EHPL
EUROPEAN HEALTH & PHARMACEUTICAL LAW REVIEW

2026 EHPL & HELT YOUNG SCHOLARS AWARD

The European Health and Pharma Law Review (EHPL) cordially invites young researchers (Master or PhD students) to submit articles for the 1st annual EHPL & HELT Young Scholars Award. Recently graduated PhDs or early Post-Docs are also welcome and can still submit their papers to be published in the special issue. This award and the special Issue is organised in collaboration with the 4th Health, Ethics, Law, and Technology Symposium (HELT 2026), a part of Health & Ageing Law Lab (HALL) of Vrije Universiteit Brussel. The winner of the competition will receive a one-year subscription to the European Health and Pharma Law Review.

The best submissions will be published in a special issue of EHPL in 2026. The selected papers will be invited to be presented at the HELT 2026, and the winner will be announced there. Please note that only those selected papers will be published in the special issue of the EHPL which are presented at the HELT 2026.

The contribution must deal with the themes/topics of the HELT2026: "EHDS Regulation, a Year On: From Vision to Reality." The preferred approach is legal, but interdisciplinary approaches are also welcome. The article should depict the core points, including key questions, hypothesis, methodology, findings and policy recommendations, if applicable. Submissions are only accepted in English. They are subject to the scrutiny of an expert jury which will evaluate their quality, degree of innovation and clarity of presentation.

Participation Requirements:

- Eligible Topic
- Format (5.000 - 7.000 words, in English)
- Deadline for submission: 15 February 2026

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"EHDS Regulation, a Year On: From Vision to Reality"

About HELT 2026

On **April 23rd, 2026** it will be a little over one year since the adoption of the European Health Data Space (EHDS) Regulation - a landmark initiative aiming to transform how health data is accessed, shared, and used across the EU. This milestone offers an opportunity to reflect on key aspects relating to the implementation of the EHDS Regulation, evaluating the scale of its impact, practical implications, and emerging challenges within the broader EU healthcare landscape. The **2026 Health, Law, Ethics and Technology (HELT) Symposium** aims to to explore what remains to be done for the Regulation to fully realise its vision of a connected, secure, and innovation-driven EU health ecosystem.

HELT 2026 will serve as a forum that brings together representatives from the academia, industry, large research organisations and SMEs, healthcare providers and public institutions. This year's edition features a wide range of panel discussions, breakout sessions and workshops, focusing around the question of how the EHDS is impacting - or is expected to impact - key stakeholder groups, processes and operations at EU and national level.

Call for Papers | 2026 Young Scholars Award : Themes and Topics

This document presents a list of suggested topics and themes for young researchers interested to submit an article for the 1st Annual **EHPL & HELT Young Scholars Award**. Kindly note this is a non-exhaustive list -- those interested to submit a paper are welcome to present their own ideas around the main theme of the event.

Scan QR code to visit **HELT 2026**

Primary use of health data

The EHDS outlines broad requirements for entities involved in healthcare provision, particularly concerning the use of EHRs and the sharing of health data among providers. While the regulation establishes a foundation, further implementing acts are expected to provide additional precision. Stakeholders will need to closely monitor these developments, as they will determine specific obligations, deadlines, and operational requirements for compliance.

- What steps are being taken to ensure electronic health records systems do not disrupt the provision of care while, at the same time, correspond to the needs of healthcare professionals?
- What are the main systemic, financial, and cultural barriers that might prevent the full, consistent, and equitable adoption of MyHealth@EU services among healthcare providers and professionals in different EU Member States?
- How does the EHDS framework empower individuals to exercise their rights, such as the right to restrict access to their electronic health data, and what are the clinical and ethical implications of such restrictions on primary care provision?
- What are the critical technical and semantic interoperability standards required to ensure high-quality and safe exchange of patient data across EU Member States?

Secondary use of health data

The EHDS provisions on secondary data use are extensive, potentially encompassing a wide range of actors who may be classified as health data holders. These entities will be required to make electronic health data available for secondary processing, which may impose a significant administrative burden. Clarifying the scope of the healthcare sector and the legitimate grounds for secondary processing will be essential. Defining these boundaries will help stakeholders understand their obligations and ensure that secondary data use aligns with the regulation's objectives.

- How should the EHDS delineate which entities qualify as "health data holders," particularly when data originate from private providers, research infrastructures, or digital-health companies operating across borders?
- What legitimate legal bases and governance mechanisms under the EHDS and the GDPR can ensure that secondary data processing remains both lawful and consistent across Member States?
- How can administrative and technical burdens on data holders (especially healthcare institutions with limited resources) be reduced while maintaining interoperability, data quality, and security?
- What mechanisms or incentive structures could help balance compliance costs and responsibilities among actors required to make electronic health data available for secondary use?
- How can transparency and accountability be strengthened so that data subjects understand how their information is reused for research, innovation, or public policy purposes under the EHDS?

- How can the national Health Data Access Bodies (HDABs) effectively balance the societal benefits of secondary use with the need for stringent protection of health data, particularly regarding the use of such data in secure processing environments?
- What methodologies are needed to ensure the uniform high quality, representativeness, and comparability of health data sets made available for secondary use across the EU?

Medical Device Manufacture and Use

The EHDS provisions on secondary data use are extensive, potentially encompassing a wide range of actors who may be classified as health data holders. These entities will be required to make electronic health data available for secondary processing, which may impose a significant administrative burden. Clarifying the scope of the healthcare sector and the legitimate grounds for secondary processing will be essential. Defining these boundaries will help stakeholders understand their obligations and ensure that secondary data use aligns with the regulation's objectives.

- How can manufacturers develop a unified compliance strategy for AI-driven medical devices that simultaneously satisfies the distinct requirements of the EHDS (for data access and reuse), the MDR/IVDR (for safety and performance), and the AI Act (for algorithmic risk) if applicable?
- What will be the implications for ethical committees approving clinical trials of medical devices, whether under the MDR or IVDR?
- Under the EHDS, what are the new responsibilities and technical burdens for healthcare users (such as hospitals and clinics) who will be classified as "data holders" for the data generated by the medical devices they operate, and how will they manage this in practice?
- What opportunities and challenges will arise for AI developers, medical device manufacturers, and digital health companies in accessing and using data under the new framework?
- How do the data-sharing obligations of the EHDS and the Data Act interact and align with requirements of the MDR and IVDR, particularly in the context of the Internet of Medical Things (IoMT)?
- What measures are necessary to ensure the EHDS enhances the global competitiveness of the European medical device industry by creating a dynamic, trustworthy, and efficient data environment for innovation compared to other jurisdictions? Will this environment include innovation in health and well-being apps?

Access health data through EHDS for AI training and testing

Under the EHDS framework, access to electronic health data may be permitted for the purpose of training and testing AI systems. This possibility gives rise to a complex interplay between the EHDS Regulation and the AI Act, particularly in relation to the obligations concerning high-risk AI.

- To what extent does the EHDS permit the use of health data for AI training and testing , and what are the appropriate legal bases under the GDPR for such processing by data users?

- How does the use of health data for AI training and testing under the EHDS interact with the obligations set out in the AI Act, particularly Article 10 concerning data quality and bias mitigation?
- To what extent can health data quality labelling system introduced by the EHDS Regulation facilitate compliance with the AI Act?

Cybersecurity and the EHDS

The EHDS introduces robust cybersecurity requirements to protect electronic health data. As health data becomes more accessible for secondary use, ensuring its confidentiality, integrity, and availability is paramount. Stakeholders will need to discuss how the regulation addresses cybersecurity risks, the measures required to safeguard data, and the responsibilities of data holders in preventing breaches. Clarifying these aspects will be critical for maintaining trust in the EHDS framework.

- Under the EHDS, how can we establish a clear and practical framework for shared cybersecurity responsibility and accountability among diverse actors, including data holders, Health Data Access Bodies, and data users?
- How will the EHDS' cybersecurity-related mandates for health data and systems practically align or potentially conflict with the broader horizontal obligations imposed on health sector entities (e.g., under the NIS2 Directive and the Cybersecurity Act of the EU)?
- What are the primary implementation challenges for healthcare entities in meeting the combined cybersecurity requirements of the EHDS, the NIS2 Directive, and the GDPR?
- What policies and technologies are necessary to ensure the continuous security and lifecycle of connected medical devices (cMDs), remote patient monitoring (RPM) systems, wellness applications and wearables within the EHDS ecosystem?
- What will be the direct or indirect impact of the Cyber Resilience Act on the EHDS Regulation, more specifically regarding the security requirements for the harmonised software components of EHR systems?
- Through what actions is the EU's Action Plan on the Cybersecurity of Hospitals and Healthcare Providers designed to contribute to the resilience and security framework of the EHDS?

Public health and the EHDS

The EHDS empowers public health agencies to access and process electronic health data for a variety of purposes. This capability allows public health efforts to be more tailored and responsive to evolving challenges, such as pandemics or chronic disease management. Crucially, these challenges now increasingly include the health impacts of environmental factors, requiring the linkage of clinical data with new cross-sectoral data sources. However, it is essential to define the scope and conditions of data access under the EHDS. Understanding what is permitted and the associated requirements will help ensure that public health initiatives are both effective and compliant.

- What current pilot projects or real-world case studies can demonstrate the tangible public health value of linking cross-sectoral data sources (e.g., environmental data) and health data?
- Which ongoing EHDS-related initiatives (such as EpiPulse, EuroHeart, or EpiTweetr) illustrate measurable public health benefits from combining environmental, geospatial, or genomic data with clinical datasets?
- In what ways can EHDS-enabled data sharing strengthen surveillance and preparedness for pandemics, climate-related health risks, and chronic disease management?
- How can EHDS-facilitated data sharing contribute to early warning systems for zoonotic disease outbreaks by integrating animal health, veterinary, and environmental monitoring data?
- How can cross-sectoral data linkages help identify and mitigate antimicrobial resistance trends at the human–animal–environment interface?
- How can the EHDS framework practically support the integration health-related datasets cross sectoral boundaries to support secondary use addressing public health challenges (e.g., scientific research)?
- What mechanisms within the EHDS framework (e.g., HealthData@EU, Health Data Access Bodies) enable secure and interoperable linkage of health, environmental, and mobility data for research and policy?
- How can the EHDS support integration of agricultural, food safety, and plant health data to improve understanding of foodborne diseases and toxin exposures?
- What governance and technical safeguards—such as secure processing environments or validation of non-traditional data sources—are needed to ensure scientific reliability and trust?
- When linking identifiable health data with cross-sectoral data (e.g., geospatial, pollution, or even wellness data), how to define the scope and conditions for data access under the EHDS while ensuring robust compliance with the GDPR and applicable ethical requirements?
- How should the EHDS Regulation specify proportionality, purpose limitation, and safeguards to maintain compliance while supporting meaningful analysis?
- How can transparency and citizen engagement - through organisations like EURORDIS or public data-permit registries—enhance legitimacy and accountability in such secondary uses?
- What safeguards are needed when combining veterinary, agricultural, and human health data to prevent misuse or stigmatisation of regions or sectors?

Wellness and the EHDS

The EHDS explicitly addresses the integration of wellness data into electronic health records (EHRs) and the potential reuse of data generated by wellness applications for secondary health processing. This inclusion is significant not only for expanding the data available for medical research but also for fostering the growth of the wellness industry. Over the past year, debates have arisen regarding the extent of wellness data integration within the EHDS. Resolving these issues will be crucial for clarifying the role of wellness data in the broader health ecosystem.

- Where is the regulatory boundary between a "medical device" and a "wellness application" under the EHDS, and how will this distinction impact a developer's obligations for both interoperability and data sharing?
- Given that wellness data is often self-reported or passively collected, what specific legal and ethical safeguards are needed for its secondary use, and how the research value of this data against the heightened privacy risks can be assessed?
- To what extent does the EHDS' legal framework for wellness apps, balance fairness and contestability with consumer welfare in the app ecosystem, particularly in light of app stores' dual roles as platform providers and app developers?

Effects on the pharmaceutical industry

The EHDS will transform the pharmaceutical industry by improving access to electronic health data, enabling more efficient clinical trials and real-world evidence use. Companies must comply with new data-sharing and transparency rules, ensuring anonymised trial data is available for secondary use while adhering to strict data protection standards. The EHDS also fosters cross-border research collaboration, accelerating innovation. Staying up-to-date with evolving guidelines will be pivotal to leveraging these opportunities effectively.

- To what extent will high-quality, large-scale, and accessible EHDS data accelerate the discovery, development, and personalised medicine strategies of the pharmaceutical and biotech industries?
- How can the EHDS support regulatory decision-making, such as for the European Medicines Agency (EMA), by providing access to real-world data for drug safety monitoring, effectiveness studies, and regulatory science?
- What measures are necessary to ensure the EHDS Regulation enhances the global competitiveness of the European pharmaceutical industry by creating a dynamic, trustworthy, and efficient data environment for innovation compared to other jurisdictions?

Governance, trust and collaboration

The EHDS Regulation introduces new governing bodies in primary and secondary use responsible for the implementation and enforcement of specific provisions of the Regulation. At national level, Digital Health Authorities, Health Data Access Bodies (HDABs), together with data protection authorities which remain competent to supervise the General Data Protection Regulation (GDPR) compliance. At EU level, the EHDS Board for exchanging best practices and preparing guidelines, the Stakeholder Forum and the Commission who coordinates the cross-border infrastructures and common specifications for interoperability and logging. Trust needs to be fostered to connect patients, healthcare professionals and healthcare providers to electronic access services under the primary use framework; and collaboration is required from HDABs, data holders and data users for data discovery and multi-country applications under the secondary use framework.

- What steps are being taken to raise awareness and educate citizens of their new rights in the EHDS Regulation?
- What is the HDABs community of practice? What are they working on?
- What initiatives are supporting EHDS to ensure it comes to light? What areas still need to be developed?
- How to respect ethical provisions under national law when granting a data permit or a data access request? What cooperation mechanisms should be established to support HDABs in this task? How could the 'single application' principle help in this process?
- The delineation of responsibilities, coordination and collaboration among digital health authorities, HDABs and data protection authorities in enforcement, such as imposing administrative fines and handling complaints.
- To what extent do the different layers of interoperability, e.g., semantic, syntactic, technological, and legal, pose challenges to the sharing of health data and the successful implementation of the EHDS Regulation? What could be the potential solutions to overcome the challenges?
- How will the EHDS affect governance structures, data standardisation, and the oversight of cross-border data flows?
- How will the EHDS change clinical workflows, access to patient data, and responsibilities for data stewardship?

The role of technology in building a European Health Data Space

The EHDS relies on technological infrastructures at both the EU and national levels to enable the secure sharing and reuse of health data. At the same time, effective safeguards, such as anonymisation, pseudonymisation, and secure processing environments, are essential to ensure privacy, security, and compliance with EU data protection law. The adequacy and reliability of these technologies must be assessed in light of ongoing technical and legal developments and the implementation of the regulation.

- How do the technologies designed to facilitate data sharing, including decentralised and federated system architectures, metadata catalogues, and the use of artificial intelligence for generating dataset descriptions and assessing data quality, operate, and what is their current stage of development and implementation?
- What is the current state of the art regarding technical safeguards such as anonymisation, pseudonymisation, and secure data-processing environments, and how reliable are these measures from a technical perspective in light of recent legal developments?

Effective exercise of data subject's rights

The promise of the EHDS is a future where citizens can access, control, and share their health data for better care and research. But this promise is based on a critical, often overlooked factor: digital equity. A large number of people still has limited digital access or lack basic digital skills to effectively exercise their new data rights.

This theme looks beyond considering the technical and legal framework of the EHDS to confront the human challenge of digital inequity.

- How do we ensure the EHDS does not create a two-tier system, empowering the digital savvy while leaving others behind? What concrete steps are needed for different stakeholders to build digital health literacy and guarantee every citizen enhances their control over their health data and exercise related rights effectively?
- What kind of digital skills should citizens develop to exercise their data rights effectively? What specific "health data literacy" competencies do citizens need to manage their electronic health records, understand data sharing, and protect their data rights? Who is responsible for defining and funding this education?
- How can we ensure healthcare professionals are equipped with the skills and the time to act as trusted guides, helping patients navigate and understand their new EHDS rights and tools?
- Where shall this educational effort begin? Through public facilities or as a mandatory part of primary care? Are there any examples?
- How can we translate the legal rights granted by the EHDS to a practical and trustworthy reality for people with limited digital accessibility and low digital literacy?
- Informed consent is a cornerstone of the EHDS. How can we present the complex concepts like secondary use of health data in a way that is easily understandable, without resorting to long, impenetrable terms and conditions?
- What safeguards and alternative pathways must be established for citizens who are entirely offline or unable to use digital tools to ensure they are not excluded from modern healthcare?
- What funding and support will be available for member states to develop training programmes and ensure local health services are equipped to support all citizens?
- What does "success" look like for an inclusive EHDS? What is one key metric we should use to determine whether we are truly bridging the digital divide and not widening it?
- Will the EHDS strengthen individuals' control over their health data and support genuine empowerment, or risk creating new asymmetries of access and understanding?

The impact of the EHDS on the health care needs of older persons and ageing societies

The EHDS is expected to contribute to mitigating the healthcare challenges posed by ageing populations and health workforce shortages. By fostering efficiency and innovation, more integrated data-driven healthcare systems are expected to better support both older patient care and research and policy for ageing. As for the potential of the EHDS to support care delivery to older persons, a series of questions can be asked.

- Will the persistent digital divide in use hinder the EHDS's objective of strengthening individual control over data? What measures can be adopted to support older persons' rights to access to information, correct it, and restrict access to their data?

- Will the EHDS facilitate cross-border care of older persons who migrate to southern European countries? How can the regulation ensure the secure exchange of health data across EU member states? How will the "MyHealth@EU" platform work for people who travel and want their medical history available to health professionals anywhere in the EU?
- Older patients with co-morbidities or suffering from chronic diseases have complex medical histories. Will the EHDS contribute to reducing the need for repeated tests and the administrative burden for both patients and healthcare providers?
- As for the potential of the EHDS to support informed research and policy for health care needs in ageing society, the benefits will depend on a series of factors, including the implementation of the EHDS.
    - First, it seems sensible to advance knowledge on how the EDHS can improve the study of conditions like dementia, cardiovascular diseases, and chronic illnesses and the development of new treatments.
    - Second, could the EHDS contribute to the development of AI-fuelled solutions in geriatric care? What large-scale health data are required for developing and training AI-powered clinical support systems or recommending personalised treatment plans?
- Better data can inform policies on preventative healthcare, resource allocation, or environmental factors impacting the health of older populations. What is the potential of the EHDS for public health monitoring and planning related to ageing populations?

Bridging Silos between the European Health and Agri-Food Data Spaces

The EHDS is part of the EU's Data Strategy which aims at creating sector-specific data spaces to unlock innovation and address societal challenges. It is important to realise that the EHDS will not occur in isolation but will be one of a number of data spaces. This gives rise to interesting questions, particularly concerning the interaction between such domains. This includes:

- How can the Health Data Space and the Agri-Food Data Space interact to create a sustainable, personalised, and equitable future?
- How to bridge health and agri-food systems?
- How data creates value for some while potentially creating risks for others in terms of privacy, equity, and access.
- What shared governance mechanisms or "rules of engagement" would be needed for the Health and Agri-Food Data Spaces to collaborate in a way that builds cross-sector and citizen trust?
- What concrete steps could be taken to start building a bridge between these two data spaces, ensuring that the benefits are widely distributed and the risks you see in these scenarios are mitigated?

Handling Intellectual Property (IP) interests under the EHDS

The EHDS states that data holder's IP should, in principle, be made available for secondary processing. The

regulation does, however, allow Data Holders to have their IP interests taken into account when decisions are made about sharing the electronic health data they possess. The relevant provisions are, however, ambiguous, requiring in any event that Data Holders must report the existence of such datasets to HDABs and leaving the final decision to that body. In this regard, a number of important questions remain. These include:

- How will the intellectual property (IP) rights and trade secrets of data holders be adequately protected, while ensuring fair and non-discriminatory access to data for research and innovation?
- Will pharmaceutical companies trust the judgment and ability of HDABs to decide upon IP issues?
- Will entities with strong IP interests in their data behave transparently?
- What kind of specific, appropriate, and proportionate measures are likely to be able to protect IP? Will these measures be feasible, protecting both IP and the aims of the EHDS?
- What are the prospects for data holders that wish to challenge a decision by the HDAB?
- Is there a commercial incentive for some data holders not to cooperate with HDABs?

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