## EHN feedback: Digital health data and services – the European health data space (EHDS)

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The European Heart Network (EHN) welcomes the publication of EHDS proposal, one of the central building blocks for a strong European Health Union. The proposal strengthens the right of people to access their electronic health data and establishes a mandatory cross-border infrastructure that will enable healthcare delivery across Member States (primary use). In addition, the proposal lays down rules, mechanisms and cross-border infrastructure for the needed use of health data for research, innovation, public health, policy-making and regulatory purposes (secondary use). The use of high-quality, interoperable, standardised and secure health data are indispensable requirements to transform health care and deliver trustworthy innovations of value to people and patients.

EHN will closely monitor and engage in the development of the proposal through the European Parliament and Council of the European Union to ensure that the great potential the use of health data holds is harnessed for good and respects the rights of the people behind the data.

### About EHN and cardiovascular disease (CVD):

EHN represents heart foundations and cardiovascular patient associations dedicated to improving cardiovascular health in Europe. Cardiovascular disease (CVD) remains by far the leading cause of death in the European Union (EU), and it impacts the lives of almost 63 million EU citizens, both young and old.[1] Around 20% of all premature deaths (before the age of 65) in the EU are caused by CVD. Many cardiovascular conditions are inherited (such as certain cardiomyopathies and arrhythmias), but they do not necessarily manifest themselves until adulthood. Risk and prevalence of CVD increase further with age. This is of utmost relevance in view of Europe's ageing population. In 2040, 155 million Europeans will be over 65. Whilst Europe is still amid the management of the COVID-19 pandemic, the repercussions of the pandemic on CVD mortality and morbidity will continue to increase and further impact the resilience of healthcare systems. Without decisive action, the number of citizens suffering from CVD and the burden of disease will invariably increase dramatically.

[1] Roth GA et al.; Global Burden of Cardiovascular Diseases Writing Group. Global Burden of Cardiovascular Diseases and Risk Factors, 1990-2019: Update From the GBD 2019 Study. J Am Coll Cardiol. 2020 Dec 22;76(25):2982-3021. doi: 10.1016/j.jacc.2020.11.010. Erratum in: J Am Coll Cardiol. 2021 Apr 20;77(15):1958-1959. PMID: 33309175; PMCID: PMC7755038.

## 1. EHN views on primary use

We welcome the aim to strengthen patient rights for primary use of electronic health data, with the introduction of the new rules, under Chapter II of the proposal.

Promising aspects include:

- People's access to their electronic health data, free of charge, in an easily accessible, consolidated and readable form
- The possibility of people to add or amend information in their electronic health record (EHR), providing a safe space to store their health information and not relying on commercial platforms
- The ability of people to give access to their electronic health data to health care professionals (e.g., medical doctors, hospitals, and pharmacies) and providers of electronic health care systems of their choice, either within their country of residence or in another Member State
- The right of people to know who in the context of healthcare has accessed their electronic health data
- Member States' obligation to ensure that patient summaries, e-Prescriptions, images and image reports, laboratory results, and discharge reports are issued in a common European format and thus facilitate cross-border health care.

**Digital health data systems**, either in place or to be developed, shall be **flexible** enough to meet people's needs and preferences, and allow people to receive personalised information and communication on their health data and its uses. **Access** to those systems **must be easy and information must be provided in lay language and formats**. For cross-border use, good translation of health information must be guaranteed for implementation.

Finally, improving health and digital health literacy for all is crucial for the uptake and successful diffusion of digital health data systems without widening existing inequalities in health.

## 2. EHN views on secondary use

### 2.1 Introduction: the value of secondary use of health data in the cardiovascular field

Investment in CVD research is particularly low relative to the disease burden, and innovation is lagging behind other clinical areas. The creation of a EHDS could help close the gap in investment in CVD research and innovation. Digitalisation is steering medicine towards real-time data extraction (real-world data) and analysis of various sources, such as EHR, wearable devices and registries. Big data and artificial intelligence (AI) hold great potential to boost clinical and pharmacological research in CVD by improving the design, speed and efficacy of more targeted and multi-country clinical trials at lower cost and less time, without compromising the safety of patients. Complementing clinical trial data, real-world data can provide important information, on the natural course of a disease, patient characteristics, therapeutic gaps and quality of life. It can also serve as an external reference for determining the comparative effectiveness of medical technologies and medicines.

The development of harmonised and comprehensive health data infrastructure based on patients' electronic health records or continuous CVD patient registries, as well as the digital

capability to enable the evidence generated within health systems, could mitigate barriers to CVD investments for novel products and services by improving the speed and efficiency of randomised controlled trials.[2]

The advantages of quality-assured national registries–aiming to support continuous quality improvement at the hospital and country level–have been demonstrated by the Swedish,[3] the Finnish[4] and more recently, the UK models[5]. Continuous data collection and provision can substantially improve quality of care, resulting in improved patient-relevant outcomes. To achieve this, the use of validated quality indicators to assess the effect of various measures on healthcare outcomes and inequalities across the EU must be guaranteed.[6] There is a need for CVD registries to be coordinated and expanded at the European level to inform evidence-based decision-making throughout the CVD pathway.

### 2.2 General comments on the legal framework and key concepts

The EHDS should contribute to the development of a **harmonised, secure and trusted legal and ethical framework for secondary use of data**. The interplay between the EHDS, the EU General Data Protection Regulation (GDPR, 2016/679), the Medical Device Regulation (2017/745), the In Vitro Diagnostic Medical Device Regulation (2017/746), the Directive concerning security of network and information systems (2016/1148) as well as rules currently still in the making, such as the Data Governance Act (COM/2020/767 final), the Data Act (COM/2022/68 final), and the AI Act (COM/2021/206 final) might result in uncertainties over implementation, whether due to contradictions or frictions between the various sets of rules. For example, already Member States' diverse implementations of the GDPR pose barriers for the secondary use of data. Between the EHDS proposals and GDPR, individuals hold various roles as they can be sources for data generation ('data subjects')[7], 'data recipients' and 'data users'[8]. The new rights conferred to individuals as 'data recipients' or 'data users' by the EHDS do not prevent them from exercising their GDPR rights. **Coordination** is therefore needed between the different legal pieces to avoid confusion and facilitate a more harmonised approach and less fragmentation at the national level.

In addition, **important concepts such as 'innovation' and 'public interest'** are open to interpretation and therefore **merit a definition**, or to the bare minimum an alignment of those concepts for a harmonised interpretation across Member States and amongst all stakeholders. On data altruism, which involves individuals and organisations making health data voluntarily

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[2] EHN ESC 'Fighting cardiovascular disease – a blueprint for EU action', June 2020
European Alliance for Cardiovascular Health (EACH) Plan for Cardiovascular Health, May 2022

[3] SwedeHeart Registry https://www.ucr.uu.se/swedeheart/; Annual report SWEDEHEART 2012. Scand Cardiovasc J. 2014 Aug;48 Suppl 63:2-133. doi:10.3109/14017431.2014.931551. PubMed PMID: 25119891

[4] Finland is using all available electronic data in the pilot quality registry for coronary artery disease. Data collected automatically from different sources, such as from diagnostics and various medical procedures, hospitalisation records, medicine purchases, laboratory measurements after discharge, and deaths. National quality register activities in health care are piloted in THL's National health care quality registers pilot project 2018–2020. This work is confirmed to continue in the coming years. More information is available at https://thl.fi/en/web/social-welfare-and-health-care-reform/health-and-social-services-system-performance-assessment/national-health-care-quality-registers

[5] BHF Data Science Centre: a partnership between Health Data Research UK (HDR UK) and the British Heart Foundation (BHF) that sits within HDR UK.

[6] L Dawson, S Biswas, D Stub, J Lefkovits, L Burchill, C Reid, D Eccleston, National cardiac registries: a systematic review, European Heart Journal, Volume 41, Issue Supplement_2, November 2020, ehaa946.3564, https://doi.org/10.1093/ehjci/ehaa946.3564

[7] As defined by GDPR and with rights conferred to them by GDPR Regulation (EU) 2016/679

[8] Article 2 of the EHDS proposal defines the various terms used in the proposal

available for research and innovation in the name of 'public interest', it is important to think about what those concepts mean to people and patients as they might differ compared to institutions or those using health data.

Artificial intelligence and big data hold great potential for research and innovation in healthcare delivery, novel medicines and medical devices that will ultimately provide value to people and patients. **What is of value to people and patients can only be defined with them in a spirit of co-creation**.

Any innovation must consider patient needs and preferences from the outset to ensure value, relevance and trustworthiness. Therefore, meaningful involvement of people and patients in the spirit of co-creation is paramount. Finally, policy makers must ensure that all upcoming innovations that harness individuals' health data, not only make it to the market but are also accessible and affordable for all.

### 2.3 Technical aspects

Interoperability, data standards, quality controls and independent scientific and regulatory validation are key to foster reliability in digital technologies and trustworthiness of real-world data generation, and are important for building public trust.

It appears that the EHDS proposal envisages that the FAIR principles are applied at the source of electronic health data. **Meeting FAIR principles of findability, accessibility, interoperability, and reusability in data management and stewardship is crucial** for high quality and trustworthiness for secondary use, whereby researchers and innovators will use data not knowing local organisational coding and registration practices in the various clinical environments. It is therefore important for the legislation to make explicit reference to the application of FAIR principles in Chapter III and the general requirements of Annex II.

There are already a variety of standards and technical requirements in place. It is important for policy makers to map what is in place already, what is missing and **identify the important denominators for high quality, interoperable, standardised and secure health data** to be applied across the Member States.

### 2.4 Data altruism for the sake of public good

The EHDS aims to provide a trusted channel for patients to grant access to their health data through data altruism (article 40) as defined and prescribed in the proposed Data Governance Act (COM/2020/767 final).[9] Though the choice of 'data altruism' is understandable, given the EU GDPR Regulation and the EU's strategy on data policy overall, **policy makers can not overlook people's preferences**, and to a certain extent, **need to have a sense of control** over their health data and their use for secondary purposes.

[9] COM/2020/767 final, article 2 'data altruism' means the consent by data subjects to process personal data pertaining to them, or permissions of other data holders to allow the use of their non-personal data without seeking a reward, for purposes of general interest, such as scientific research purposes or improving public services;
COM/2020/767 final, Chapter IV on data altruism establishes the possibility for organisations engaging in data altruism to register as a 'Data Altruism Organisation recognised in the EU' in order to increase trust in their operations. In addition, a common European data altruism consent form will be developed to lower the costs of collecting consent and to facilitate portability of the data (where the data to be made available is not held by the individual).

Research[10] has shown that people, including patients, are generally supportive of sharing their health data for research. Public and patient motivations and willingness to share health data relate to their perception of contributing to the **'common public good'**. The latter relates, for example, to:

- improve health policies based on scientific evidence and good epidemiological data
- identify 'unmet needs' per disease area and drive public and private investments towards research, innovation and development of medicinal products to address those needs
- deliver safe and effective clinical and pharmacological innovations that meet patients' real needs and will improve patient-relevant outcomes, and most notably quality of life
- assess whether existing therapies and treatments produce patient-relevant outcomes
- improve the speed and efficiency of multi-country randomised clinical trials without compromising patient safety
- monitor the availability of medicines and medical devices with a view to predict and mitigate potential shortages, especially in emergency situations.

Nonetheless, the support for secondary use is not unconditional. Conditions such as privacy, personal control, a proper balance between risks and benefits, transparency, awareness, understanding and communication, trust, and accountability need to be met for people to be more supportive of the secondary use of data. **The following public considerations** are important to be included in legislation and in practice to increase public trust in the secondary use of data: [11]

- **Commercial use**: overall, existing research suggests that when commercial parties/ private companies, such as pharmaceutical companies, are involved and when research is financially-/profit- driven, the public is strongly averse and often opposes data sharing. Actively warranting the pursuit of 'common good' or 'public interest' is paramount.
- **Risks** of data sharing relate to potential breaches of confidentiality and misuse or abuse of health data. Public and patient concerns over confidentiality are linked to the risk of reidentification, fear of discrimination, stigmatisation or other repercussions as a consequence of data being shared. **Safeguards** and mechanisms to mitigate risks are crucial. In addition, a common understanding of what constitutes 'misuse' and 'abuse' of health data is needed together with a clear framework of consequences (whether fines or sanctions) in cases of overstepping boundaries set.
- **Access and the sentiment of personal control**: Electronic Health Records (EHR) are not well established across all EU Member States and are currently not easily accessible by all people. Though for primary use, the EHDS proposal strengthens people's access to and gives them a certain level of control of their electronic health data, for secondary use, the proposal gives a more passive role to people. Lack of personal controllability can be a compromising factor for public trust. **Transparency in governance and meaningful patient and public involvement** in governance and mechanisms, such as health data access bodies (article 36) or digital health authorities (articles 10-11), could

[10] Kalkman S, van Delden J, Banerjee A, et al. Patients' and public views and attitudes towards the sharing of health data for research: a narrative review of the empirical evidence, Journal of Medical Ethics 2022;48:3-13.
TEHDS - Towards European Health Data Space, results https://tehdas.eu/results/
[11] Ibid

potentially overcome the need of personal control by raising control at a collective level.

- **Trust in public structures**: low levels of trust in governments and public authorities[12] increase the public need and wish for more personal control over health data use. Improving access to personal health data coupled with meaningful patient and public involvement in a spirit of co-creation[13] is a must.
- **Digital health literacy**: this is a blurry notion for most people. There is a lack of understanding of what it entails and how it can add value, and there is even less information on common solutions and issues in a cross-border context, combined with concerns over data protection and confidentiality. In its 2020 report, the eHealth Stakeholder Group (EHSG),[14] created by the EC, underlined that digital health literacy is key to facilitating secondary use of health data and building trust in the potential of digitalisation and data-use for research and innovation.

Recommendations to increase patient and public trust in data altruism for secondary use:

**The concepts of 'innovation' and 'public interest' must be defined** clearly and consistently in a spirit of co-creation with people and patients. To the minimum, the EHDS should address uncertainties over the meaning of those concepts and contribute to building stakeholders' and Member States' common understanding and interpretation of those concepts in line with public and patient perceptions that drive their motivation and willingness to share health data.

As investments in electronic health data systems (e.g., EHRs, registries) increase, policy makers must ensure that those **systems are flexible** enough to respect different public preferences, education levels and digital health literacy levels.

Most importantly, **electronic health data systems and data sharing mechanisms must protect people and respect their privacy**. Many EU-funded research projects, such as the IMI-funded BigData@Heart project,[15] have studied the various legal and ethical aspects of data-intensive research, the different aspects of patient and public preferences, and various approaches to data governance frameworks, models for digital interfaces and dynamic consent. Many scientific papers are already published and many more are yet to be published. **Policy making must be based on scientific evidence** and therefore, lessons learnt and proposals deriving from EU-funded and independent research must be considered by policy makers as they shape the EHDS.

## 3. EHN views on the Governance system

Under the EHDS proposal, Member States must designate and/or establish:

- An independent digital health authority responsible for the implementation and enforcement of the rules of primary use of health data;
- One or more health data access bodies responsible for granting access to data for secondary use.

[12] Eurobarometer 94, April 2021, https://europa.eu/eurobarometer/surveys/detail/2355
[13] Muller, S.H.A., Kalkman, S., van Thiel, G.J.M.W. et al. The social licence for data-intensive health research: towards co-creation, public value and trust. BMC Med Ethics 22, 110 (2021). https://doi.org/10.1186/s12910-021-00677-5
[14] https://digital-strategy.ec.europa.eu/en/policies/ehealth-experts
[15] https://www.bigdata-heart.eu/Publications

In addition, a European Health Data Space (EHDS) Board would also be formed, composed by high level representatives of digital health authorities and health data access bodies of all Member States, to facilitate cooperation and the exchange of information. The EHDS Board would have to coordinate with the European Data Protection Board (EDPB), the European Data Protection Supervisor (EDPS) and the European Data Innovation Board (to be set up under the Data Governance Act).

**In such a multi-level governance approach, it is important to:**

- Clarify the roles and responsibilities of the different bodies for governance and coordination
- Ensure meaningful public and patient involvement in the various levels of governance.

To strengthen the social license[16] of data altruism, the governance framework should balance the diverse patient and public values, needs and interests. Their meaningful involvement in the governance framework is therefore of paramount importance and will contribute to increasing public trust.

## 4. Conclusions and Recommendations:

Individuals are both the sources for and the ultimate beneficiaries of the wealth of health data. The success of the EHDS depends on the readiness and the buy-in by patients and citizens, who stand to ultimately gain the most. Therefore, a balanced regulatory approach weighing digital innovations against 'public interest', public preferences in governance, data sharing and protection of personal data is needed. Accountability, reciprocity, non-exploitation and service of the public good is what the public and patients expect overall.

It is recommended that the EU and Member States:

- Define important concepts such as 'innovation' and 'public interest' together with people and patients.
- Create a secure and privacy-preserving system that delivers for people, patients, healthcare professionals, researchers and innovators.
- Create flexible systems that allow people to receive personalised information and communication on their health data and its uses.
- Ensure meaningful public and patient involvement by putting in place governance mechanisms that give a place to people–including patients, their representatives, and professionals– to allow secondary use of health data that supports the public interest, promotes the safe and ethical reuse of data, and is conducted in a transparent and inherently trust-building manner.
- Ensure that the FAIR principles are applied at the source (data shall be findable, accessible, interoperable and reusable).
- Ensure that structures put in place, such as digital health authorities, health data authorities and surveillance authorities, and infrastructure, such as registries, are also fair, i.e., transparent, equal, trustworthy and righteous.

[16] Muller, S.H.A., Kalkman, S., van Thiel, G.J.M.W. et al. The social licence for data-intensive health research: towards co-creation, public value and trust. BMC Med Ethics 22, 110 (2021). https://doi.org/10.1186/s12910-021-00677-5

- Apply good and validated practices as evidenced by independent research (evidence-based policy making), whether funded by EU or other sources independent of private, commercial or other economic interests.
- Invest in increasing digital literacy and digital health literacy to ensure uptake and successful diffusion of digital health data systems without widening existing inequalities in health, and with a view to building up public trust in secondary use of health data.

## 5. Additional sources:

EHN paper 'What is the value of digital tools for cardiovascular patients?', July 2020, https://ehnheart.org/publications-and-papers/publications/1285:digital-tools-cardiovascular-patients.html

European Alliance for Cardiovascular Health (EACH) Plan for Cardiovascular Health, May 2022, https://www.cardiovascular-alliance.eu/wp-content/uploads/2022/05/EACH-Plan-Final_130522.pdf

EHN input to the Healthier Together Initiative, April 2022, https://ehnheart.org/publications-and-papers/responses-to-consultations/1339:healthier-together-initiative.html

EHN responses to the EC Roadmap on the Pharmaceutical Strategy, December 2021 https://ehnheart.org/publications-and-papers/responses-to-consultations/1334:ehn-submission-pharma-legislation.html and April 2021 https://ehnheart.org/publications-and-papers/responses-to-consultations/1316:ehn-ec-pharma-roadmap.html

EHN ESC 'Fighting cardiovascular disease – a blueprint for EU action', June 2020, https://ehnheart.org/eu-action-on-cvd.html

BigData@Heart publications: https://www.bigdata-heart.eu/Publications