

EUHA Statement:

Key aspects for a successful EHDS – University Hospitals are ready to help unlock its potential

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Summary statement: University hospitals play an essential role in society and host a significant part of health data. The members of the European University Hospital Alliance (EUHA) combine healthcare with research and innovation, as well as with education and training. We collaborate on several projects to improve healthcare, drive health innovation, and foster data exchange for European citizens. **EUHA supports the Proposal for a Regulation of the European Parliament and of The Council on the European Health Data Space (EHDS) published May 3, 2022.** With this statement, EUHA would like to communicate the aspects that it considers essential for a successful EHDS implementation: The EHDS cooperation rules for data altruism require a clear recommendation on patient information and consent as well as alignment with data protection authorities in member states. A governance framework is needed with common principles for data processing under the General Data Protection Regulation (GDPR). The primary use of data by patients and providers is highly encouraged and will benefit healthcare delivery. Making healthcare data available in a machine-readable format leads to enormous efforts for providers. The resulting functional requirements for Electronic Health Records (EHRs) will increase development costs, which will be reallocated to providers. Therefore, funding shall be provided for hospitals not only for making specific data elements accessible but also for meeting the prerequisites of making data digitally available. In secondary use, EUHA believes in a federated approach and differentiates between data ownership, data access, and data use. Patients need to be informed about the secondary use of healthcare data and should be able to opt out. Data use should always be transparent for patients. For the implementation of secondary use, it should prioritize which data elements need to be available for re-use first. In industry cooperations, a governance model is needed to position public healthcare institutions as custodians of patients' health data. **EUHA university hospitals are committed to pro-actively driving the development and implementation of the EHDS, in line with our multiple actions and roles for care, research and education, and with the cross-border collaborative nature of the EUHA itself.**

The mission of the European University Hospital Alliance (EUHA) is to improve patient outcomes through excellence in clinical research, innovation, and education. The cornerstone of achieving this mission, and meeting the needs of patients, providers, and healthcare systems, is creating a digital reality that allows the exchange and reuse of health data. EUHA, therefore, welcomes the creation of the European Health Data Space (EHDS). The EHDS will facilitate a better exchange and access to different types of health data (e.g., Electronic Health Records (EHRs), genomics and other 'omics, patient registries, etc.) to support healthcare delivery (primary use), as well as health research and health policy (secondary use). EUHA and its individual members, being academic hospitals and socially engaged, strive to become trusted parties in data collection, exchange, and access in their own countries. Three key success factors include: the EHDS having strong data protection mechanisms, relying on a robust business plan, and that necessary implementation steps take place at the national level.

To support the EHDS, EUHA and its Digital Health and Data Network, are taking part in the 'Towards the European Health Data Space' (TEHDAS) programme, and we are active in several European and self-funded projects to enable cross-border data exchange. In addition, [through this statement, EUHA would like to communicate its view on critical aspects of the EHDS and affirm its willingness and suitability to be drivers and pioneers in the implementation of the EHDS.](#)

[EUHA's view on the key aspects of a successful EHDS](#)

To successfully collect, store, share and exchange high-quality healthcare data, it is important that the EHDS overcomes challenges posed by siloed organisation of healthcare at regional, and national levels, and the different progress levels of digitalisation across Europe.

A general requirement for the implementation of the EHDS is the digital maturity of healthcare systems. While some countries have digitised most of their national health systems, international semantic and syntactic interoperability standards have hardly been used. Other countries have an urgent need to catch up and have only started to build national EHR infrastructures in recent years. Solutions for patient engagement that can also be used as a mean to provide patients access to their data are hardly implemented. Differences between European countries remain, due to different views on data storage, privacy, and handling, because of diverse historical and cultural backgrounds. In our view, to successfully establish the EHDS, it is important that the EHDS is a suitable and sustainable platform for the future collaboration of all stakeholders across European healthcare systems.

EUHA considers the following aspects essential for the EHDS:

→ **Governance**

The EHDS needs a [governance framework](#) to regulate consent, establish integrated user workflows and create trust in the operation of the EHDS. To achieve this, the governance framework needs to be comprehensive and integrated in its approach to regulate the different classes of health data in line with the intended use for healthcare, research, or policymaking. To facilitate data sharing, especially cross-border, the EHDS needs [common principles for data processing](#) under the General Data Protection Regulation (GDPR). This is needed to eliminate its fragmented implementation resulting from different interpretations in national legislation or deviating additional regulations on the federal or state level. On national levels, structures for data harmonisation are needed which can also be set up regionally if culturally preferred by the population. Stakeholder engagement is important to avoid backlashes hindering a successful EHDS implementation. The EHDS promotes cooperation rules for data altruism in health. '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. General interest is, for example, scientific research purposes or improving public services. The regulation shall provide a clear recommendation on patient information and consent in this context that will need to be aligned with the position of the data protection agencies in member states, given that some data protection agencies, e.g., in France, authorize secondary use of hospital healthcare data on an opt-out basis. Given our experience in the clinical data warehouse, we strongly recommend an opt-out basis for EHDS. An opt-in basis will not allow real fluid data share. We strongly recommend not creating a joint data protection authority in order not to create cronyism. Moreover, the accumulation of different acts (GDPR, Data Governance Act, Data Act, etc.) can create confusion. The regulation should align with the Data Governance Act, which allows fees for all data preparation processes. It

should be recommended to choose sovereign cloud infrastructures to host MyHealth@EU and HealthData@EU.

→ Funding

The budget allocated to the EHDS project is underestimated compared to the project's ambition (220 million EUR EHDS funding between 2023 and 2027, additional 170 million EUR funding from the EU4Health programme and 50 million EUR from the Digital Europe Programme).

→ Primary Use of Data

Health data belongs to the citizens. Health and sensor data from personal devices need to be integrated into EHRs and presented in a user-friendly manner to avoid clinician overload. Likewise, health data need to be portable and made available to patients. Patients need to be empowered in using their data by strengthening their digital health literacy. The exchange of health and sensor data will enable the establishment of more complex telehealth services. To ensure the rapid adoption of these and other digital health solutions, patients need to be engaged in transparent planning and implementation processes. Digital solutions need to improve clinical, operational, and financial processes so that professionals benefit from them in everyday practice and can spend more of their time with patients through digitalisation, not less.

A dedicated budget shall be provided for this action if we share the general objective of fluid circulation of health data for the benefit of patients. The EHDS business model shall be specified and especially consider necessary expenditures of data holders. Moreover, some services are expected to be available for the EHDS, e.g., the provision of personal health data in an electronic format. Health data that was initially recorded in paper format requires significant digitization work. These efforts to meet the prerequisites are not funded.

The regulation shall reinforce the obligations of manufacturers of medical devices and providers of high-risk Artificial Intelligence (AI) systems. These should not only prove interoperability with EHR systems but systematically and immediately transfer the generated data to the respective EHR free of charge.

The high expectations of the regulator and customers create equally high obligations for vendors of EHR systems. Implementing the required functionalities will incur significant development costs that will impact healthcare providers.

→ Secondary Use of Data

Citizens should be empowered to provide access to their data for research purposes and should be helped to understand how collected health data underpin research and innovation to improve healthcare. In this context, a distinction should be made between data ownership (including rights and responsibilities), data access (that is given by default to anonymised data) and data use. For the establishment of a research infrastructure enabling the secondary use of health data, patients need to be informed about secondary use and able to opt out. Opt-out and electronic consent are not necessary if data is used for societal benefits on the legal basis of public interest in the GDPR. Transparency of data use is of great importance. Patients need to be able to see by whom, for what purpose, which data and for how long data is used. Additionally, citizens should decide whether they want to be informed about incidental findings (about their health status) and it should be regulated

how healthcare providers should deal with these. [Aggregated data sets](#) can be made available for third parties and could enable the development of innovative health services such as artificial intelligence tools. The governance of such a research infrastructure should include a (scientific) data permit authority as proposed and ethical rules to establish trust between all parties involved.

The minimum categories of electronic data for secondary use mentioned in the legislative proposal (Article 33) constitute a very heterogeneous set of data associated with significant differences in the effort that data holders shall provide to make the data reusable. The regulation should require a progressive implementation of data reuse by prioritizing structured and coded data.

The provision of personalized healthcare by assessing, maintaining or restoring the health of natural persons, based on the health data of other natural persons (Article 34.1 (h)), classified as a secondary use of data, is more related to primary use for patient care.

The regulation does not state the process/body in charge of assessing prohibited secondary use of health data such as developing services which are designed or modified in such a way that they contravene public order or morality (Article 35 (e)).

Critical aspects regarding the duties of data holders shall be addressed. A two-month delay for the delivery of eHealth data is achievable for structured and coded data but questionable for unstructured data (Article 41.4). The rules for defining cost reduction for the fees for SMEs and public bodies are not explicitly defined (Article 42.4). A data holder excluded from participation in the EHDS shall still have the right to provide access to health data (Article 43).

Once again, a dedicated budget must be provided to achieve these ambitious goals. Moreover, public institutions should be allowed to charge data secondary users for all data processing work, not only for accessing data.

→ **Architecture**

For secondary use, EUHA supports a [federated approach](#), in which data is stored locally but can be processed by other users in secure environments without leaving the national borders. Metadata e.g., for big data, can be stored and queried on a central level. The establishment of secure research environments is essential for fuelling the secondary use of healthcare data.

→ **Data**

EUHA strongly believes in the use of [international interoperability standards, terminologies, and data models](#), such as HL7 FHIR, SNOMED CT, LOINC, UCUM, openEHR and OHDSI's OMOP CDM. Due to the different standards, it is appreciated if the standards to be used for data entities are specified. EUHA advocates for considering the [FAIR-principles](#), findability, accessibility, interoperability, and reusability, regarding data handling and data infrastructure.

→ **Workforce**

For the successful digital transformation of the European health systems, Europe and its member states need to [invest in teaching the new multi-disciplinary digital reality](#) within healthcare and life sciences education and to develop a health IT workforce, especially in the fields of data analytics, data sciences and health IT management. As the technological landscape will always evolve, a culture of lifelong learning needs to be established.

EUHA's unique role and how we can support the development and implementation of the EHDS

EUHA's strong commitment to the EHDS is clearly present in its strategic plan for 2021-2023, with three out of six goals related to digital health and data exchange:

- We harness the potential of data exchange by understanding our unique strengths and shared challenges, increasing interoperability, and developing common approaches to help establish the EHDS
- We engage and empower patients through data and tools that enable them to optimise their outcomes and experience. This explicitly includes data generated by patients themselves, e.g., patient-reported outcomes measures (PROM), wearables, and patient apps.
- We develop a responsible research and innovation culture, through joint projects in clinical trial results publication and FAIR research data.
- In the intended cooperation with industry, not only from the healthcare sector, we also emphasize the importance of setting up a transparent governance model that includes the role of healthcare providers as custodians of our patients' health data. Consequently, we are not in favour of databases with health-related data of any kind governed by industry or any other commercial enterprise. All health-related data must be governed by public healthcare institutions.

In addition, by establishing [the EUHA Digital Health and Data Network](#), which brings together 15 Chief Digital/Information Officers, IT directors and health data science researchers, EUHA can drive the digitalisation of university hospitals in Europe at scale. The network is already active in two work packages of the 'Towards the European Health Data Space' (TEHDAS) programme and supports EUHA's digitalisation projects.

EUHA pioneers the development and implementation of cross-border health exchange through several projects. Our member Erasmus MC coordinates the IMI EHDEN project of which now all EUHA members are data partners, and we are working to empower patients to report and use their outcomes in the IMI Health Outcomes Observatories (H2O) project (coordinated by the Medical University of Vienna). Additionally, EUHA has started a self-funded project to establish an OMOP-based European benchmark on breast cancer care outcomes. As such, [EUHA has expertise in generating, processing, and exchanging health data in the context of patient-centred inter-organisational medical documentation](#). Finally, our members rank high in the Newsweek 'World's Best Smart Hospitals 2021'.

[With the triple role across healthcare, research and education, and its long-term committed partnership EUHA hospitals are the perfect fit as test beds for future digital health services that will be developed within the framework of the EHDS](#). Examples of these include, that EUHA hospitals can:

- Act as testbeds and pilot sites for cross-border digital health services
- Develop curricula and training on digital health competencies
- Validate the translation of policy objectives into concrete steps for EHDS development
- Review technological solutions for data sharing among health and biomedical data repositories
- Translate SNOMED CT into various languages

EUHA is looking forward to helping drive the implementation of the EHDS and would be delighted to discuss any questions or comments on this statement.

About the European University Hospital Alliance

The European University Hospital Alliance is formed by nine leading European University Hospitals with demonstrated excellence in healthcare, education and research which collaborate to improve outcomes for today's and tomorrow's patients:

Aarhus University Hospital, Aarhus, Denmark | **Assistance Publique – Hôpitaux de Paris**, AP-HP, France | **Charité - Universitätsmedizin Berlin**, Berlin, Germany | **Erasmus MC**, Rotterdam, the Netherlands | **Karolinska University Hospital**, Stockholm, Sweden | **King's Health Partners**, London, United Kingdom | **Ospedale San Raffaele**, Milan, Italy | **Universitätsklinikum AKH Wien & MedUni Wien**, Vienna, Austria | **University Hospitals Leuven**, Belgium | **Vall d'Hebron Barcelona Hospital Campus**, Barcelona, Spain.

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