



On behalf of the Center for Data Innovation (Transparency Register #: 367682319221-26), we are pleased to submit this feedback on the European Commission’s roadmap on “Digital health data and services—the European health data space.”

INTRODUCTION

In its Communication on a European Strategy for Data, the European Commission outlines its plans to create a common European Health Data Space (EHDS).¹ The EHDS aims to unlock the value of data for public health, treatment, research, and innovation. To achieve this outcome, it aims to foster primary uses of health data to directly support health care delivery for individuals, as well as secondary uses of health data, such as for medical research and health policymaking purposes.²

The roadmap identifies three pillars for the EHDS: (i) a system of data governance and rules for data exchange; (ii) data quality; and (iii) infrastructure and interoperability. The Commission will remove barriers to intra-EU trade by promoting data-sharing and interoperability across the member states while safeguarding and reinforcing data protection rights through transparency and portability.

The Center for Data Innovation welcomes the goals of the EHDS initiative and agrees that adopting measures to enable better data exchange will facilitate artificial intelligence (AI)-enabled healthcare applications in the EU and allow firms to pursue economies of scale across EU markets. Our feedback stresses the need to (i) avoid market fragmentation of the Digital Single Market, (ii) ensure data interoperability, and (iii) support the development of AI-enabled healthcare applications.

AVOID MARKET FRAGMENTATION IN THE DIGITAL SINGLE MARKET

Market fragmentation is a barrier to trade as it increases legal uncertainty, raises transaction and compliance costs, and prevents firms from scaling-up across markets.³ As a result, firms might not have the ability and incentive to invest in the Single Market as the costs might exceed trade benefits.

¹ European Commission, “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,” February 19, 2020.

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0066&from=EN>.

² European Commission, “European Health Data Space,” (accessed January 21, 2021), https://ec.europa.eu/health/ehealth/dataspace_en.

³ Visscher, L., “A Law and Economics View on Harmonization of Procedural Law,” Rotterdam Institute Of Law And Economics (RILE) Working Paper Series, No. 2010/09, 2010.

https://www.researchgate.net/publication/228185045_A_Law_and_Economics_View_on_Harmonization_of_Procedural_Law; Wagner, H., “Economic Analysis of Cross-Border Legal Uncertainty-The Example of the European Union,” Discussion Paper No. 371, Forthcoming In: Jan Smits (Ed.), The Need For A European Contract Law. Empirical And Legal Perspectives, Groningen: Europa Law Publishing 2005, October 2004.

https://www.researchgate.net/publication/259781408_Economic_Analysis_of_Cross-Border_Legal_Uncertainty_the_Example_of_the_European_Union.



Accordingly, citizens will be worse-off and economic efficiency will not be reached compared to the harmonized market's counterfactual scenario with legal certainty.

Market fragmentation, created by national and regional data protection policies, exacerbates costs for adopting data-driven solutions. Different legal frameworks, especially regarding access to sensitive health data, prevent organizations from sharing data.⁴

We support a common approach to foster data-sharing across multiple sectors. As the Commission notes, the governance of the EHDS will be based on the proposal on the Data Governance Act (DGA)—an initiative that the Center welcomes subject to improvements (see our feedback on the DGA).

ENSURE DATA INTEROPERABILITY AND REAL-TIME DATA ACCESS

Article 20 of the General Data Protection Regulation (GDPR) establishes a data portability right that enables users to move their data from one provider to another. However, many important data-driven solutions in healthcare, including to prevent and monitor diseases, require access to real-time health data and this data needs to be in an interoperable format to communicate seamlessly between different technologies and services.⁵ As of today, this type of real-time, interoperable health data access is not available for most consumers.⁶

The European Commission should use the EHDS to ensure patients have the ability to port real-time data in an interoperable format, such as through the development of standardized health data APIs. In addition, the Commission should clarify precisely which data sets should be subject to these access rights, and under what conditions. The Commission should not prevent individuals from

⁴ EDPS, "Preliminary Opinion 8/2020 on the European Health Data Space," November 17, 2020, p. 8. https://edps.europa.eu/data-protection/our-work/publications/opinions/preliminary-opinion-82020-european-health-data-space_en.

⁵ Furman, J. et al, "Unlocking digital competition-Report of the Digital Competition Expert Panel," March 2019, p. 69. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/785547/unlocking_digital_competition_furman_review_web.pdf; Crémer J. et al, Competition policy for the digital era, pp. 81-82, <https://op.europa.eu/en/publication-detail/-/publication/21dc175c-7b76-11e9-9f05-01aa75ed71a1/language-en>; Schallbruch, M. et al, A "new competition framework for the digital economy-Report by the Commission 'Competition Law 4.0,'" September 2019, p. 39, https://www.bmwi.de/Redaktion/EN/Publikationen/Wirtschaft/a-new-competition-framework-for-the-digital-economy.pdf?__blob=publicationFile&v=3.

⁶ European Commission, "Communication from the commission to the European parliament, the council, the European economic and social committee and the committee of the regions on enabling the digital transformation of health and care in the digital single market; empowering citizens and building a healthier society," April 25, 2018, p. 1. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018D0233&from=EN>.



authorizing third-party service providers, including foreign ones, from accessing their health data on their behalf.

SUPPORT THE DEVELOPMENT OF AI-ENABLED HEALTHCARE APPLICATIONS

AI applications need data. Unlocking access to data is an essential but not a sufficient condition to unlock the power of data through AI applications. AI, especially in healthcare, requires investments in both skills and technologies (e.g., supercomputing), and an innovation-friendly legal framework that addresses both safety and liability issues.⁷ Without the former, firms might not have the talent and technologies available to make use of data, and without the latter, firms might not have the incentive to develop new products and services as the legal costs in case of liability are too uncertain.

Furthermore, consumers and healthcare providers might be reluctant to adopt AI-enabled healthcare applications if safety and liability rules are unclear. We recommend the Commission expand its investment in AI and create a risk-based approach to updating its safety and liability framework for AI.

PURSUE GLOBAL PARTNERSHIPS IN HEALTH DATA

Healthcare is a global concern, and EHDS should have a global outlook. If the EHDS only creates an opportunity for sharing data within the EU, it will fail to deliver on its potential. For example, many recent European immigrants would benefit from medical research targeting populations in other parts of the world. These individuals should be able to both share their data for medical research outside the EU and benefit from AI-enabled health services that operate on a global scale and use data from abroad. Similarly, the EU should not exclude non-European researchers and AI firms who can add value to the EHDS as this would undercut the opportunities to improve healthcare for Europeans, as well as the global community.

CONCLUSION

The Center for Data Innovation welcomes the goals of the EHDS. As the Commission moves forward, it should strive to ensure the regulation avoids market fragmentation, ensures data interoperability and real-time data access, and supports financially and legally the development of AI-enabled healthcare applications.

⁷ European Commission, "White Paper- On Artificial Intelligence - A European approach to excellence and trust," February 19, 2020. https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf.