European University Hospital Alliance

EUHA Perspective on Secondary Use of Health Data and Intellectual Propery under the European Health Data Space

EUHA Position Paper

Full Title: EUHA Perspective on Secondary Use of Health Data and Intellectual Property under the European Health Data Space (EHDS).

Credits

This paper has been written by Johan Van Eldere (EUHA Secretary-General).

This paper has been submitted for review and feedback to the EUHA Digital Health Data Network, the Policy Working Group, and through the EUHA Steering Committee members to various stakeholders in the EUHA member hospitals. Reviewers are: Christian Fynbo (Aarhus University Hospital), Roberto Buccione, Marco Soriano, Marco Morelli (Ospedale San Raffaele), Georg Duftschmid (University Hospital Vienna, Medical University Vienna), Bart De Greef, Bart Hamers (UZ Leuven), Peter Rijnbeek, Martijn de Vlaming, Renske Los, Robert Veen (Erasmus MC), Rikard Lövström (Karolinska University Hospital), experts from Helsinki University Hospital (unnamed), Petra Ritter (Charité - Universitätsmedizin Berlin), Sigal Hachlili Dwyer and Richard Dobson (King's Health Partners) and Joan Carles Peiró (Vall d'Hebron Barcelona Hospital Campus).

The paper was approved by the EUHA Members' Assembly in May 2026.

EUHA extends its gratitude to all those mentioned above for their valuable contributions and feedback.

Image Credits
This paper includes photographs courtesy of Aarhus University Hospital.

June 2026

To cite this work, please use the following reference:
European University Hospital Alliance. EUHA Perspective on Secondary Use of Health Data and Intellectual Property under the European Health Data Space. 2026. Brussels.

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Executive Summary

The European University Hospital Alliance (EUHA) supports the objectives of the European Health Data Space (EHDS) regulation: strengthening interoperability of health data, facilitating secondary use for research, innovation, and public health, and enabling cross-border data access for patients while protecting citizens' rights through harmonised governance. However, the implementation of the EHDS regulation must recognise that large healthcare institutions, in addition to being data users, are not passive data suppliers but data controllers, custodians, and guarantors of data quality, contextual integrity, and patient trust. The EHDS regulation should reinforce—rather than weaken—this institutional role.

EUHA acknowledges that several concerns raised in the debate require nuance. In particular, Open Science (OS) and Intellectual Property (IP) protection should not be framed as opposing paradigms. A balanced, legally coherent approach is both possible and necessary.

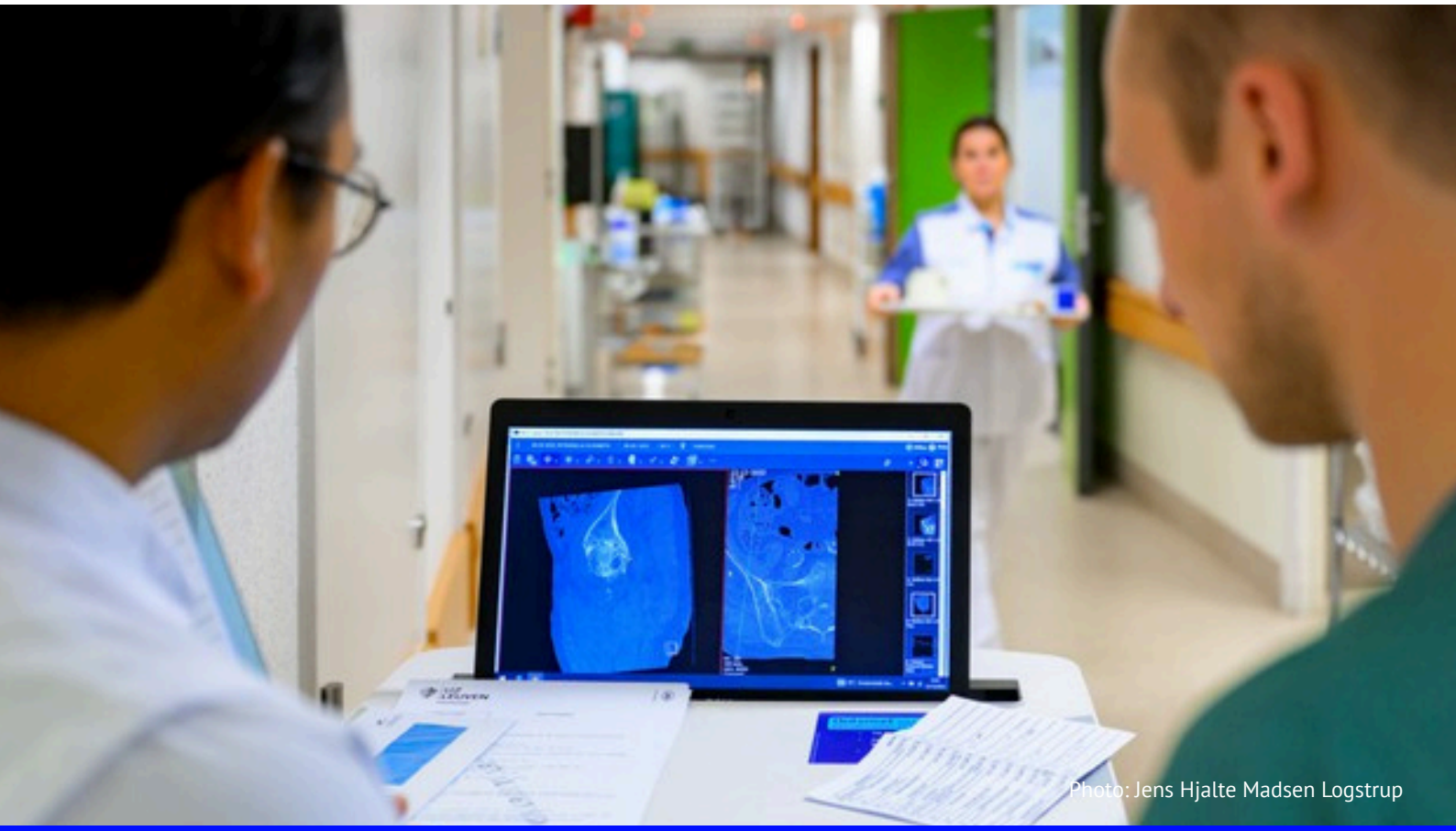

Photo: Jens Hjalte Madsen Logstrup

EUHA Calls for a Careful Balance between Opennes and Protection

Federated Governance as the Default Model

The EHDS foresees secondary use of health data via Health Data Access Bodies (HDABs) and Secure Processing Environments (SPEs). EUHA strongly advocates for access-based models rather than data transfer, with processing conducted within secure environments, strong traceability and logging, and complemented by federated validation infrastructures across major healthcare institutions. This will secure data integrity, quality, and privacy when needed.

EUHA does not support de facto centralised warehousing of raw data at EU or national/regional level detached from originating institutions or governance structures, as this risks diluting data controller responsibility. The EHDS must therefore preserve GDPR-aligned controllership at the institutional level and maintain accountability structures linked to the real clinical environment.

Open Science vs. Intellectual Property and Trade Secret Protection

The EHDS promotes the reuse of health data in the public interest. EUHA supports this objective but stresses that hospitals invest substantial resources in structured Electronic Health Record (EHR) implementation, data curation and annotation, data harmonisation, and quality control. In addition, there is significant clinical know-how embedded in structured clinical registries and biobank linkage. In EUHA's view, these activities are sufficient to constitute database rights. They require institutional know-how that constitutes trade secrets and represents a major public investment.

EUHA therefore maintains that the secondary use under the EHDS must respect intellectual property, and the rights and valorisation potential of data holders. This includes recognising database rights, protecting trade secrets relating to curated clinical datasets and derived insights, and safeguarding the legitimate confidentiality interests of health data holders.

The core principle of Open Science (OS) is to enhance transparency, reproducibility, and accessibility of scientific knowledge, while preserving justified IP protection mechanisms. OS does not imply automatic and unrestricted commercial exploitation, nor a loss of control over derivative outputs. Such interpretation, would lead to the erosion of incentives for high-quality data collection and curation. Proportionate compensation mechanisms and governance agreements should therefore remain possible under the EHDS. Thus, open dissemination and IP protection should be seen not as mutually exclusive, but complementary components of responsible research governance.

Attribution and Academic Recognition under EHDS are Essential

The EHDS enables secondary use without requiring direct involvement of the originating institution in downstream research. As the originating institution has first-hand knowledge of the provenance, value, and maturity of its data, not involving the originating institution in the analysis of its data may lead to a loss of context and less reliable interpretation. Importantly, it may also create tension with academic incentive systems. In academic medicine, data quality is driven by scientific culture and recognition, and authorship remains a core incentive mechanism. Responsible data sharing contributes to an open innovation ecosystem in which the value of high-quality, well-curated data is recognised, originating institutions are appropriately acknowledged and compensated, and incentives are preserved to maintain data quality and accountability.

To prevent this tension, EUHA advocates mandatory attribution mechanisms within secondary use frameworks, robust provenance tracking within EHDS infrastructures, recognition of dataset creation and curation as a form of research output, and transparent reporting of secondary research outcomes back to data-originating institutions. However, institutional recognition must be addressed in a manner consistent with international authorship standards.

High-quality health data ecosystems depend on academic motivation, scientific recognition, and reputational incentives. EHDS implementation should therefore strengthen data stewardship culture rather than commoditise hospital-generated data. Reputational integrity and academic credit are not peripheral concerns; they are structural enablers of high-quality health data ecosystems.

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Reuse of Research Data: Safeguards Expected by Health Data Holders

The EHDS enables secondary use beyond the original research purpose, including for Artificial Intelligence (AI) development. EUHA expects that such reuse remains within a clearly defined legal basis (public interest research or equivalent), that it occurs within secure, validated environments, that data quality and contextual metadata accompany the dataset, bias testing and representativeness assessment are mandatory, post-market monitoring includes feedback to originating institutions, and commercial use is transparent and subject to governance agreements.

Importantly, EUHA emphasises that data reuse frameworks must not shift liability risk to data-originating hospitals when AI systems are developed by third parties.

Health Data Holders as Structural Actors in the EHDS

EUHA proposes that under the EHDS framework, health data holders should retain their GDPR-defined controller status, participate in governance networks with HDABs, contribute to federated AI validation infrastructures, be recognised as ethical gatekeepers, and remain central in post-market validation loops for AI systems.

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Conclusion

The implementation of the EHDS must ensure a federated, secure access model rather than centralised data extraction, and must ensure the preservation of data controllership, the protection of intellectual property, and institutional know-how. EUHA also advocates for mandatory attribution, recognition, and compensation mechanisms, strong safeguards for reuse in AI development, and clear liability boundaries for downstream use.

It is essential to avoid a false opposition between OS and IP protection. European research policy demonstrates that openness and proportionate IP management are complementary. A model based on overly restrictive dataset control would be inconsistent with European principles of research integrity, reproducibility, and responsible innovation, and would diverge from the trajectory set by the EHDS initiative itself. Conversely, overly open access to datasets may hamper the development of high-quality data collections. The objective should therefore be a balanced, federated, secure, and scientifically responsible implementation of the EHDS that protects institutional stewardship and legitimate IP interests while enabling transparency, reproducibility, innovation, and societal benefit across Europe.

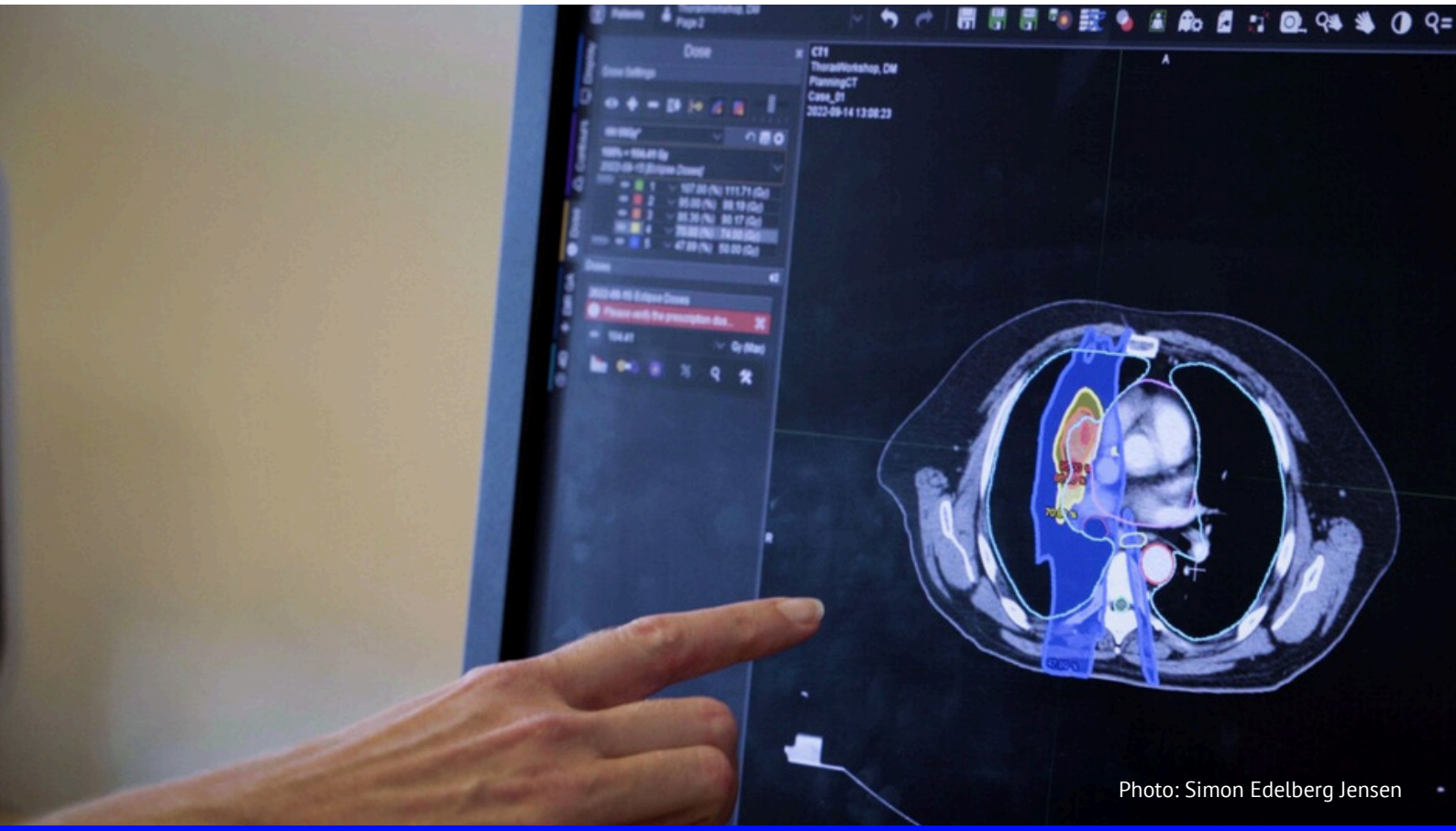
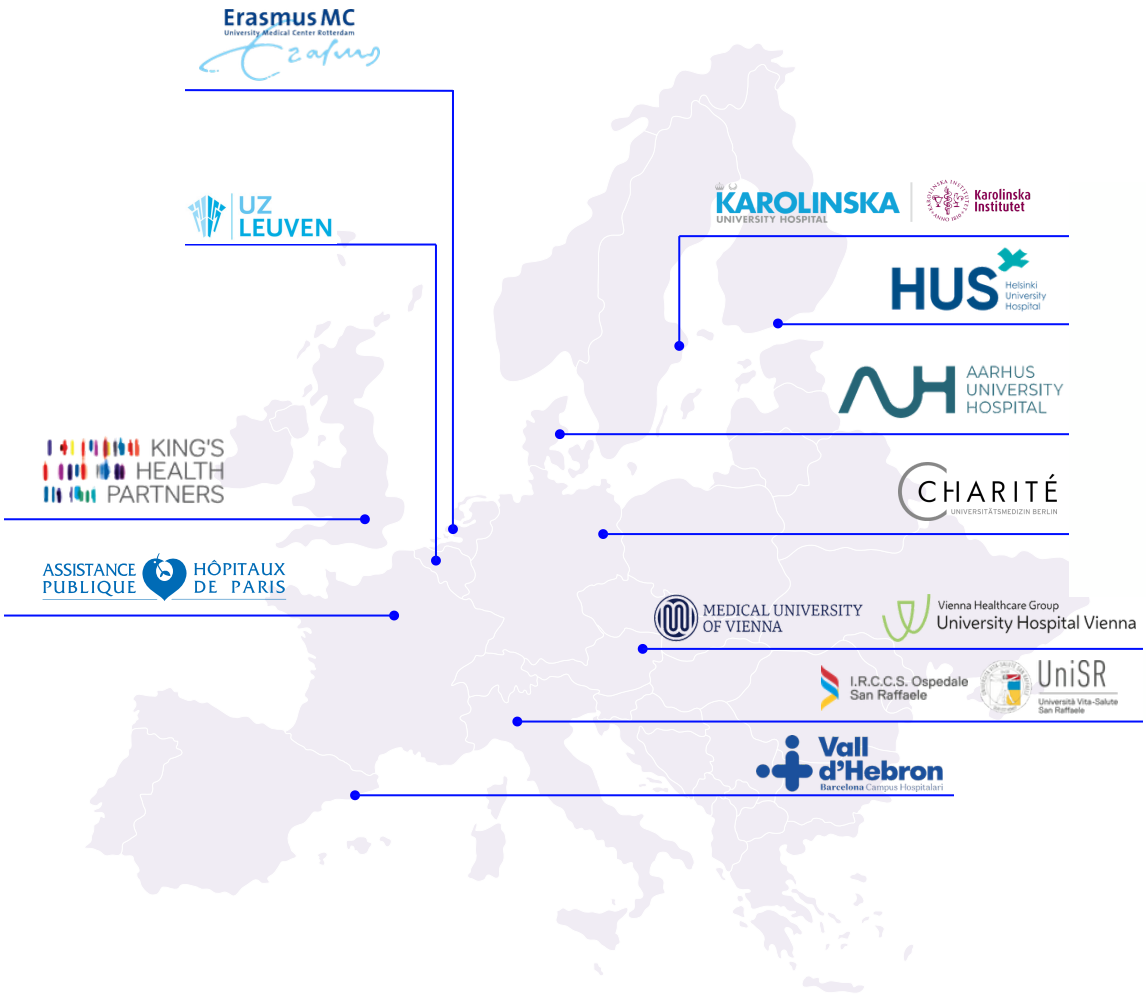


Photo: Simon Edelberg Jensen

About EUHA

The European University Hospital Alliance, founded in 2017, is formed of 11 leading European university hospitals. University hospitals play an essential role in healthcare systems and society, taking care of the most complex patients, performing research, pioneering healthcare and innovation, and training the next generation of healthcare professionals.



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