Technology and Regulation

Health data between health(care) and the data economy
Editorial

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Earlier this year, the European Commission presented its highly anticipated proposal for the European Health Data Space, with a view to harness "the power of health data for people, patients and innovation". Considering this objective, the present special issue addresses the governance of health data for research uses by discussing the balancing approach among the diverse aspirations of this ambitious proposal and ways to ultimately preserve trust in such endeavours.

1. Introduction

Health data is reported to make up 30% of the world's stored data.[1] Nevertheless, much of this data remains "largely untapped", also in the EU, despite its potential beneficial effects on (health)care, as it is mostly 'siloed' and unstructured.[2] Against this background, discussing the policy options for health data access and sharing and their implications was the goal of an online workshop on EU health data governance held in November 2021,[3] that I co-organised with Prof Giorgio Monti and Dr Robin Pierce. Bringing together speakers from academia and the European Commission, and attended by close to 100 participants ranging from scholars to industry representatives, employees of government agencies, and others, the workshop aimed to explore the emerging contours of EU health data governance regime and, in particular, examine the Commission's plans for the European Health Data Space (EHDS).

The special issue 'EU health data governance and the proposed European Health Data Space' is the outcome of that workshop. Comprising two peer-reviewed papers, it delves in depth into secondary use of health data, a broad umbrella term for its (re-)use for research, innovation, policy-making, regulative activities or patient safety. After this editorial provides a general introduction to the envisioned EHDS and some background thoughts on (sharing) health data and what it means for data governance, **Mahsa Shabani** and **Sami Yilmaz**, first, address the interplay of EU's regulatory frameworks related to data processing, namely the General Data Protection Regulation (GDPR), the upcoming Data Governance Act (DGA), and the recently proposed EHDS Regulation, with a focus on the legal bases for secondary use of health data, specifically for data-driven research purposes. Next, **Santa Slokenberga** further analyses the emerging EU regime for the uses of health data for research, with a view to explore whether it is in line with the established ethico-legal standards governing scientific research. It is my hope that the special issue will further elucidate the complexities surrounding EU health data governance in this area and contribute to the growing body of literature on the topic,[4] point to some remaining open questions, and help move the debate forward in light of the ongoing legislative process.

2. Setting the scene: health data and the EHDS

In light of technological and scientific developments, health data is becoming an increasingly wide notion; conventionally associated with medically-relevant data in varied formats, like data from lab results,

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1 Shwen Gwee, 'The importance of increasing access to high-quality health data' (*OECD Forum Network*, 11 January 2021) https://www.oecd-forum.org/posts/the-importance-of-increasing-access-to-high-quality-health-data accessed 4 November 2022.

2 Gwee (n 1); see also Fruzsina Molnár-Gábor et al., 'Harmonization after the GDPR? Divergences in the rules for genetic and health data sharing in four member states and ways to overcome them by EU measures: Insights from Germany, Greece, Latvia and Sweden' (2022) 84 *Seminars in Cancer Biology* 271.

3 TILT, 'A workshop on EU health data governance and the proposed European Health Data Space' (2021) https://www.tilburguniversity.edu/current/events/ehds-workshop accessed 4 November 2022.

4 See, to this end, e.g. Stephen H. Bradley et al., 'Healthcare systems must get fair value for their data' (2022) 377 *BMJ*; André Caravela Machado and Daniel Ferreira Polónia, 'Legal and technological aspects for the creation of a European Health Data Space' (2022) *17th Iberian Conference on Information Systems and Technologies (CISTI)*, doi:10.23919/CISTI54924.2022.9820577; Minna Hendolin, 'Towards the European Health Data Space: From Diversity to a Common Framework' (2021) 27 *Eurohealth* 15; Denis Horgan et al., 'European Health Data Space – An Opportunity Now to Grasp the Future of Data-Driven Healthcare' (2022) 10 *Healthcare* 1629; Nadina Iacob and Felice Simonelli, 'Towards a European Health Data Ecosystem' (2020) 11 *European Journal of Risk Regulation* 884; Anastasiya Kiseleva and Paul de Hert, 'Creating a European Health Data Space: Obstacles in Four Key Legal Areas' (2021) 5 *European Pharmaceutical Law Review* 21; Petros Terzis, 'Compromises and Asymmetries in the European Health Data Space' (2022) 29 *European Journal of Health Law*; Effy Vayena, 'Value from health data: European opportunity to catalyse progress in digital health' (2021) 397 *The Lancet* 652, and others.

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diagnoses and patient records, medical images, public health registry data, and data produced in the context of clinical research, it has expanded to include also data generated outside strict boundaries of healthcare and health research, like genomic sequencing and -omics data, data from wearables, smartphone apps, and platforms, and even environmental and socio-economic data.[5] This indicates that practically any kind of data can become health-related or -relevant data.[6] Moreover, used for a wide array of objectives and purposes, ranging from personal health management and healthcare processes and organisation to health policy and planning, and from health research to innovation and business competitiveness,[7] health data is relevant to a large number of parties, including the individual (patient or consumer), healthcare professionals, providers, and systems, academic researchers, businesses and industry, insurers, policy-makers and regulators, civil society and the third sector etc.[8] This indicates that health data can have different meanings and value[9] to stakeholders both within and beyond health(care) sectors with their respective, possibly diverging, interests and expectations.[10] Taking these on board and balancing them accordingly is therefore a vital task for (EU) health data governance in the context of increasingly digit(al)ised, data-driven health.[11]

In view of this, the proposal for the Regulation on the European Health Data Space (EHDS) was published on 3 May 2022.[12] Proclaimed not only a regulation, but "a vision for the future of health and care for Europe",[13] the proposal for a regulation on the European Health Data Space (EHDS) was welcomed as a "huge opportunity /to enable/ better use of the vast amounts of health data that are currently neglected".[14] The ambitious proposal is conceived as a European approach to managing diverse, interrelated data sources[15]

and enabling "connectivity and interoperability in an efficient and secure way".[16] It has grand aspirations as a "'new beginning' for the EU's digital health policy, making health data work for citizens and science."[17] Specifically, the EHDS proposal aims to empower individuals in regards to their health data, enable its sharing within the EU for direct care provision (i.e. *primary use*), and foster a single market for digital health goods and services. In addition, the proposal intends to make a wide range of health data, "accessed under strong safeguards for security and privacy /.../ a treasure trove for scientists, researchers, innovators and policy-makers working on the next life-saving treatment"[18] (i.e. *secondary use*). As such, the EHDS is by its nature a complex and "cross-cutting file", concerned not only with advancing (public) health and enforcement of fundamental rights and data protection principles, but also with fostering the EU's single market.[19]

There are multiple reasons behind the need for EHDS, from difficulties in cross-border provision of healthcare and related data exchanges to fragmented digital standards and national divergences in the implementation of the GDPR to the importance of digital health services, as it became evident during the Covid-19 pandemic.[20] Against this background, the EHDS attempts to provide a harmonised regulatory framework for health data sharing,[21] which is reflected in the legal basis consisting of Articles 16 and 114 of the Treaty on the Functioning of the European Union (TFEU).[22] While the latter, pertaining to the functioning of the internal market, reflects the need for overcoming technical and legal or administrative barriers to the free movement of health data across Member States and health systems, the former, concerning the right to the protection of personal data, provides the scope "to put in place additional legally binding provisions and safeguards" particular to the health sector.[23] With the EU having limited legislative competence with regards to health policy, Article 168 TFEU is not among the legal bases. Still, the EHDS will undoubtedly have significant implications also in this area. Drawing its strength from EU's economic powers, it therefore seems that the EHDS might further bolster the internal market dimension as "the most important face of EU health policy".[24]

5   Effy Vayena and Alessandro Blasimme, 'Biomedical Big Data: New Models of Control Over Access, Use and Governance (2017) 14 *Bioethical Inquiry* 501, 502; see also Amelia Fiske et al., 'Value creation in the health data domain: a typology of what health data help us do' (2022) *BioSocieties*, https://doi.org/10.1057/s41292-022-00276-6, 3.

6   Vayena and Blasimme (n 5), 503; see also Nadezhda Purtova, 'Health data for common good: Defining the boundaries and social dilemmas of data commons' in Samantha Adams, Nadezhda Purtova, and Ronald Leenes (eds), *Under observation: The interplay between eHealth and surveillance* (Springer International 2017), 10

7   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; Sonja Marjanovic et al., 'Understanding value in health data ecosystems' (2018) 7 *Rand Health Quarterly*; Marthe Stevens, Rik Wehrens, and Antoinette de Bont, 'Conceptualizations of Big Data and their epistemological claims in healthcare: A discourse analysis' (2018) 5 *Big Data & Society*.

8   Marjanovic et al. (n 7); Tamar Sharon and Federica Lucivero, 'Introduction to the Special Theme: The expansion of the health data ecosystem – Rethinking data ethics and governance' (2019) 6 *Big Data & Society*.

9   See further Fiske et al. (n 5), 2-18.

10   (Wilson et al. in) Fiske et al. (n 5), 4.

11   See Vayena and Blasimme (n 5), 503; see also Inge Graef, 'Paving the Way Forward for Data Governance: a Story of Checks and Balances' (2020) *Technology and Regulation* (Special issue Governing Data as a Resource) 24

12   European Commission, 'European Health Union: A European Health Data Space for people and science' (3 May 2022) https://ec.europa.eu/commission/presscorner/detail/en/ip_22_2711 accessed 4 November 2022.

13   Digital Europe, 'Initial reactions to the European Health Data Space proposal' (29 July 2022) https://www.digitaleurope.org/resources/initial-reactions-to-the-european-health-data-space-proposal/ accessed 4 November 2022.

14   Horgan et al. (n 4).

15   See, for a definition of a data space, Michael Franklin, Alon Halevy, and David Maier, 'From Databases to Dataspaces: A New Abstraction for Information Management' (2005) 34 *ACM SIGMOD Record* 27; Alon

Halevy, Michael Franklin, and David Maier, 'Principles of Dataspace Systems' (2006) *Proceedings of the twenty-fifth ACM SIGMOD-SIGACT-SIGART symposium on Principles of database systems*, https://doi.org/10.1145/1142351.1142352, 1.

16   European Commission, 'Proposal for a Regulation on the European Health Data Space' COM (2022) 197 final, Recitals 24 and 25.

17   European Commission (n 12).

18   European Commission (n 12).

19   Amalie Holmgaard Mersh, 'Health committee will co-lead health data space dossier in the European Parliament' (*Euractiv, 13 September 2022*) https://www.euractiv.com/section/health-consumers/news/health-committee-will-co-lead-health-data-space-dossier-in-the-european-parliament/ accessed 4 November 2022.

20   European Commission, 'Combined Evaluation Roadmap/Inception Impact Assessment' (23 December 2020) https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-Digital-health-data-and-services-the-European-health-data-space_en accessed 4 November 2022; Proposal for a Regulation on the European Health Data Space (n 16), 1; see also Michael G. Jacobides, Sergio Levi, and Jeroen Tas, 'Digital Platforms and Ecosystems in Healthcare: promises and pitfalls' (11 May 2021) Evolution White Paper https://www.evolutionltd.net/post/digital-platforms-and-ecosystems-in-healthcare-promises-and-pitfalls accessed 4 November 2022, 8, 25; Molnár-Gábor et al. (n 2).

21   Mahsa Shabani, 'Will the European Health Data Space change data sharing rules?' (2022) 375 *Science* 1357, 1357

22   European Commission (n 16), 21.

23   European Commission (n 16), 6.

24   See, for further discussion on the matter of EU health policy, Eleanor Brooks, Anniek de Ruijter, and Scott L. Greer (...), 'Covid-19 and European Union health policy: from crisis to collective action' in Bart Vanhercke,

As a piece of the data regulatory puzzle, EHDS originates from the EU's Strategy for Data, where the Commission among other things stressed the importance of creating European data spaces, including in the strategic sector of health, to make the most out of data-driven innovation.[25] Building on several horizontal legislative acts, including existing data protection and cybersecurity rules and the recent frameworks that will address processes and structures to facilitate data sharing on one hand, and clarify who can create value from data and under which conditions on the other,[26] the EHDS proposal represents the sectoral regulation for data sharing in the health sector.[27] The Commission's proposal for the EHDS will, in the coming months, be discussed by the Council and the European Parliament;[28] the Commission counts on the negotiations to last up to 2 years, followed by 1 year for implementation. This means that the EHDS should become functional sometime in 2025.[29]

3.   Seeking for a balance: from saving lives to unleashing the potential of health data economy

"There is no doubt that sharing data will save lives" is the statement made by European Commissioner for Health and Food Safety Stella Kyriakides to Member States' ministers for employment, social affairs, health and consumer policy,[30] after the publication of the EHDS Regulation proposal. Once operational, the EHDS will in this light facilitate a more efficient and seamless access to healthcare in the EU and enable "EU-wide collaboration for better healthcare, better research and better health policy making".[31] It will become "a key pillar" of the European Health Union that has the objective to improve health crises response, enable the availability of medical supplies, and ensure better disease detection, prevention, and treatment.[32] It

will also importantly contribute to the EU deployment and regulation of health AI.[33]

Moreover, marking a more assertive EU's industrial policy in terms of data (re-)use,[34] the aspirations of the EHDS demonstrate the enormous value of health data for the health sector and health of individuals and populations, but also beyond. Namely, aside from contributing to health research and reaching "a quantum leap forward in the way healthcare is provided to people across Europe",[35] sharing health data also fuels the data economy as noted in the Communication on the EHDS.[36] That is to say, the EHDS presents "an opportunity to unleash the potential of health data economy",[37] wherein data (and the capabilities to make sense of it) is considered an essential resource for growth and competitiveness.[38] The EHDS therefore appears not only an initiative upholding an ecosystem that would advance healthcare delivery and health research, but a step towards making Europe "the place-to-go for high quality industrial data" and for extracting and leveraging this precious resource for wealth creation,[39] almost as if running a 'goldmine'.[40]

In that regard, it is clear that the EU health data governance aims to reconcile the objectives of providing for a strict control by an individual over 'their' health data and ensuring the free movement and optimal use of health data as an input for decision-making in care provision, research, and policy formulation or a source of innovation and profit for the industry.[41] Accordingly, it focuses on (conditions of) access to health data and its uses, and on the incentives that stimulate its sharing and re-use.[42]

But, when it comes to secondary use of health data, how can individual data subjects negotiate their position in the EHDS? Both contributions included in the special issue tackle various aspects of this question by assessing where the emerging EU regime for health data tries to locate the balancing point. **Shabani** and **Yilmaz** look into consent and public interest as legal bases for processing health data for research purposes and discuss the newly introduced concept for data

Slavina Spasova, and Boris Fronteddu (eds), *Social policy in the European Union: state of play 2020* (ETUI 2021), 39, 45.

25   European Commission, 'A European Strategy for data' (7 June 2022) https://digital-strategy.ec.europa.eu/en/policies/strategy-data accessed 4 November 2022.

26   I.e. the Data Governance Act and the proposal for the Data Act. See European Commission, 'Data Act: Commission proposes measures for a fair and innovative data economy' (23 February 2022) https://ec.europa.eu/commission/presscorner/detail/en/ip_22_1113 accessed 4 November 2022.

27   European Commission, 'Commission and Germany's Presidency of the Council of the EU underline importance of the European Health Data Space' (11 November 2020) https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2049 accessed 4 November 2022.

28   European Parliament, 'Proposal for a regulation on the European Health Data Space' (*Legislative Train Schedule*, 2022) https://www.europarl.europa.eu/legislative-train/theme-promoting-our-european-way-of-life/file-european-health-data-space accessed 4 November 2022; Holmgaard Mersh (n 19).

29   Gerardo Fortuna, 'Commission wants GDPR+ protection to facilitate health data revolution' (*Euractiv*, 4 May 2022) https://www.euractiv.com/section/health-consumers/news/commission-wants-gdpr-protection-to-facilitate-health-data-revolution/ accessed 4 November 2022.

30   European Commission, 'Opening Remarks by Commissioner Stella Kyriakides at the EPSCO Council – European Health Data Space' (14 June 2022) https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_22_3708 accessed 4 November 2022.

31   PubAffairs Bruxelles, 'European Health Union: Commission publishes open public consultation on the European Health Data Space | EU Commission Press' (2021) https://www.pubaffairsbruxelles.eu/eu-institution-news/european-health-union-commission-publishes-open-public-consultation-on-the-european-health-data-space-eu-commission-press/ accessed 4 November 2022.

32   European Commission, 'European Health Union' (2022) https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en#key-initiatives accessed 4 November 2022

33   European Commission, 'Europe fit for the Digital Age: Commission proposes new rules and actions for excellence and trust in Artificial Intelligence' (21 April 2021) https://ec.europa.eu/commission/presscorner/detail/en/IP_21_1682 accessed 4 November 2022.

34   Andrea Renda, 'Making the digital economy "fit for Europe"' (2020) 26 *European Law Journal* 345, 8.

35   European Commission (n 32).

36   European Commission, 'Communication A European Health Data Space: harnessing the power of health data for people, patients and innovation' COM (2022) 196 final, 18.

37   European Commission (n 36), 18.

38   Dexter Whitfield, 'A Typology of Privatisation and Marketisation' (2006) ESSU Research Report No.1, https://www.european-services-strategy.org.uk/wp-content/uploads/2006/11/essu-research-paper-1-2.pdf accessed 4 November 2022, 4; see also Aaro Tupasela, Karoliina Snell, and Heta Tarkkala, 'The Nordic data imaginary (2020) Big Data & Society, doi.org/10.1177/2053951720907107, 1-2.

39   José Van Dijck, 'Seeing the forest for the trees: Visualizing platformization and its governance' (2021) 23 New Media & Society 2801, 2803; see further Aaro Tupasela, *Populations as Brands. Marketing National Resources for Global Data Markets* (Springer Nature 2021), 2-3, 81-2.

40   See further Tupasela, Snell, and Tarkkala (n38), 4-5, 11.

41   Fiske et al. (n 5), 5; Horgan et al. (n 4), 1630; Vayena (n 4), 653.

42   See Heiko Richter and Peter R. Slowinski, 'The Data Sharing Economy: On the Emergence of New Intermediaries' (2019) 50 *IIC - International Review of Intellectual Property and Competition Law* 4; Gintare Surblytė, 'Data as a Digital Resource' (2016) Max Planck Institute for Innovation and Competition Research Paper No. 16-12 http://dx.doi.org/10.2139/ssrn.2849303 accessed 4 November 2022; see also European Commission (n 26)

sharing: data altruism. In particular they focus on respecting individuals' control and transparency on one hand and promoting data access for the purposes of general interest on the other and, lastly, analyse the shifts introduced by the EHDS Regulation proposal. Investigating the enhanced role of the EU in data-driven research, **Slokenberga** further examines if the EHDS Regulation proposal provides solutions to issues that emerged with regards to scientific research under the GDPR and whether individuals' interests are properly safeguarded in the planned EHDS. She scrutinises the proposed balance in the EHDS between data subject's protection and other aspirations, pointing out among other things that healthcare and health research are "two areas where the trust is key".

4.   Instead of conclusion: how to cultivate trust in the EHDS?

Like with any intervention, public acceptance will therefore be of utmost importance also when it comes to sharing data for research and innovation. Considering this, the European Commission recognises that people "are keen to share their data, if there is a framework that merits their trust"; for this, the plans of the EHDS are to strengthen people's trust by means of security and privacy and data protection elements.[43] However, I submit there is more to trust than data protection and security. For instance, "while a majority / of people living in the EU/ hold positive attitudes towards the use of health data for multiple purposes, the positive attitudes are typically conditional on the expectation that data will be used to further the common good".[44] That (the use of health data for) research is something that should deliver benefit to society is hence an important part of the balancing equation, as also highlighted in both papers of this special issue.

A recent experience from the UK can be telling here; last year, a scheme that envisaged everyone's general practice health data would be made available for health research and planning, had to be halted due to a public backlash,[45] as masses opted out of the scheme over concerns regarding maintaining patients' trust and, more notably, questions over ensuring public benefit for the NHS.[46] Taking this into account, answers are required in any conversation about data governance and specifically about the EHDS also to the following: who can benefit from (extracting value from) health data and how will the outcomes and the benefits of health data re-use be generated and ultimately distributed.[47] I would argue it is therefore high time we start discussing EU health data governance not only in terms of *sharing of health data*, but also as regards *sharing of the value* stemming

from its use, to sustain trust and assure the EHDS will deliver upon its promise to work for people and science.

43   European Commission (n 36), 3, 8.

44   Lea L. Skovgaard, Sarah Wadmann, and Klaus Hoeyer, 'A review of attitudes towards the reuse of health data among people in the European Union: The primacy of purpose and the common good' (2019) 123 *Health Policy* 564.

45   Chaminda Jayanetti, 'NHS data grab on hold as millions opt out' (*The Observer*, 22 August 2021) https://www.theguardian.com/society/2021/aug/22/nhs-data-grab-on-hold-as-millions-opt-out accessed 4 November 2022.

46   Foxglove, 'The NHS Data Grab has been forced to be put on hold – here's what comes next' (*Keep Our NHS Public*, 11 August 2021) https://keepournhspublic.com/nhs-data-grab-what-next/ accessed 4 November 2022.

47   See further Seliem El-Sayed and Barbara Prainsack, 'Rapid Response: Success of European Health Data Space hinges on operationalizing public value, in addition to bridging digital divides' (2022) 378 *BMJ*; Richard Milne et al., 'Demonstrating trustworthiness when collecting and sharing genomic data: public views across 22 countries' (2021) 13 *Genome Medicine*; Shabani (n 21), 1359; Jenifer Sunrise Winter and Elizabeth Davidson, 'Big data governance of personal health information and challenges to contextual integrity' (2019) 35 *The Information Society* 36; Vayena (n 4).