: A Systematic Literature Review" (2019) 41 Library & Information Science Research 109; Anna Middleton and others, "Global Public Perceptions of Genomic Data Sharing: What Shapes the Willingness to Donate DNA and Health Data?" (2020) 107 The American Journal of Human Genetics 743; Roberta Biasiotto and others, "Public Preferences for Digital Health Data Sharing: Discrete Choice Experiment Study in 12 European Countries" (2023) 25 Journal of Medical Internet Research e47066.
[22] See discussion of the contested nature of the "public interest" as a concept in Annie Sorbie, "The Public Interest", in Graeme Laurie and others (eds.), *The Cambridge Handbook of Health Research Regulation* (Cambridge University Press 2021), 65-72. See also John Bell, "Public Interest: Policy or Principle?" in Roger Brownsword (ed.), *Law and the Public Interest: Proceedings of the 1992 ALSP Conference* (Stuttgart: Franz Steiner Verlag 1993) 27–36; Annie Sorbie, "Sharing Confidential Health Data for Research Purposes in the UK: Where Are 'Publics' in the Public Interest?" (2020) 16 Evidence & Policy 249.
[23] For example, in the COVID-19 context, in early stages of the pandemic there were limited global supplies of COVID-19 vaccines available—and given the way the applicable intellectual property and technology transfer issues played out in practice—national States and regions competed with each other for first access to such vaccines. See discussion in Aisling McMahon, "Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance" (2021) 47 Journal of Medical Ethics 142.
[24] Ulrike Felt and Maximilian Fochler, "Machineries for Making Publics: Inscribing and De-Scribing Publics in Public Engagement" (2010) 48 Minerva 219; Sara Chandros Hull and David R Wilson (Diné), "Beyond Belmont: Ensuring Respect for AI/AN Communities Through Tribal IRBs, Laws, and Policies" (2017) 17 The American Journal of Bioethics 60.
[25] Sonja Erikainen and others, "Public Involvement in the Governance of Population-Level Biomedical Research: Unresolved Questions and Future Directions" (2021) 47 Journal of Medical Ethics 522.
[26] The public interest as set out in data protection law does not take such a granular approach to considering the differing publics and their differing interests. In considering the public under the GDPR and its interests, the public is seen as a monolithic entity, thus not reflecting the reality that what is in the interest of one public is not necessarily in the others.
[27] Acknowledging that there are differing publics with competing interests should cause us to re-consider the legal concept of public interest, but this is beyond the scope of this chapter.
[28] Article 8(1) of the European Convention on Human Rights stipulates that "Everyone has the right to respect for his private and family life, his home and his correspondence."
[29] Biasiotto and others (n 21).
[30] In the context sharing of benefits in the biobank context based on donors contribution of biomaterials/data, see discussion in Aisling McMahon, "Patents, Human Biobanks and Access to Health Benefits: Bridging The Public–Private Divide", in Jessica Lai and Antoinette Maget Dominicé (eds.) *Intellectual Property and Access to Im/material Goods* (Edward Elgar 2016) 176-203; Aisling McMahon and Opeyemi Kolawole, "Biobank Donation in Search of Public Benefits Amidst the Potential Impact of IPRs over Access to Health-Technologies Developed: A Focus on the Bioethical Implications" *Medical Law Review* (forthcoming).
[31] Ibid.
[32] On the role of "harm mitigation" bodies, see McMahon and others, n 2; Barbara Prainsack and Alena Buyx, "A Solidarity-Based Approach to the Governance of Research Biobanks" (2013) 21 Medical Law Review 71; Barbara Prainsack and Alena Buyx, *Solidarity in Biomedicine and Beyond* (Cambridge University Press 2017).
[33] Victoria Nembaware and others, "A Framework for Tiered Informed Consent for Health Genomic Research in Africa" (2019) 51 Nature Genetics 1566; Nicki Tiffin, "Tiered Informed Consent: Respecting Autonomy, Agency and Individuality in Africa" (2018) 3 BMJ Global Health e001249; Sheehan, n 3; Isabelle Budin-Ljøsne and others, "Dynamic Consent: A Potential Solution to Some of the Challenges of Modern Biomedical Research" (2017) 18 BMC Medical Ethics 4; Roberta Biasiotto, Peter Pramstaller, and Deborah Mascalzoni, "The Dynamic Consent of the Cooperative Health Research in South Tyrol (CHRIS) Study: Broad Aim within Specific Oversight and Communication" (2021) 21 BioLaw Journal - Rivista di BioDiritto 277; Deborah Mascalzoni and others, "Ten Years of Dynamic Consent

in the CHRIS Study: Informed Consent as a Dynamic Process" (2022) 30 European Journal of Human Genetics 1391; Jane Kaye and others, "Dynamic Consent: A Patient Interface for Twenty-First Century Research Networks" (2015) 23 European Journal of Human Genetics 141.

[34] Raphaël Gellert, "Understanding the Notion of Risk in the General Data Protection Regulation" (2018) 34 Computer Law & Security Review 279.

[35] Staunton and others, n 11.

[36] Staunton, n 9; Ciara Staunton and others, "Appropriate Safeguards and Article 89 of the GDPR: Considerations for Biobank, Databank and Genetic Research" (2022) 13 Frontiers in Genetics 719317 (doi: 10.3389/fgene.2022.719317); Marelli and others, n 11; Peloquin and others, n 11; Pormeister, n 11; Anne-Marie Duguet and Jean Herveg, "Safeguards and Derogations Relating to Processing for Scientific Purposes: Article 89 Analysis for Biobank Research", in Santa Slokenberga, Olga Tzortzatou, and Jane Reichel (eds.), *GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe* (Springer 2021) 105-120; Dara Hallinan, "Broad Consent under the GDPR: An Optimistic Perspective on a Bright Future" (2020) 16 Life Sciences, Society and Policy 1.

[37] Slokenberga and others, n 11; Peloquin and others, n 11; Marelli, n 11; Pormeister, n 11.

[38] Staunton, n 9.

[39] Ibid.

[40] Slokenberga, n 8.

[41] Staunton and others, n 3.

[42] EDPB-EDPS, *EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space* (adopted 12 July 2022), available at: https://edpb.europa.eu/system/files/2022-07/edpb_edps_jointopinion_202203_europeanhealthdataspace_en.pdf.

[43] Walport and Brest, n 2.

[44] Fatumo and others, n 14.

[45] On the limitations of risk-based frameworks to data within the digital and big data contexts, see McMahon and others, n 2, 160-161.

[46] Staunton and others, n 11.

[47] Staunton and others, n 3.

[48] Biasiotto and others, n 20.

[49] Christine Critchley, Dianne Nicol, and Margaret Otlowski, “The impact of commercialisation and genetic data sharing arrangements on public trust and the intention to participate in biobank research” (2015) 18 Public Health Genomics 160; Dianne Nicol and others, “Understanding public reactions to commercialization of biobanks and use of biobank resources” (2016) 162 Social Science & Medicine 79; Gill Haddow and others, “Tackling community concerns about commercialization and genetic research: a modest interdisciplinary proposal” (2007) 64 Social Science & Medicine 272, 277.

[50] Pam Carter, Graeme Laurie and Mary Dixon-Woods, "The Social Licence for Research: Why Care.Data Ran into Trouble" (2015) 41 Journal of Medical Ethics 404. See also discussion in Graeme Laurie and others, “A Review of Evidence Relating to Harm Resulting from Uses of Health and Biomedical Data” (Report for Nuffield Council on Bioethics Working Party on Biological and Health Data and the Wellcome Trust’s Expert Advisory Group on Data Access) (June 2014), 161, available at: https://www.nuffieldbioethics.org/wp-content/uploads/FINAL-Report-on-Harms-Arising-from-Use-of-Health-and-Biomedical-Data-30-JUNE-2014.pdf.

[51] Staunton and others (n 32).

[52] See also discussion in: Guido Noto La Diega, “Ending Smart Data Enclosures: The European Approach to the Regulation of the Internet of Things between Access and Intellectual Property”, in Stacy-Ann Elvy and Nancy Kim (eds.), *The Cambridge Handbook on Emerging Issues at the Intersection of Commercial Law and Technology* (Cambridge University Press, forthcoming).

[53] The tensions between IPRs and data sharing in the digital age are discussed in detail in Timo Minssen and Justin Pierce, “Big Data and Intellectual Property Rights in the Health and Life Sciences”, in I. Glenn Cohen and others (eds.), *Big Data, Health Law, and Bioethics* (Cambridge University Press 2018) 311-323; Guido Noto La Diega, “Ending Smart Data Enclosures: The European Approach to the Regulation of the Internet of Things between Access and Intellectual Property”, in Stacy-Ann Elvy and Nancy Kim (eds.), *The Cambridge Handbook on Emerging Issues at the Intersection of Commercial Law and Technology* (Cambridge University Press, forthcoming). On the database right more generally, see Jasper A. Bovenberg, “Should companies set up databases in Europe?” (2000) 18 Nature Biotechnology 907.

[54] For a discussion of some of the industry objections, including a framing of IP as a human right, see MedTech Europe, "MedTech Europe's position on the proposed European Health Data Space Regulation" (22 February 2023), available at: https://www.medtecheurope.org/wp-content/uploads/2023/02/230222-ehds-position-paper-final.pdf; European Federation of Pharmaceutical Industries and Associations, "European Health Data Space: key aspects to be considered in the trilogue discussions" (31 January 2024), available at: https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/european-health-data-space-key-aspects-to-be-considered-in-the-trilogue-discussions/; DigitalEurope, "Position Paper on the European Health Data Space proposal" (January 2023), available at: https://cdn.digitaleurope.org/uploads/2023/01/DIGITALEUROPEs-Position-Paper-on-the-European-Health-Data-Space-proposal-1.pdf.

[55] The nature and role of IPRs in the health context, focusing on COVID-19 context, is discussed in Aisling McMahon, "Global equitable access to vaccines, medicines and diagnostics for COVID-19: The role of patents as private governance" (2021) 47 Journal of Medical Ethics 142.

[56] For a discussion of IPRs in biobank context and tension that can arise, see McMahon, n 30. For a discussion of the broader bioethical issues posed in such contexts, see McMahon and Kolawole, n 30.