Supported by:

Federal Ministry of Health

on the basis of a decision by the German Bundestag

ELNET

GIHF AI

German Israeli Health Forum for Artificial Intelligence

Statement "Regulation" by Nicole Formica-Schiller

European Health Data Space: Transforming health data access and sharing

This report is an overview of the current proposal for the European Health Data Space (EHDS) and its potential implications for the healthcare system. As outlined by the European Commission (Commission) Proposal, dated 3rd May 2022, for a Regulation of the European Parliament and of the Council on the European Health Data Space, the general objective of the intervention is to establish the rules governing the EHDS to ensure natural persons' access and control over their own health data, to improve the functioning of the single market for the development and use of innovative health products and services based on health data, and to ensure that researchers, innovators, policy-makers and regulators can make the most of the available health data for their work, while preserving trust and security.[1]

Ultimately, the use of this these real-world data would enable healthcare professionals, public authorities, regulators, industry, and innovators to ensure that healthcare practice, health systems, products, innovative technologies, and therapies meet a patient's needs and lead to favourable health outcomes. Such outcomes should include improvement of understanding of health and disease; better anticipation of disease outbreaks; faster prevention and diagnosis as well as development of more effective preventive measures and treatments.

It is planned that by 2025, European member state citizens will have access to their Electronic Health Record (EHR) and be able to share them with healthcare professionals across EU member state borders. This should lead to a real freedom of movement for many patients. In practice however, this would require medical records issued in a common exchange format, interoperability becoming a compulsory requirement and health data becoming more available for secondary purposes such as research and innovation, and policymaking among others. Furthermore, the inclusion of data generated by health and wellness applications etc., that could potentially be used for secondary data, is likely to create privacy risks and other issues as this type of data typically do not have the same level of quality and controls as data generated through medical practice.

Companies and researchers who want to use electronic health data will need a permit from one of the new health data access bodies, to be set up in each EU state. Access will only be granted if the requested data is used for specific purposes, in closed, secure environments and without revealing the identity of the individual it refers to.

The national health data access bodies will be connected to a decentralised EU infrastructure for secondary use, called HealthData@EU, which will be set up to support cross-border projects. Innovators and researchers from outside the EU might also be able to access this European data for secondary use, under the same conditions.

Challenges and Issues with Implementation

International interoperability standards might need to be reviewed and established to avoid uncertainty and complications for industry and users. **Secure data sharing** is fundamental to the success of the EHDS and providing effective collaborative treatments for patients. Despite the importance of sharing healthcare data, currently some healthcare systems often require patients to obtain and share their medical records with other providers by sharing physical paper copies or electronic hard disk copies. This system is far from ideal for many reasons, not least of which is because it is a slow process that may compromise patients in poor health. Furthermore, the ineffective data sharing process in healthcare is partially due to the lack of trust between users and the lack of interoperability between health IT systems and applications. It will be important to make sure that the **additional standards are consistent with current frameworks** to ensure a smooth transition.

The complex governance issues involved in protecting the very personal and private data require a clear need for more **transparency in the areas of consent, anonymisation, and data ownership**. To achieve this, healthcare systems need to overcome the challenges of meeting the combined needs of the **legal and ethical frameworks of both patient care and pan-European data requirements**. Sharing of data is seen as problematic not just because of technical limitations, but also because of the need to meet complex information governance rules, organizational needs and priorities, public expectations of privacy for their health data, and even a distrust between different care providers. Any new legislation that is adopted in connection with the EHDS and its data uses, should provide a **trustworthy framework** for health data collection, access and use that is employed when datasets are made available to users.

How the EHDS will **interplay with other data legislation** will need to be sufficiently addressed. Legislation such as the EU General Data Protection Regulation (GDPR) was perceived to make research more difficult and thereby deterring international investment. The EHDS could provide a unique opportunity to overcome some of these uncertainties by clarifying the legal basis for the use of health data in a way that is consistent with other existing and upcoming regulations, such as e.g., **the Medical Device Regulation, the EU Data Act, and the regulation of Artificial Intelligence (AI) namely the EU AI Act**.

This legal framework should encourage national and regional health data providers, researchers, and health agencies to **increase and coordinate investments** that support the creation and management of data infrastructure. Furthermore, this framework should encourage data integration into EHRs and health systems from consumer devices. This should include **standards and data quality rules** applicable to patient generated data through apps, wearables, sensors etc.

Genome analysis and disease predisposition planning are the cornerstones of precision health, which is an emerging approach focused on improving an individual's health by diagnosing, preventing, and treating a future illness through wellness and prevention interventions. Enabled through integrated AI technologies, precision health combines advances in genomics medicine with enhanced data collection from EHRs, environmental sensors, wearables, and other devices.[2] Determining a diagnosis involves not only assessing clinical information, but also an analysis of data generated by a patient's lifestyle, biometric data, genetics, and socioeconomics. Soon, **precision health is poised to disrupt the business, operational, and technical models of healthcare** to an even greater degree by combining genomic analysis with more robust data and AI capabilities to optimize treatment and reduce the prevalence of certain illnesses. The ability to recognize a future health risk and intervene with preventative measures will **fundamentally alter the paradigm of healthcare**. In the future, it is likely that healthcare organizations will find themselves increasingly focused on **proactively monitoring healthy individuals, performing preventative and wellness interventions**, and managing prevention and wellness for not only at-risk individuals.

These **precision health models will be underpinned by the EHDS**. However, the Commission has not sufficiently clarified **how such data can be shared in a timely manner with third parties**, therefore, impacting innovation and development of new precision medicines. In addition, both the **cost and monetary retribution for data** is uncertain. Any legislation will need to take measures to ensure and improve data quality at health care provider level and guarantee that data from devices and/or reported by patients can migrate to a common health data space.

Finally, **citizens' trust in the data space and its governance rules will likely be one of the most critical issues** to realize the goals of the EHDS.

Implications for Germany

Germany's digital transformation in healthcare has been making substantial progress over recent years. However, there is still room for improvement when it comes to the progress and level of innovation of pioneering EU countries such as Sweden, Estonia and Demark and non-EU countries such as Israel. A recent study has demonstrated that the adoption of digital infrastructure by physicians has increased significantly.[3] However, digitization has not yet resulted in sufficient digital data exchange between hospitals and outpatient physicians. Most of the communication between outpatient physicians and hospitals is still paper-based.

One part of the problem is Germany's fragmentation with different software and standards across the country. Germany's digital health ranking has been at the lower end compared to other countries in recent years.[4] Further compounding this issue is a lack of willingness to share data across federal states and healthcare providers.

The COVID-19 pandemic has catalysed the benefits of digitization and the pace of progress for a national e-health infrastructure must grow exponentially in preparation for the EHDS in 2025, partly because of the significant legislative activity of recent years and still upcoming. "The Health Data Lab" (HDL; German: "Forschungsdatenzentrum Gesundheit") at the German "Federal Institute for Drugs and Medical Devices" (BfArM; German: "Bundesinstitut für Arzneimittel und Medizinprodukte) aims at converting highly sensitive health data into new, "synthetic" datasets for anonymisation purposes. Data will be made available to researchers by the HDL. This involves billing data that is transmitted to the HDL by the German National Association of Statutory Health Insurance Funds in pseudonymised form and contains, e.g., information on diagnoses, treatments, and costs.

The HDL will guarantee security of the data in accordance with state-of-the-art practices and technologies. To ensure this, the HDL works together closely with the "Federal Office for Information Security" (BSI, German: "Bundesamt für Sicherheit in der Informationstechnik") and the "Federal Commissioner for Data Protection and Freedom of Information" (BfDI, German: "Bundesbeauftragter für den Datenschutz und die Informationsfreiheit").

Key Findings and Recommendations

The legislative EHDS proposal will profoundly change how patients, doctors, researchers and policymakers, access and use health data while realising billions in economic gains. In anticipation of the EHDS in 2025, numerous interconnected regulations and frameworks will need to be formulated and communicated to all stakeholders participating in the EHDS. It will therefore be necessary to consider and address the following:

- Provide strong safeguards for security and privacy reconciling the fragmented and sometimes diverse interpretation of GDPR rules. To overcome fragmentation and differing interpretations, ensure that EHDS legislation is to the best extend possible uniformly implemented across member states.
- New legislation should specify the elements of a trustworthy framework for health data collection, access, and use. It should also make provisions for secondary analysis legislation.
- The legal framework should encourage national and regional health data providers, researchers, and

health agencies to increase and coordinate investments that support the creation and management of data infrastructure.

- Furthermore, this framework should encourage data integration into EHRs and health systems from consumer devices.
- This should include standards and data quality rules applicable to patient generated data through apps, wearables, sensors etc.
- Ensure compliance with interoperability standards across member states and embedded in and supported by EU level legislation, which can readily be translated into national or regional level legislations and policies.
- Consider and endorse a Common Data Model approach to ensure standards, consistency, and quality of data across member states.
- Regulations, frameworks, and standards need to be built on international interoperability standards.
- Implement measures to improve data quality at the health care provider level and ensure that data from devices and/or reported by patients can migrate to a common health data space according to established data standards.
- Integrate data from major digital health consumer ecosystems and mobile health solutions.
- Include information on resource usage and health care costs from social insurance registries and funds.
- Integrate disease registries held in health care institutions and appropriate organisations such as rare disease registries.
- Invest in research and development areas particularly for high priority disease areas.
- Enable integration of transformative technologies to leverage the EHDS such as AI, digital twins, wearables etc.
- Ensure scalability to capture and integrate genomic, biomarker and microbiome information.

Based on the above outline including key findings and recommendations about the EHDS, its challenges and implications, it is without any doubt that the potential of the EHDS is significant. In particular, as it would represent one of the largest health databases in the world providing data on over 500 million Europeans and coverage across diverse healthcare systems.

Therefore, the EHDS should be seen as a major opportunity towards an advanced, interconnected digital healthcare ecosystem. In particular for the current German federal government, elected in September 2021, which has placed a specific focus on driving forward the digitalization of the healthcare system.

However, it needs to be kept in mind that to achieve this important milestone, it needs an efficient alignment in a timely manner between all stakeholders. For a sustainable digital healthcare system and best possible health outcomes for all involved.

About the author

Nicole Formica-Schiller is CEO & Founder of Pamanicor Health AG, a global boutique advisory firm for transformative technologies and Life Science, as well as Member of the Board of Trustees at GIHF-AI (German Israeli Health Forum for Artificial Intelligence). She has been appointed as OECD AI expert and selected by Forbes for "most innovative ideas" in AI & Blockchain. As international digital expert Mrs Formica-Schiller is a sought-after speaker and regularly featured in the media including her latest book ("AI & Blockchain in Healthcare", Elsevier). She sits on various Boards (German AI Association; Head Steering Committee "EU AI-Regulation" etc.) and advises governments, ministries, academia, and industry in digital, geopolitics, and policy. Mrs. Formica-Schiller graduated as an Attorney-at-law with an additional business degree and has been working globally throughout her whole career.

LinkedIn: https://www.linkedin.com/in/nicoleformicaschiller/
Twitter: https://twitter.com/FormicaSchiller
Web: www.pamanicorhealth.com I www.formicaschiller.com

Bibliography

1. **European Commission:** "Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space" COM/2022/197 final, 3.5.2022 in *https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197.*

2. **Formica-Schiller, Nicole:** "Künstliche Intelligenz und Blockchain im Gesundheitswesen – Wie COVID-19 und zukunftsweisende Technologien den Status quo revolutionieren", 2021 in *https://shop.elsevier.de/kuenstliche-intelligenz-und-blockchain-im-gesundheitswesen-9783437235917.html*.

3. **IGES:** "PraxisBarometer Digitalisierung 2020", November 2020 in *https://www.kbv.de/media/sp/IGES_KBV_PraxisBarometer_2020.pdf.*

4. **Bertelsmann Stiftung:** "Digital-Health-Index", 2022 in *https://www.bertelsmann-stiftung.de/de/unsere-projekte/der-digitale-patient/projektthemen/smarthealthsystems#c1203567.*

Supported by:

Federal Ministry of Health

on the basis of a decision by the German Bundestag

ELNET

GIHF AI

German Israeli Health Forum for Artificial Intelligence

ELNET Deutschland e.V.

Albrechtstraße 22
10117 Berlin
deutschland@elnetwork.eu

elnet-deutschland.de

@ElnetD

@ELNETDeutschland

GIHF-AI
German Israeli Health Forum for Artificial Intelligence

Albrechtstraße 22
10117 Berlin
info@gihf-ai.eu

gihf-ai.eu

@GIHFAI

CONTACT

Carsten Ovens

Executive Director
ELNET Deutschland

Lea Ledwon

Program Manager GIHF-AI
ELNET Deutschland

Date: 31.08.2022