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**Publication date**

2026

**Published in**

NEJM AI

[Link to publication](#)

**Citation for published version (APA):**

Cervera de la Cruz, P., Hazel III, J. W., Shabani, M., & Cohen, G. (2026). Driving AI Health Innovation through the European Health Data Space: Opportunities and Challenges for Non-EU Country Participation. *NEJM AI*.

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## POLICY CORNER

# Driving AI Health Innovation through the European Health Data Space: Opportunities and Challenges for Non-EU Country Participation

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Received: November 18, 2025; Revised: December 19, 2025; Accepted: January 4, 2026; Published: February 6, 2026

## Abstract

In March 2025, the European Union (EU) launched the European Health Data Space (EHDS) to streamline access to and sharing and reuse of health data across all 27 Member States. The EHDS aims to give patients greater control over electronic health records and permits secondary use of data for research, policy, and innovation under strong safeguards. Pooling diverse clinical, genomic, and wearable-device data across borders could create one of the world's most comprehensive health data ecosystems, providing an unprecedented resource for advancing data-driven innovation, including artificial intelligence in health care. For non-EU researchers and companies, including those in the United States, this development presents both opportunities and challenges. Strict reciprocity requirements and divergent legal frameworks may limit direct U.S. participation in the near term, but partnerships with EU institutions or EU-based subsidiaries could provide entry points. Beyond the EU, the EHDS is poised to set global benchmarks for responsible secondary use of health data. This article explores its potential and the implications for third-country participation (i.e., participation by countries that are not part of the EU) and global health data governance. (Funded by Novo Nordisk Foundation, grant no. NNF23SA0087056.)

## Introduction

**A**rtificial intelligence (AI) systems in health care rely on large, diverse, and high-quality datasets to train and validate their models. The European Health Data Space (EHDS), which entered into force on March 26, 2025, establishes a legal, technical, and ethical framework to facilitate responsible data use and accelerate AI-driven innovation in health care ([Table 1](#)).<sup>1-3</sup> As part of the broader European Data Union Strategy,<sup>4</sup> the regulation implements the FAIR principles (findable, accessible, interoperable, reusable),<sup>5</sup> establishes rules and obligations for data usage, and introduces governance structures to enable greater access to health data in the European Union (EU). This article explains the EHDS's requirements and objectives, with a focus on how it supports AI-driven innovations in health care. We highlight the challenges and opportunities the EHDS presents for non-EU entities, especially those in the United States, and compare it with the U.S. landscape, underscoring the importance for stakeholders in third countries

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**Table 1. Explanatory Summary of the European Health Data Space Regulation.\***

Key Features of the EHDS	Description
Nature and purpose of the EHDS	Like the General Data Protection Regulation <sup>1</sup> and the Medical Device Regulation, <sup>2</sup> the EHDS is a directly applicable EU regulation; it is automatically incorporated into the domestic legal frameworks of all 27 Member States. Its overarching aim is to establish a common legal and technical infrastructure for the access, sharing, and reuse of health data across national borders.
Scope and definition of health data	The EHDS defines health data broadly, including EHRs as well as claims data, genomic data, data from medical devices and wellness applications, and even social determinants of health. Both public and private data holders are required to make certain categories of data available for secondary use under strict conditions.
Individual rights and governance framework	The regulation strengthens individuals' rights over their health data by ensuring easier access to and cross-border sharing of EHRs (primary use); enabling the responsible secondary use of health information for research, innovation, and policy; and building a unified EU-wide framework of common standards to ensure interoperability of EHR systems. The EHDS also requires each Member State to establish a national Health Data Access Body to manage requests from health data users for secondary data use. These entities are tasked with evaluating data access requests, ensuring that proposed uses comply with the regulation's safeguards, and managing the rights of citizens — including the right to opt out from secondary use of health data.

\*EHDS denotes European Health Data Space; EHR, electronic health record; and EU, European Union.

(i.e., any country that is not an EU Member State) to remain engaged as global standards evolve.

## The EHDS Regulation

### ANONYMIZATION AND PSEUDONYMIZATION

To safeguard privacy and data protection, the EHDS mandates that health data reused for secondary purposes be anonymized whenever possible. Under the General Data Protection Regulation (GDPR), anonymization refers to the process of rendering personal data anonymous such that the data subject is no longer identifiable. As a result, anonymized data are no longer considered personal data and fall outside the scope of the GDPR (Recital 26). In contrast, pseudonymization replaces identifiable information with pseudonyms or codes and, because data can still be reidentified with the use of additional information, the data remain subject to the GDPR (Article 4[5]). The EHDS's default rule is that data users may only access anonymous information; access to pseudonymized data is permitted only when the user demonstrates that the personal data are necessary to achieve a permitted purpose. Processing, including training and validation of AI models, occurs within secure processing environments (SPEs) designed to prevent reidentification. These environments allow downloads only of nonpersonal electronic health data (e.g., anonymized statistical outputs) and do not permit the downloading of personal health data, including pseudonymized data.

The EHDS's inclusion of anonymized data within its regulatory sphere marks a departure from the GDPR, which excludes these data from its scope. This change is important for life sciences companies, including those based in the

United States, that have historically made use of European datasets for AI model training and drug development. Under the EHDS system, accessing such data will require a permit, the payment of data-handling fees, the use of SPEs, and broader compliance with EHDS requirements.

Moreover, the EHDS will impose additional safeguards for the transfer of nonpersonal (i.e., anonymous) health data to participants in third countries or international organizations. This requirement stems from the Data Governance Act,<sup>6</sup> which classifies such nonpersonal health data as highly sensitive “where the transfer of such nonpersonal electronic data to third countries presents a risk of reidentification through means going beyond those reasonably likely to be used, in particular in view of the limited number of natural persons to whom those data relate, the fact that they are geographically scattered or the technological developments expected in the near future” (Article 88, EHDS). As a result, such types of nonpersonal health datasets may require additional safeguards for transfers outside the EU, which could have significant implications for the development of health AI systems with European health data.

Specifically, under Article 5(13) of the Data Governance Act, a delegated act will establish “special conditions” for international transfers when there is a risk of reidentification. These may include terms applicable to the transfer or technical arrangements; limitations regarding the reuse of data in third countries; restrictions on the categories of persons entitled to transfer such data; or, in exceptional cases, outright prohibitions on certain transfers to third countries. Such requirements could further complicate international health data sharing. These stricter controls on international transfers reflect a growing recognition that advanced

analytical approaches — including AI algorithms — could reidentify individuals from data presumed anonymous.<sup>7</sup>

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## A Policy Engine for AI-Driven Innovation in Health Care

Among the most transformative features of the EHDS is that it creates an unprecedented opportunity to accelerate AI innovation in health care. The AI Act, the EU’s legal framework for responsible AI development and deployment,<sup>8</sup> explicitly refers to the EHDS as a potential data platform or hub for training, validating, and testing AI systems using health data (Recital 68, EU AI Act).

By enabling structured, cross-border access to health datasets — including clinical, genomic, and wearable-generated information — the EHDS could help overcome one of the most significant barriers to effective AI-driven innovation in health care: limited access to diverse datasets. The regulation is poised to enable AI developers to train algorithms on larger, more heterogeneous datasets, promoting the development of AI systems that deliver clinically relevant results across diverse populations.

Interest in European health data for AI development is already high. For example, the controversial awarding of the contract to build the English National Health Service’s Federated Data Platform to the U.S.-based data firm Palantir illustrates the strategic value of large-scale health data ecosystems.<sup>9-11</sup> Such developments highlight why the EHDS is likely to draw attention from international companies aiming to stake a claim in the future of AI-driven health care.

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## Access by Third Countries: Challenges and Potential Pathways

The EHDS represents a potentially valuable resource for non-EU third-country entities, including U.S.-based life sciences companies and research institutions seeking to access European health data for AI innovation. For AI developers and companies especially, Europe’s rich health datasets, including the valuable longitudinal health datasets maintained by Nordic countries, are a major draw.<sup>12</sup>

Recognizing this potential, in its public consultation response to the European Commission on digital health data, the U.S. Chamber of Commerce urged EU regulators to ensure that the EHDS enabled international data

exchange and adopted globally harmonized standards.<sup>13</sup> However, the Chamber strongly opposed mandatory data sharing obligations, warning that compelling private companies to disclose proprietary datasets without adequate control — or compensation — would disincentivize future research and development in Europe.

While the EHDS regulation contains provisions for third-country access for both primary use and secondary use purposes, significant barriers currently exist for direct participation by entities located outside the EU, especially for U.S. entities. Here, we focus on access related to secondary use.

### BARRIERS TO SECONDARY USE

Access for secondary use purposes, which encompass broader research, public health, and commercial purposes, is regulated by the HealthData@EU infrastructure. Third countries and international organizations may become authorized participants only if they comply with the EHDS requirements, including providing reciprocal access rights and equivalent safeguards to EU-based researchers (Recital 80, Recital 94, and Article 75, EHDS). However, obtaining such an authorized participant status would be highly challenging for the U.S. entities, given the differences between U.S. and EU data protection frameworks.

Recognition of reciprocity would involve the European Commission formally determining, through implementing acts, that the third country offers access and protections for electronic health data on terms equivalent to those within the EU (Article 75[5] and Article 91, EHDS). Authorized users must also operate within SPEs and would be restricted from downloading personal data. It is also important to note that Member States may maintain or introduce additional conditions and limitations on international access to, and transfers of, personal electronic health data in addition to GDPR requirements and the EHDS reciprocity framework (Article 90).

The foundational differences in legal philosophy between the United States and the EU (e.g., the United States’ reliance on industry-specific statutes such as the Health Insurance Portability and Accountability Act and its lack of a unified, rights-based data protection framework) mean that significant legal reforms and intensive bilateral negotiations would likely be necessary for the United States to achieve reciprocity status. Moreover, because HealthData@EU still depends on the European Commission implementing acts, the establishment of national health data access bodies (HDABs) and SPEs, and a reciprocity test requiring

“equivalent” access for EU researchers, a near-term determination by the European Commission for the United States seems unlikely.

Entities in third countries may also submit applications for data permits or data requests where they are established in a third country that has become an authorized participant in HealthData@EU pursuant to Article 75(5) of the EHDS Regulation. Becoming an authorized participant allows a third-party national contact point to link its data catalogs with the EU’s, receive data access requests via HealthData@EU, and make access decisions while complying with EHDS rules like standardizing catalog formats (Article 79[1] and Article 91, EHDS). However, entities based in third countries will only be able to apply to join once Article 75(5) takes effect on March 26, 2035.

### PATHWAYS FOR ENGAGEMENT

Given these barriers, a more feasible short-term approach for U.S.-based researchers and companies may be to engage indirectly with the EHDS through collaborative partnerships with EU-based institutions. Alternatively, organizations wishing to engage more directly with the EHDS may establish subsidiaries or other legal establishments within EU Member States. Such entities would typically be established in the EU and therefore able to act as domestic data users and/or controllers under the EHDS, allowing them to apply for data permits via national HDABs (Article 57, EHDS).

In this case, GDPR data transfer restrictions would still apply; therefore, data transfers from the EU to the United States would need to continue meeting conditions under the GDPR for international transfers (e.g., an adequacy decision, standard contractual clauses, or other approved mechanisms). As a result, health data transfers between the EU and the United States remain challenging for research collaborations.<sup>14</sup> Moreover, as previously mentioned, the EHDS sets new rules for anonymized health data, which, up until now, under the GDPR, were excluded from data protection regulatory oversight. This could have significant implications for entities currently using anonymized health data from the EU.

Considering these challenges, third-country engagement may instead take the form of participation in EHDS working groups or public consultations. For example, the Second Joint Action Towards the European Health Data Space’s ongoing consultations on draft guidelines<sup>15</sup> invite comments on issues such as fee structures and penalties, privacy techniques, data access procedures, and opt-out

obligations. A public consultation on collaboration with third countries is expected in May 2026. By engaging in these forums, U.S. researchers and companies can stay aligned with evolving standards, offer feedback on early implementation challenges, and lay the groundwork for more formal participation once reciprocity arrangements are in place. AI innovators should likewise take an active role in these discussions to ensure their perspectives are represented and industry-specific concerns are addressed.

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## Conclusion

The EHDS represents a potentially transformative shift in health data governance. By establishing structured cross-border data access to diverse datasets under a unified framework, it aims to catalyze responsible AI-driven innovation in health care. For non-EU countries such as the United States, the EHDS presents both opportunities and challenges. Legal and procedural barriers will limit direct participation in the near term, but strategic collaboration, efforts at regulatory alignment, and early engagement in EHDS governance structures could enable meaningful access over time.

The EHDS’s ultimate success will hinge on navigating a lengthy and complex implementation process. Its secondary use rules will not fully apply until 2029, with certain sensitive data types (e.g., genetic and genomic data) following in 2031. Member States must first build interoperable electronic health records, deploy SPEs, and establish national HDABs. Such foundational tasks are already proving difficult in countries such as Germany,<sup>16</sup> where the rollout of electronic health records has been repeatedly postponed due to technical hurdles, data protection concerns, and cybersecurity upgrades.<sup>17</sup> Similar tensions have emerged during debates over the EU AI Act; amid calls to give companies more time to adapt, the European Commission has thus far resisted pressure to pause implementation and instead stressed the need to make the rules work in practice. This balancing act between responsible regulation and innovation is likely to shape the EHDS rollout as well.

Many other questions regarding third-country access and participation remain unanswered and will need to be addressed in the coming years. Stakeholders outside the EU will need to closely monitor the adoption of EHDS implementing acts and any further regulatory developments and court rulings, such as recent changes to the rules on pseudonymization.<sup>18</sup> We encourage the European Commission to

establish a dedicated advisory group to incorporate input from non-EU stakeholders and explore mechanisms to responsibly share health data with trusted third-country partners. Much like the GDPR, the EHDS could set de facto international norms well beyond Europe, making it essential for global stakeholders to stay attuned to its evolving implementation.

## Disclosures

Author disclosures are available at [ai.nejm.org](https://www.nature.com/ai.nejm.org).

Supported by a Novo Nordisk Foundation grant for a scientifically independent International Collaborative Bioscience Innovation and Law Program (grant no. NNF23SA0087056, to Dr. Cohen).

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