The European Health Data Space: Expanding access to health data while preserving incentives for medical innovation

Status, points of attention and insights

The nexus between biomedical research, data and digital opportunities has become a critical and crucial driving force in fostering innovation and competitiveness in the life science sector. To that end, human materials and, associated clinical and research data, are becoming increasingly important as a basis for fundamental, basic and translational research as well as innovation to enhance the competitive space of startups, scale-ups and incumbents in the life science industry.

A rich variety of extensive data collections, originating from across different geographies and trial conditions, add scientific power to clinical studies and treatment investigations by better capturing patient heterogeneity. Currently, the use of human materials and associated clinical and research data can be further optimized by overcoming the fragmented conditions for accessing samples and data across Europe.

The European Health Data Space (EHDS) attempts to harmonize those fragmented conditions and to ensure maximal access of data related to human materials and clinical investigations for scientific research. EHDS therefore has the potential to create value for innovation and subsequent competitive performance. To that end, well-organized access via secured processing environments enables data security and privacy while respecting both patient and ownership rights. It provides an opportunity to turn health data into strategic assets in an era where the success of AI for health will be determined by how robust and comprehensive the data to train it is. Assets and benefits are judged to be multiple, for patients, for hospitals, for research and its translation into market-relevant innovations through business ventures (newly created and incumbent).

At the same time, for health data to be translated into meaningful and sustainable innovations, intellectual property regimes are essential. While data should be easily available for research, patent protection of inventions generated from research with human data (as an input) is essential to guarantee exclusivity for industry or investors to invest in the long and capital-intensive development of novel therapies, treatments, diagnostics, ...

EHDS does not overrule IP rights. Access to data under the EHDS framework does not affect the allocation of intellectual property rights on the results of the underlying research. Patient data are owned by the patient, while care and research institutions, biobanks, etc. are the guardians of the data. The role of EHDS is to regulate data access and reuse conditions, but intellectual property in resulting research outputs is determined independently under existing legal frameworks by the relevant and involved institutional actors. Ownership is determined by general IP law (patent law), inventorship rules, copyright law, database regulation, know-how protection, employment law and contracts, and hence not by EHDS, considering inventorship basics:

- Contributes to the conception (“devising”) of the invention, and makes a technical contribution reflected in at least one claim, when

focusing on patent applications. The differences between US and Europe should be considered, whereby inventorship in Europe is defined by national law which leads to potentially different interpretations.

- Mere execution, routine experimentation, supervision, funding, or administrative involvement does not confer inventorship. While adding the nuance that research may lead to ownership residing with, e.g., the institution even if the invention was conceived by the researcher or employee.
- Providing access to human data is not an inventive contribution.
- Tangible contributions based on clinical-basic collaborations are a basis for co-inventorship (e.g. unique investigator-driven trials, 'devising' the research path to actionable insights…).

Timing of the obligation to make data available should hence be aligned with the relevant processes for scientific publication, regulatory strategy (for regulatory clinical trials) and patenting. Peer review ensures data quality and robustness of the conclusions drawn from these data. Peer reviewed publications on "omics data" often summarize 2-5 years of research. Time for seeking patent protection, which guarantees incentives for industry to innovate, should be provided. Data on clinical trials in a regulatory context (e.g. product approvals) can only be made available at publication of clinical trial results, given legitimate concerns around the disruption of regulatory process, the need for additional patenting, as well as securing exclusivity and securing competitive dynamics. It is obvious that enforcement of publication on companies developing novel agents would cause real economic damage. It would cause companies to avoid Europe as a center stage for health innovation. Publications, patenting, communication, fund-raising, etc. are dimensions of a highly orchestrated process for any biotech or pharma actor. Hence, companies should be able to reasonably postpone accessibility until publication. Also, data on failed clinical trials should be made accessible to create both a research and innovation flywheel.

Remarks and concerns raised during EHDS legislative process

The importance of a clear definition of scientific research for the correct application of the scope of the new regulation has been stressed. The following needs have been identified by the League of European Research Universities (LERU):

a. A definition of scientific research should be adopted, which is consistent with other EU data frameworks adopted in the context of the European strategy for data, as well as with the GDPR framework.
b. The definition of scientific research must ensure that health-related algorithmic or AI projects are not exempted from the robust ethical and methodological standards that would apply in scientific research falling within the scope of the regulation. Hence, the training and testing of AI systems should be included.
c. Avoid narrowing the scope of scientific research to health and care sectors only. Define scientific research more broadly to include all research projects that require health data (for example, sociology, anthropology, etc.)

d. A clear definition of public interest is required to ensure that all scientific research which comes within the scope of the new regulation, is in the public interest (as defined), and that each Health Data Access Body (HDAB) tasked with reviewing data users' applications adheres to recognised ethical standards of scientific research and a clear understanding of how to contribute to open science in a standardised way. The EHDS is an opportunity to bring clarity to the concept of public interest, which is under the GDPR essentially left for the member states to define.

There is a need for a harmonised definition of data categories across the EU Member States, and across the various Data Acts that have come into place both for personal and non-personal data. The inclusion of insurance status, e.g., could lead to risks of insurance discrimination, particularly if incidental findings are shared back to the individual because of scientific research being conducted under the EHDS.

We should hence avoid inconsistencies between the EHDS, the GDPR, and the Data Act regarding the data holders' right to refuse to share their data, as well as contradictions between the EHDS and the AI Act about any use of AI in scientific research projects.

The EHDS opt-out mechanism must be aligned with data subject rights under the GDPR, which permit exemptions in certain situations which could seriously impair the research results (such as if information has been published or is about to be published). Significant patient involvement in the decision-making of health data access bodies is recommended, to avoid the risks of under-representation and biased datasets due to certain sub populations opting out because of e.g. public trust. The conditions for valid opt-out identified in the guidelines of the Council for International Organizations of Medical Sciences (CIOMS) can serve as valuable basis for building it up.

A standard ethics assessment should be carried out by ethics bodies within health data access bodies. And, moreover, the health data applicant should make available any previously obtained approval of a competent ethics committee in accordance with their national law, as part of the data access application.

Non-standardisation of ethical review, as at present, ethical review is non-harmonised across the EU, should be avoided.

Uncertainties in the provisions on the protection of intellectual property (IP) rights and trade secrets must be avoided to alleviate challenges to determine the criteria for safeguarding data holders' IP rights effectively, and to predict how IP-protected data will be managed in the future EHDS framework.

Concretely, the conditions under EHDS for the sharing of data should not mandate the use of shared data obtained under EHDS for unfair commercial use or other unfair competition. Furthermore, the requirement for data users to publish the results of the output should be high level enough not to erode IP rights.

Finally, any intention to give the responsibility to the HDAB to act as a gatekeeper for assessing and protecting intellectual property and trade secrets would be inadequate. Data holders shall make electronic health data from EHRs available for secondary use.

Finally, a similar impact to that produced by Regulation (EU) 2017/745 on medical devices, which led to some medtech being withdrawn from the European market, should be avoided. The co-legislators should consider the relationship between primary and secondary use of health data.

Based on engagements with universities' partner hospitals, concerns have been raised about how such findings may impact on primary care, and in relation to any genetic findings, which may require further resources at Member State level (such as genetic counsellors). Clear timelines are warranted for the interaction of data holders with the HDABs, standard operating procedures on data-sharing, and reassurances on the security of the data.

Conclusion

Access to health data can both be an engine and an impediment to innovation and competitiveness, reminding us of the open science tenet: As open as possible, as exclusive as needed. Taking the above caveats into account, EHDS may become a booster for European health innovation.

Koenraad Debackere, June 2026, revised July - August 2026

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